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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

[Docket ID: OPM–2023–0009]

RIN 3206–AO58

General Schedule Locality Pay Areas

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management is issuing final regulations on behalf of the President's Pay Agent to change the geographic boundaries of General Schedule locality pay areas. The changes in locality pay area definitions under these final regulations will be applicable on the first day of the first applicable pay period beginning on or after January 1, 2024. The locations that will be included in a locality pay area separate from the Rest of U.S. locality pay area under these final regulations have all met criteria previously recommended by the Federal Salary Council and approved by the Pay Agent for nationwide use in the locality pay program.

DATES: The regulations are effective on December 18, 2023. The regulations are applicable for pay purposes on the first day of the first applicable pay period beginning on or after January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Joe Ratcliffe by email at *pay-leave-policy@opm.gov* or by telephone at (202) 606–2858.

SUPPLEMENTARY INFORMATION:

Summary of Final Rule

The changes these final regulations make in locality pay area definitions include linking geographic boundaries of locality pay areas to the updated definitions of metropolitan statistical areas and combined statistical areas (MSAs and CSAs, respectively) in Office of Management and Budget (OMB) Bulletin No. 20–01; establishing four new locality pay areas having pay disparities significantly exceeding that for the Rest of U.S. locality pay area over an extended period; and changing the criteria by which locations adjacent to an MSA or CSA comprising a basic locality pay area can be included in the locality pay area as an area of application. However, while any location may be subject to a change in locality pay area designation in the future based on a recommendation by the Federal Salary Council which is approved by the Pay Agent, locations that are currently in a locality pay area other than the Rest of U.S. locality pay area and would otherwise be redesignated as part of a lower-paying locality pay area due to application of approved criteria will remain in their current locality pay area under these final regulations.

The four new locality pay areas established by the final regulations are Fresno-Madera-Hanford, CA; Reno-Fernley, NV; Rochester-Batavia-Seneca Falls, NY; and Spokane-Spokane Valley-Coeur d'Alene, WA-ID. Locality pay rates for these four areas will be set by the President.

Background

Section 5304 of title 5, United States Code (U.S.C.), authorizes locality pay for General Schedule (GS) employees with duty stations in the United States and its territories and possessions. Paragraph (f) of 5 U.S.C. 5304 authorizes the President's Pay Agent (the Secretary of Labor, the Director of the Office of Management and Budget (OMB), and the Director of the Office of Personnel Management (OPM)) to determine locality pay areas. The boundaries of locality pay areas are based on appropriate factors, which may include local labor market patterns, commuting patterns, and the practices of other employers. The Pay Agent considers the views and recommendations of the Federal Salary Council (''the Council''), a body composed of experts in the fields of labor relations and pay policy and representatives of Federal employee organizations. The President appoints the members of the Council, which submits annual recommendations to the Pay Agent about the administration of the locality pay program, including the geographic boundaries of locality pay areas. (The Council's recommendations are posted on the OPM website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/#url=Federal-Salary-Council*.) The establishment or modification of pay area boundaries conforms to the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553).

On June 28, 2023, OPM published a proposed rule in the **Federal Register** on behalf of the Pay Agent to propose the changes summarized above. (See 88 FR 41855.) The proposed rule provided a 30-day comment period. Accordingly, the Pay Agent reviewed comments received through July 28, 2023. After considering those comments, the Pay Agent has decided to implement the locality pay area definitions identified in the proposed rule, except that the Washington State Counties of Clallam and Jefferson are added as areas of application to the Seattle-Tacoma, WA, locality pay area.

Comments on the Proposed Rule

OPM received 405 comments on the proposed rule. Most commenters supported the proposed changes in the geographic definitions of locality pay areas.

A number of comments reflected misunderstanding of the proposed rule's geographic definitions of locality pay areas, with some comments indicating a mistaken belief that certain counties actually included in a proposed locality pay area were excluded and that a correction would therefore be needed prior to publication of a final rule. As explained in the proposed rule, locality pay areas consist of (1) the MSA or CSA comprising the basic locality pay area and, where criteria recommended by the Council and approved by the Pay Agent are met, (2) areas of application. These comments all expressed concern about locations which, while not listed as individual counties in paragraph (b) of § 531.603, were all included in the MSA or CSA listed for the locality pay area and therefore did not need to be listed as individual counties. OPM plans to post the definitions of locality pay areas at the county level on its website after these final regulations are issued.

Many commenters expressed the belief that various indicators of living costs are or should be considered in defining locality pay areas or in setting locality pay rates. Under 5 U.S.C. 5304, locality pay rates are based on comparisons of GS pay and non-Federal

pay at the same work levels in a locality pay area rather than on any consideration of local living costs. Relative living costs may indirectly affect non-Federal pay levels, but living costs are just one of many factors that affect the supply of and demand for labor, and therefore labor costs, in a locality pay area. A comparison of living costs between geographic areas is not permitted under the locality pay law, but even if it were, it would not be a reliable indicator of local labor costs.

Many commenters proposed that a change in locality pay designation be made for locations that have not met the standard criteria for such designation that the proposed rule explained. As noted in the Pay Agent's December 2022 annual report (available at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/pay-agent-reports/2021report.pdf*), the P ay Agent agrees with the Council that locality pay areas should continue to be defined by consistently applying standard criteria to all locations throughout the country. However, the Pay Agent also agrees with the Council that stakeholder input regarding the criteria used to define and establish locality pay areas can be helpful to the Council as it continues to consider what criteria are best to apply consistently for all locations throughout the country for purposes of establishing locality pay area boundaries. Stakeholders concerned about the criteria used in the locality pay program may submit input to the Council.

In some cases, commenters arguing for exceptions to the use of standard criteria cited possible recruitment and retention difficulties they said they believed agencies would have in certain locations that would remain in the Rest of U.S. locality pay area when these final regulations are put into effect. The Pay Agent has no evidence that the changes these final regulations will make in locality pay area definitions will create recruitment and retention challenges for Federal employers, and it has been the case since the very first locality pay areas were established for January 1994 that many counties with Federal employees are in the Rest of U.S. locality pay area while being adjacent to a separate locality pay area. However, should recruitment and retention challenges exist in a location, Federal agencies have considerable administrative authority to address those challenges through the use of current pay flexibilities. Information on these flexibilities is posted on the OPM website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-and-leave-flexibilities-for-recruitment-and-retention/.*

A number of commenters expressed concern that various rural locations have not been established as separate locality pay areas. In some cases, comments expressing such concerns reflected a mistaken belief that such locations have not been established as separate locality pay areas based solely on the relatively small numbers of GS employees they often have. The proposed rule does mention that when the Council began using the current salary survey methodology in 2012, selection of Rest of U.S. research areas was limited to MSAs and CSAs having 2,500 or more GS employees. However, the proposed rule also explains that the Council has begun requesting that the Bureau of Labor Statistics (BLS) deliver non-Federal salary estimates for areas that had fewer than 2,500 GS employees, that so far BLS resources have allowed for delivery of NCS/OEWS estimates for 10 such statistical areas, and that those 10 areas had the highest levels of GS employment among areas not previously established as Rest of U.S. research areas. Also, the Council has indicated that it plans to continue its work with BLS to establish more Rest of U.S. research areas where feasible in MSAs and CSAs with fewer than 2,500 GS employees. Thus, the proposed rule does not imply that locations are excluded from consideration based on their GS employment alone. Rather, rural locations that have not been recommended for a change in their locality pay area designation do not meet the criteria that the proposed rule explained.

Regarding the criteria by which four new locality pay areas will be established under these final regulations, some commenters expressed concern regarding the BLS conclusion that it is not feasible for the BLS salary survey methodology to produce reliable salary estimates for micropolitan statistical areas or rural counties. One commenter characterized that conclusion as unacceptable and opined that all locations throughout the country should have pay disparities calculated regardless of that BLS conclusion. In response to these concerns, the Pay Agent notes that a pay disparity calculated for purposes of locality pay must have sufficient occupational and work level coverage for non-Federal positions that are comparable to GS positions in the same locality pay area, and micropolitan statistical areas and rural counties do not have enough non-Federal salary data to calculate reliable pay disparities in the same way as with MSAs and CSAs because of the relatively small populations and labor markets typical of such locations.

Some commenters disagreed it is appropriate to use March 2020 OMB-defined metropolitan areas to define locality pay areas as proposed. Some of those commenters made living-cost comparisons between Rest of U.S. locations and portions of March 2020 OMB metropolitan areas that comprise basic locality pay areas. Other commenters suggested that locality pay area boundaries should be defined based not on March 2020 OMB-defined metropolitan areas but rather on the boundaries of sets of duty stations comprising entire states, national parks, the regional definitions agencies may use for their workforces, or other data or information the commenters regarded as relevant with respect to locations of concern to them. Under the final regulations, the boundaries of locality pay areas will reflect the use of OMB-defined metropolitan areas described in the proposed rule.

Prior to implementation of locality pay, the Council recommended, and the Pay Agent approved, the use of OMB-defined metropolitan areas as the basis for locality pay area boundaries, and OMB-defined metropolitan areas have been the basis for locality pay area boundaries since locality pay was implemented in 1994. (A detailed history of the use of OMB-defined metropolitan areas in the locality pay program can be found in the Council's January 2014 recommendations available at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/federal-salary-council/recommendation13.pdf.*) The Pay Agent continues to believe it is appropriate to use OMB-defined metropolitan areas as the basis for locality pay area boundaries and has no evidence that it is appropriate to split an OMB-defined metropolitan area into separate locality pay areas. Since OMB-defined metropolitan areas will continue to serve as the basis for locality pay area boundaries, the Pay Agent believes it makes sense to update the metropolitan areas used in the locality pay program to the March 2020 OMB-defined metropolitan areas, since the definitions of those metropolitan areas reflect more recent information on population distribution and commuting patterns. (Regarding the definitions of metropolitan areas in OMB Bulletin No. 23–01, which was issued on July 21, 2023, the Council can consider whether to recommend their use for purposes of defining locality pay areas for 2025.) Departing from the practice of defining basic locality pay areas based on OMB-

defined metropolitan areas as in the proposed rule would be a significant change, and the implications would have to be carefully considered. Individuals interested in recommending alternatives for defining locality pay areas using standard criteria nationwide may provide input to the Council.

Some commenters suggested that all portions of California should be covered by a higher locality pay percentage than for the Rest of U.S. locality pay area, with one commenter noting that the entire states of Alaska and Hawaii each comprise a single locality pay area and suggesting the same thing could be done for the state of California. These final regulations will provide the same locality pay area designations within California as the proposed rule proposed. The establishment of Alaska and Hawaii as locality pay areas was part of the Nonforeign Areas Retirement Equity Assurance Act of 2009 (NAREAA) (as contained in subtitle B of title XIX of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), which does not cover locations in California or other portions of the contiguous United States. As explained more fully in 76 FR 32859, the Pay Agent established the states of Alaska and Hawaii as locality pay areas effective July 7, 2011. That change was consistent with the *sense of the Congress* statement in NAREAA that the two states each would be covered by a single separate locality pay area.

Some comments were outside of the scope of these regulations. For example, some commenters suggested specific pay levels they claimed should be implemented for one or more locality pay areas. Other commenters expressed concern that employees covered by certain Federal pay systems outside of the General Schedule, such as the Federal Wage System, would not benefit from the changes planned for the geographic definitions of GS locality pay areas. Some commenters offered views on changes they think should be made to the General Schedule that would require changes in law, such as eliminating the statutory pay limitation that limits locality pay rates to the rate for level IV of the Executive Schedule (5 U.S.C. 5304 (g)(1)).

The purpose of these regulations is to define the boundaries of locality pay areas established for the General Schedule pay system and other pay systems that receive locality pay under 5 U.S.C. 5304, not to determine locality pay percentages, adjust location coverage for pay systems that do not receive locality pay under 5 U.S.C. 5304, or consider ideas for reforms to the General Schedule that would require changes in law.

One commenter suggested the final regulations include Clallam and Jefferson Counties, WA, in the Seattle locality pay area as areas of application (*https://www.regulations.gov/comment/OPM-2023-0009-0226*). The Council recommended in its February 4, 2023 report *(https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/federal-salary-council/recommendation22.pdf)* that the Washington State Counties of Clallam and Jefferson be included in the Seattle-Tacoma, WA, locality pay area as areas of application. Because the Pay Agent was still considering the Council's recommendation regarding Clallam and Jefferson Counties for locality pay in January 2024 when OPM published the proposed rule, these counties were not included as proposed areas of application.

The commenter recommended the two counties be included in the Seattle locality pay area because the Council recommended in its February 4, 2023, annual report that the Pay Agent do so. In addition, review of the report of the Council Working Group read into the record at the Council's public meeting held on October 28, 2022, has provided additional context for the Council's February 2023 recommendation and provides further justification to support the commenter's recommendation. With respect to isolation as a Rest of U.S. location, Jefferson County is analogous to an island location such as San Juan County, WA, which the proposed rule and final regulations both include in the Seattle locality pay area as an area of application. Jefferson County is located on the Olympic Peninsula within western Washington State and is divided by the Olympic Mountains into an eastern portion and a western portion with no access by road between those two portions without crossing into either Clallam County, WA, or Grays Harbor County, WA. The western portion is bordered by the Pacific Ocean coastline, and the eastern portion is bordered by the marine waters of the Strait of Juan de Fuca and the Puget Sound. Jefferson County's small GS workforce consists mostly of Department of Navy positions located at Naval Magazine Indian Island, across the Puget Sound from Seattle.

With Jefferson County included in the Seattle locality pay area, Clallam County, WA, would be completely bordered by water and a higher-paying locality pay area, so the Council recommended also including Clallam County in the Seattle locality pay area as an area of application.

Based on the Pay Agent's review of the Council's analysis of those two counties for locality pay in January 2024, the Pay Agent agrees with the Council's reasoning on those two counties. Accordingly, the Pay Agent agrees with the commenter and finds it prudent not to delay treating the counties the same as other similarly situated locations. Jefferson County and Clallam County, WA, are therefore being included in the Seattle, WA locality pay area in this final rule.

One commenter suggested that all GS employees should receive the same locality pay rates regardless of location after adjusting all GS pay rates nationwide so that they equal the GS pay rates now applicable in the San Jose-San Francisco-Oakland, CA, locality pay area, which currently has the highest locality pay percentage. Such an approach would not be permissible under current law. The ultimate goal of locality pay is to reduce pay disparities to the same extent in each locality pay area (5 U.S.C. 5304). Therefore, it is appropriate that locality rates differ between locations.

Expected Impact of This Rule

This rule establishes four new locality pay areas based on updated pay disparity data and adds many locations to existing locality pay areas as a result of using the revised criteria the Pay Agent has approved for areas of application. Wage rates for employees who receive GS locality pay will increase in these areas relative to the baseline as a result. However, when locality pay percentages are adjusted at the time of an annual pay adjustment, they are scaled to a targeted overall salary outlay, regardless of the number or composition of locality pay areas. Thus, the larger annual increases locations will receive as a result of being redesignated to a higher-paying locality pay area will be offset by the annual increases elsewhere being smaller than they would absent such redesignation. These changes will result in geographic differences in Federal salaries better reflecting the overall geographic differences in salary in line with statutory goals. In the proposed rule, OPM noted that this could affect Federal recruitment and retention across the U.S. and requested comments on this issue. However, OPM received no comments on the proposed rule establishing that recruitment and retention will be negatively impacted as a result of implementing these final regulations.

OPM expects that this rule will most directly impact approximately 33,300 GS employees. Modifying existing

locality pay areas will affect approximately 17,100 GS employees, and establishing the four new locality pay areas will affect approximately 16,200 GS employees. As discussed above, other Federal employees who receive GS locality pay will be indirectly impacted at the time of an annual pay adjustment. Due to the scope of this rule, OPM does not anticipate that it will substantially impact local economies or have a large ripple effect in local labor markets.

OPM is highly interested in any impacts of locality pay adjustments resulting from this rulemaking and will continue to study the implications of such impacts as needed.

Regulatory Review

Executive Orders 13563, 12866, and 14094 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule is not a ''significant regulatory action'' under the provisions of Executive Order 14094 and, therefore, was not reviewed by OMB.

Regulatory Flexibility Act

The Director of OPM certifies that this rule will not have a significant economic impact on a substantial number of small entities because this rule will affect only Federal agencies and employees.

Federalism

OPM examined this rule in accordance with Executive Order 13132, Federalism, and determined that it will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This rule meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA) (5 U.S.C. 801 *et seq.*) requires most final rules to be submitted to Congress before taking effect. OPM will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this rule before its effective date. The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this rule is not a major rule as defined by the CRA (5 U.S.C. 804).

Paperwork Reduction Act

This rule does not impose or affect any reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 531

Government employees, Law enforcement officers, Wages.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

Accordingly, OPM amends 5 CFR part 531 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

■ 1. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Public Law 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304, 5305, and 5941(a); E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart F—Locality-Based Comparability Payments

■ 2. In § 531.602, the definitions of CSA and MSA are revised to read as follows:

§ 531.602 Definitions.

* * * * *

CSA means the geographic scope of a Combined Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 20–01.

* * * * *

MSA means the geographic scope of a Metropolitan Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 20–01.

* * * * *

■ 3. In § 531.603, paragraph (b) is revised to read as follows:

§ 531.603 Locality pay areas.

* * * * *

(b) The following are locality pay areas for the purposes of this subpart:

(1) Alaska—consisting of the State of Alaska;

(2) Albany-Schenectady, NY-MA—consisting of the Albany-Schenectady, NY CSA and also including Berkshire County, MA, Greene County, NY, and Hamilton County, NY;

(3) Albuquerque-Santa Fe-Las Vegas, NM—consisting of the Albuquerque-Santa Fe-Las Vegas, NM CSA and also including Cibola County, NM, and McKinley County, NM;

(4) Atlanta—Athens-Clarke County—Sandy Springs, GA-AL—consisting of the Atlanta—Athens-Clarke County—Sandy Springs, GA-AL CSA and also including Cherokee County, AL, Cleburne County, AL, Lee County, AL, Randolph County, AL, Russell County, AL, Banks County, GA, Chattahoochee County, GA, Elbert County, GA, Franklin County, GA, Gilmer County, GA, Gordon County, GA, Greene County, GA, Harris County, GA, Lumpkin County, GA, Marion County, GA, Muscogee County, GA, Putnam County, GA, Rabun County, GA, Stewart County, GA, Talbot County, GA, Taliaferro County, GA, and White County, GA;

(5) Austin-Round Rock-Georgetown, TX—consisting of the Austin-Round Rock-Georgetown, TX MSA and also including Blanco County, TX, Burnet County, TX, Lee County, TX, and Milam County, TX;

(6) Birmingham-Hoover-Talladega, AL—consisting of the Birmingham-Hoover-Talladega, AL CSA and also including Calhoun County, AL, Clay County, AL, Coosa County, AL, Etowah County, AL, Greene County, AL, Hale County, AL, Pickens County, AL, Tallapoosa County, AL, Tuscaloosa County, AL, and Winston County, AL;

(7) Boston-Worcester-Providence, MA-RI-NH-CT-ME-VT—consisting of the Boston-Worcester-Providence, MA-RI-NH-CT CSA and also including Androscoggin County, ME, Cumberland County, ME, Sagadahoc County, ME, York County, ME, Dukes County, MA, Nantucket County, MA, Carroll County, NH, Cheshire County, NH, Grafton County, NH, Sullivan County, NH, Orange County, VT, and Windsor County, VT;

(8) Buffalo-Cheektowaga-Olean, NY—consisting of the Buffalo-Cheektowaga-Olean, NY CSA and also including Allegany County, NY, and Wyoming County, NY;

(9) Burlington-South Burlington-Barre, VT—consisting of the Burlington-South Burlington-Barre, VT CSA and also including Addison County, VT, and Lamoille County, VT;

(10) Charlotte-Concord, NC-SC—consisting of the Charlotte-Concord, NC-SC CSA and also including Alexander County, NC, Burke County, NC, Caldwell County, NC, Catawba County, NC, and Chesterfield County, SC;

(11) Chicago-Naperville, IL-IN-WI—consisting of the Chicago-Naperville, IL-IN-WI CSA and also including Boone County, IL, Iroquois County, IL, Ogle County, IL, Stephenson County, IL, Winnebago County, IL, and Starke County, IN;

(12) Cincinnati-Wilmington-Maysville, OH-KY-IN—consisting of the Cincinnati-Wilmington-Maysville, OH-KY-IN CSA and also including Ripley County, IN, Switzerland County, IN, Carroll County, KY, Fleming County, KY, Lewis County, KY, Owen County, KY, Robertson County, KY, Adams County, OH, and Highland County, OH;

(13) Cleveland-Akron-Canton, OH-PA—consisting of the Cleveland-Akron-Canton, OH CSA and also including Ashland County, OH, Columbiana County, OH, Crawford County, OH, Harrison County, OH, Holmes County, OH, Mahoning County, OH, Richland County, OH, Trumbull County, OH, and Mercer County, PA;

(14) Colorado Springs, CO—consisting of the Colorado Springs, CO MSA and also including Fremont County, CO, and Pueblo County, CO;

(15) Columbus-Marion-Zanesville, OH—consisting of the Columbus-Marion-Zanesville, OH CSA and also including Coshocton County, OH, Hardin County, OH, Morgan County, OH, Noble County, OH, Pike County, OH, and Vinton County, OH;

(16) Corpus Christi-Kingsville-Alice, TX—consisting of the Corpus Christi-Kingsville-Alice, TX CSA and also including Brooks County, TX, Live Oak County, TX, and Refugio County, TX;

(17) Dallas-Fort Worth, TX-OK—consisting of the Dallas-Fort Worth, TX-OK CSA and also including Carter County, OK, Love County, OK, Delta County, TX, Hill County, TX, Hopkins County, TX, Jack County, TX, Montague County, TX, Rains County, TX, Somervell County, TX, and Van Zandt County, TX;

(18) Davenport-Moline, IA-IL—consisting of the Davenport-Moline, IA-IL CSA and also including Carroll County, IL, Lee County, IL, Whiteside County, IL, Cedar County, IA, Jackson County, IA, and Louisa County, IA;

(19) Dayton-Springfield-Kettering, OH—consisting of the Dayton-Springfield-Kettering, OH CSA and also including Allen County, OH, Auglaize County, OH, Mercer County, OH, Preble County, OH, and Van Wert County, OH;

(20) Denver-Aurora, CO—consisting of the Denver-Aurora, CO CSA and also including Larimer County, CO, and Lincoln County, CO;

(21) Des Moines-Ames-West Des Moines, IA—consisting of the Des Moines-Ames-West Des Moines, IA CSA and also including Adair County, IA, Clarke County, IA, Greene County, IA, Hamilton County, IA, Lucas County, IA, Monroe County, IA, and Poweshiek County, IA;

(22) Detroit-Warren-Ann Arbor, MI—consisting of the Detroit-Warren-Ann Arbor, MI CSA and also including Clinton County, MI, Eaton County, MI, Huron County, MI, Ingham County, MI, Jackson County, MI, Sanilac County, MI, Shiawassee County, MI, and Tuscola County, MI;

(23) Fresno-Madera-Hanford, CA—consisting of the Fresno-Madera-Hanford, CA CSA and also including Mariposa County, CA, and Tulare County, CA;

(24) Harrisburg-Lebanon, PA—consisting of the Harrisburg-York-Lebanon, PA CSA, except for Adams County, PA, and York County, PA, and also including Juniata County, PA, and Lancaster County, PA;

(25) Hartford-East Hartford, CT-MA—consisting of the Hartford-East Hartford, CT CSA and also including Franklin County, MA, Hampden County, MA, and Hampshire County, MA;

(26) Hawaii—consisting of the State of Hawaii;

(27) Houston-The Woodlands, TX—consisting of the Houston-The Woodlands, TX CSA and also including Colorado County, TX, Grimes County, TX, Jackson County, TX, Madison County, TX, San Jacinto County, TX, and Trinity County, TX;

(28) Huntsville-Decatur, AL-TN—consisting of the Huntsville-Decatur, AL CSA and also including Colbert County, AL, DeKalb County, AL, Lauderdale County, AL, Marshall County, AL, and Lincoln County, TN;

(29) Indianapolis-Carmel-Muncie, IN—consisting of the Indianapolis-Carmel-Muncie, IN CSA and also including Benton County, IN, Blackford County, IN, Carroll County, IN, Clinton County, IN, Fayette County, IN, Fountain County, IN, Grant County, IN, Lawrence County, IN, Monroe County, IN, Owen County, IN, Randolph County, IN, Rush County, IN, Tippecanoe County, IN, Tipton County, IN, Warren County, IN, and Wayne County, IN;

(30) Kansas City-Overland Park-Kansas City, MO-KS—consisting of the Kansas City-Overland Park-Kansas City, MO-KS CSA and also including Anderson County, KS, Jackson County, KS, Jefferson County, KS, Osage County, KS, Shawnee County, KS, Wabaunsee County, KS, Carroll County, MO, Daviess County, MO, Gentry County, MO, Henry County, MO, and Holt County, MO;

(31) Laredo, TX—consisting of the Laredo, TX MSA and also including Jim Hogg County, TX, and La Salle County, TX;

(32) Las Vegas-Henderson, NV-AZ—consisting of the Las Vegas-Henderson, NV CSA and also including Mohave County, AZ;

(33) Los Angeles-Long Beach, CA—consisting of the Los Angeles-Long Beach, CA CSA and also including Imperial County, CA, Kern County, CA, San Luis Obispo County, CA, and Santa Barbara County, CA;

(34) Miami-Port St. Lucie-Fort Lauderdale, FL—consisting of the Miami-Port St. Lucie-Fort Lauderdale, FL CSA and also including Okeechobee County, FL;

(35) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA and also including Fond du Lac County, WI, and Sheboygan County, WI;

(36) Minneapolis-St. Paul, MN-WI—consisting of the Minneapolis-St. Paul, MN-WI CSA and also including Blue Earth County, MN, Brown County, MN, Dodge County, MN, Fillmore County, MN, Kanabec County, MN, Meeker County, MN, Morrison County, MN, Mower County, MN, Nicollet County, MN, Olmsted County, MN, Pine County, MN, Sibley County, MN, Wabasha County, MN, Waseca County, MN, and Polk County, WI;

(37) New York-Newark, NY-NJ-CT-PA—consisting of the New York-Newark, NY-NJ-CT-PA CSA and also including Warren County, NJ, Sullivan County, NY, Carbon County, PA, Lehigh County, PA, Northampton County, PA, Wayne County, PA, and all of Joint Base McGuire-Dix-Lakehurst;

(38) Omaha-Council Bluffs-Fremont, NE-IA—consisting of the Omaha-Council Bluffs-Fremont, NE-IA CSA and also including Fremont County, IA, Shelby County, IA, and Burt County, NE;

(39) Palm Bay-Melbourne-Titusville, FL—consisting of the Palm Bay-Melbourne-Titusville, FL MSA;

(40) Philadelphia-Reading-Camden, PA-NJ-DE-MD—consisting of the Philadelphia-Reading-Camden, PA-NJ-DE-MD CSA, except for Joint Base McGuire-Dix-Lakehurst, and also including Sussex County, DE, Somerset County, MD, Wicomico County, MD,

Worcester County, MD, and Schuylkill County, PA;

(41) Phoenix-Mesa, AZ—consisting of the Phoenix-Mesa, AZ CSA;

(42) Pittsburgh-New Castle-Weirton, PA-OH-WV—consisting of the Pittsburgh-New Castle-Weirton, PA-OH-WV CSA and also including Belmont County, OH, Cambria County, PA, Greene County, PA, Somerset County, PA, Marshall County, WV, and Ohio County, WV;

(43) Portland-Vancouver-Salem, OR-WA—consisting of the Portland-Vancouver-Salem, OR-WA CSA and also including Wahkiakum County, WA;

(44) Raleigh-Durham-Cary, NC—consisting of the Raleigh-Durham-Cary, NC CSA and also including Caswell County, NC, Cumberland County, NC, Edgecombe County, NC, Halifax County, NC, Harnett County, NC, Hoke County, NC, Lee County, NC, Moore County, NC, Nash County, NC, Northampton County, NC, Robeson County, NC, Scotland County, NC, Warren County, NC, Wayne County, NC, and Wilson County, NC;

(45) Reno-Fernley, NV—consisting of the Reno-Carson City-Fernley, NV CSA, except for Carson City, NV, and Douglas County, NV, and also including Churchill County, NV;

(46) Richmond, VA—consisting of the Richmond, VA MSA and also including Brunswick County, VA, Cumberland County, VA, Essex County, VA, Greensville County, VA, Louisa County, VA, Nottoway County, VA, and Emporia city, VA;

(47) Rochester-Batavia-Seneca Falls, NY—consisting of the Rochester-Batavia-Seneca Falls, NY CSA;

(48) Sacramento-Roseville, CA-—consisting of the Sacramento-Roseville, CA CSA and also including Alpine County, CA, Amador County, CA, Butte County, CA, Colusa County, CA, Sierra County, CA, Carson City, NV, and Douglas County, NV;

(49) San Antonio-New Braunfels-Pearsall, TX—consisting of the San Antonio-New Braunfels-Pearsall, TX CSA and also including Gillespie County, TX, Gonzales County, TX, Karnes County, TX, Kerr County, TX, and McMullen County, TX;

(50) San Diego-Chula Vista-Carlsbad, CA—consisting of the San Diego-Chula Vista-Carlsbad, CA MSA;

(51) San Jose-San Francisco-Oakland, CA—consisting of the San Jose-San Francisco-Oakland, CA CSA and also including Calaveras County, CA, and Monterey County, CA;

(52) Seattle-Tacoma, WA—consisting of the Seattle-Tacoma, WA CSA and also including Clallam County, WA, Grays Harbor County, WA, Jefferson County, WA, Pacific County, WA, San Juan County, WA, and Whatcom County, WA;

(53) Spokane-Spokane Valley-Coeur d'Alene, WA-ID—consisting of the Spokane-Spokane Valley-Coeur d'Alene, WA-ID CSA and also including Benewah County, ID, Shoshone County, ID, Ferry County, WA, Lincoln County, WA, and Pend Oreille County, WA;

(54) St. Louis-St. Charles-Farmington, MO-IL—consisting of the St. Louis-St. Charles-Farmington, MO-IL CSA and also including Fayette County, IL, Greene County, IL, Montgomery County, IL, Randolph County, IL, Washington County, IL, Crawford County, MO, Gasconade County, MO, Iron County, MO, Madison County, MO, Montgomery County, MO, Pike County, MO, Ste. Genevieve County, MO, and Washington County, MO;

(55) Tucson-Nogales, AZ—consisting of the Tucson-Nogales, AZ CSA and also including Cochise County, AZ;

(56) Virginia Beach-Norfolk, VA-NC—consisting of the Virginia Beach-Norfolk, VA-NC CSA and also including Chowan County, NC, Hertford County, NC, Tyrrell County, NC, Middlesex County, VA, and Surry County, VA;

(57) Washington-Baltimore-Arlington, DC-MD-VA-WV-PA—consisting of the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA CSA and also including Allegany County, MD, Caroline County, MD, Dorchester County, MD, Kent County, MD, Adams County, PA, Fulton County, PA, York County, PA, Caroline County, VA, King George County, VA, Orange County, VA, Shenandoah County, VA, Westmoreland County, VA, Hardy County, WV, and Mineral County, WV; and

(58) Rest of U.S.—consisting of those portions of the United States and its territories and possessions as listed in 5 CFR 591.205 not located within another locality pay area.

[FR Doc. 2023–25153 Filed 11–15–23; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2023–2220; Airspace Docket No. 23–AWP–59]

RIN 2120–AA66

Amendment of Restricted Area R–2512 Holtville, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the using agency listed for restricted area R–2512 Holtville, CA from ''U.S. Navy, Fleet Area Control and Surveillance Facility, San Diego, CA'' to ''U.S. Marine Corps, Commanding Officer, Marine Corps Air Station Yuma, Yuma, AZ.'' This action does not change any boundaries, altitudes, times of designation, or activities conducted within the restricted areas.

DATES: Effective date 0901 UTC, January 25, 2024.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it updates the using agency listed for restricted areas R–2512 Holtville, CA.

Background

The United States (U.S.) Navy Director, Air Warfare requested that the FAA amend the description of restricted area R–2512 Holtville, CA by changing the using agency listed for each from ''U.S. Navy, Fleet Area Control and Surveillance Facility, San Diego, CA'' to ''U.S. Marine Corps, Commanding Officer, Marine Corps Air Station Yuma, Yuma, AZ.'' The request is the result of the Department of the Navy determining it to be in the best interest of airspace and aircraft operations management. The U.S. Navy and U. S. Marine Corps support the using agency change.

The Rule

This action amends 14 CFR part 73 by changing the using agency name listed for restricted area R–2512 Holtville, CA, from ''U.S. Navy, Fleet Area Control and Surveillance Facility, San Diego, CA'' to ''U.S. Marine Corps, Commanding Officer, Marine Corps Air Station Yuma, Yuma, AZ.'' This action is necessary in

order to reflect the current organization tasked with using agency responsibilities for the restricted areas.

This is an administrative change that does not affect the boundaries, designated altitudes, times of designation, or activities conducted within restricted areas R–2512 Holtville, CA; therefore, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of amending the using agency information for R–2512 Holtville, CA, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5d, which categorically excludes from further environmental impact review the modification of the technical description of special use airspace (SUA) that does not alter the dimensions, altitudes, or times of designation of the airspace (such as changes in designation of the controlling or using agency, or correction of typographical errors). This airspace action is an administrative change to the description of restricted area R–2512 Holtville, CA, to update the using agency name. It does not alter the restricted area dimensions, designated altitudes, times of designation, or use of the airspace. Therefore, this airspace action is not expected to result in any significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

Lists of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for 14 CFR part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.22 [Amended]

■ 2. Section 73.22 is amended as follows:

* * * * *

R–2512 Holtville, CA

Using Agency. U.S. Marine Corps, Commanding Officer, Marine Corps Air Station Yuma, Yuma, AZ.

* * * * *

Issued in Washington, DC, on November 13, 2023.

Karen Chiodini,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–25347 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 101

[CBP Dec. No. 23–05]

RIN 1651–AB44

Management of Customs Ports of Entry and Customs Stations

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Final rule.

SUMMARY: In this final rule, the Department of Homeland Security clarifies that the Secretary of Homeland Security has the authority to establish, rearrange or consolidate, and discontinue Customs ports of entry and Customs stations and revises the Customs and Border Protection regulations to reflect this clarification.

DATES: This rule is effective on November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Siobhan Chambers, Branch Chief, Modeling and Optimization, Office of Field Operations, Planning, Program Analysis and Evaluation, Operational and Enterprise Analytics, U.S. Customs and Border Protection, at *siobhan.m.chambers@cbp.dhs.gov* or (202) 325–3935.

SUPPLEMENTARY INFORMATION:

I. Background

U.S. Customs and Border Protection (CBP), a component of the Department of Homeland Security, operates two types of ports of entry, commonly referred to as immigration ports of entry and Customs ports of entry. Immigration ports of entry are those ports of entry used for the processing of travelers arriving by any means of travel into the United States. *See* title 8 Code of Federal Regulations (CFR) section 235.1 (8 CFR 235.1). Customs ports of entry, which include customs service ports, are those entry locations authorized to receive entries of merchandise for the collection of duties and for the enforcement of the various provisions of the customs and navigation laws. *See* 19 CFR 101.1. In addition, CBP operates Customs stations, which are locations outside the boundaries of Customs ports of entry, but which, like Customs ports of entry, are authorized to receive entries of merchandise and enforce the various provisions of the customs and navigation laws.[1] *See* 19 CFR 101.1.

[1] 19 CFR 101.3 lists both the Customs ports of entry and the Customs service ports. 19 CFR 101.4

Continued

In most cases, Customs ports of entry and Customs stations exist within the same physical location as immigration ports and utilize the same CBP personnel for processing travelers and merchandise. Despite the use of the same location and personnel, there are separate regulations governing the authority to establish, rearrange, consolidate, and close the immigration and Customs ports and stations. Authority regarding management of immigration ports is addressed in title 8 of the CFR, while Customs port and Customs station authority is addressed in title 19 of the CFR. *See* 8 CFR 100.4 and 234.4; 19 CFR 101.3 and 101.4.

With regard to customs ports of entry, 19 U.S.C. 2, authorizes the President ''to discontinue [customs] [2] ports of entry by abolishing the same or establishing others in their stead.'' President Truman delegated this authority to the Secretary of the Treasury in 1951.[3] The Secretary of the Treasury then delegated this authority to the Deputy Assistant Secretary (Regulatory, Tariff, and Trade Enforcement) through the regulation in Section 101.3 of Title 19 of the CFR (19 CFR 101.3). That regulation authorizes the Assistant Secretary to ''establish, rearrange or consolidate, and to discontinue customs ports of entry as the needs of the Customs Service may require.'' The Homeland Security Act of 2002 (the Act) transferred this authority to the Secretary of DHS.[4] See Public Law 107–22296, Section 403, 6 U.S.C. 203. Despite this transfer of authority to the Secretary of DHS, the regulation at 19 CFR 101.3 still refers to the Treasury officers.

The authority to establish, rearrange or consolidate, and to discontinue Customs stations is held by the Secretary of DHS pursuant to the Act. *See* Sec. 403, Public Law 107–296, 6 U.S.C. 203. This authority is not specifically referenced in the title 19 CFR regulations.

Prior to the passage of the Act, the authority to manage immigration ports of entry was held by the Commissioner of the Immigration and Nationality Service (INS). The Act transferred immigration related authorities, including those related to immigration ports of entry, from the Commissioner of the INS to the Secretary of DHS. *See* title IV, Public Law 107–296, 6 U.S.C. Chapter 1. The applicable regulations, 8 CFR 100.4 and 234.4, specify that the Commissioner of CBP (the Commissioner) has the authority to manage immigration ports of entry.[5]

In this rule, DHS is clarifying that the authority to establish, rearrange or consolidate, and to discontinue Customs ports of entry and Customs stations rests with the Secretary of Homeland Security and not the Secretary of the Treasury. This rule revises the applicable regulations in title 19 of the CFR so that they are consistent with the Act.

Specifically, DHS is amending 19 CFR 101.3 to reflect that the Secretary of DHS has the authority to establish, rearrange or consolidate, and discontinue Customs ports of entry and Customs service ports. DHS is also amending this section to include a reference to ''Customs service ports,'' which are a type of ''Customs port of entry'' as noted above. The specific reference to ''Customs service ports'' clarifies that the Secretary has the authority to establish, rearrange or consolidate, and to discontinue all Customs ports of entry, including service ports.

DHS is also amending 19 CFR 101.4 to reflect that the Secretary has the authority to establish, rearrange or consolidate, and discontinue Customs stations as operational needs may require.

II. Statutory and Regulatory Requirements

A. Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking in the **Federal Register** and provide interested persons the opportunity to submit comments. 5 U.S.C. 553(b), (c). The APA also generally requires that substantive rules have a 30-day delayed effective date from the date of publication. *See* 5 U.S.C. 553(d). However, certain exceptions are provided.

The APA provides an exception from notice and comment procedures as well as the requirement for a 30-day delayed effective date when the rule is a matter relating to agency management. *See* 5 U.S.C. 553(a)(2). In this rule DHS is merely updating regulations to reflect that the Secretary of DHS has the authority to establish, rearrange or consolidate, and discontinue Customs ports of entry and Customs service ports. Therefore, this is merely a matter of agency management.

Additionally, the APA provides an exception to notice and comment requirements when the rule is one of ''agency organization, procedure, or practice.'' *See* 5 U.S.C. 553(b)(A). This exception also applies because this rule merely amends the regulations to accurately reflect the Secretary of DHS's authority regarding ports and has no effect on the public.

Based on the above considerations, this rule is exempt from the notice and comment and delayed effective date provisions of the APA pursuant to 5 U.S.C. 553(a)(2) and 5 U.S.C. 553(b)(A).

B. Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this regulation.

These regulatory changes are being made to reflect the transfer of authority to establish, rearrange and close Customs ports of entry and Customs stations from the Secretary of the Treasury to the Secretary of DHS pursuant to the Act. These changes have no effect on the public as there will be no changes to services at the ports and no economic costs or benefits. Therefore, this rule has no economic impact.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined

lists the Customs stations, all of which are supervised by a Customs port of entry. The supervising port of entry for each Customs station is also listed in 19 CFR 101.4.

[2] The word ''customs'' added here for clarity. Although the word ''customs'' does not appear in this section, Title 19 of the U.S. Code specifically deals with customs duties and therefore this section relates to customs ports as defined herein.

[3] Executive Order 10289 (16 FR 9499).

[4] In 2006, the Secretary of Homeland Security issued a Delegation Order in which he delegated certain authorities to the Commissioner of CBP but specifically reserved to himself the authority to ''discontinue [Customs] ports of entry by abolishing the same and establishing others in their stead.'' *See* DHS Delegation Order 7010.3.

[5] 8 CFR 1.2 provides that after March 1, 2003, references to ''Commissioner'' mean the Director of U.S. Citizenship and Immigration Services, the Commissioner of U.S. Customs and Border Protection, and the Director of U.S. Immigration and Customs Enforcement, as appropriate in the context in which the term appears. In the context of immigration port authority in 8 CFR 100.4 and 234.4, ''Commissioner'' means the Commissioner of CBP.

as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people). Since a notice of proposed rulemaking was not necessary, a regulatory flexibility analysis is not required.

List of Subjects in 19 CFR Part 101

Harbors, Organization and functions (Government agencies), Seals and insignia, and Vessels.

For reasons set forth in the preamble, part 101 of title 19 of the Code of Federal Regulations is amended as set forth below:

PART 101—GENERAL PROVISIONS

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 5 U.S.C. 301; 6 U.S.C. 101, et. seq.; 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a. Section 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b; Section 101.5 also issued under 19 U.S.C. 1629; Section 101.9 also issued under 19 U.S.C. 1411–1414.

■ 2. Amend § 101.3 by revising paragraph (a) to read as follows:

§ 101.3 Customs service ports and ports of entry.

(a) *Designation of Customs field organization.* The Secretary of Homeland Security is authorized to establish, rearrange or consolidate, and to discontinue Customs ports of entry and Customs service ports as operational needs may require.

* * * * *

■ 3. Amend § 101.4 by revising paragraph (c) to read as follows:

§ 101.4 Entry and clearance of vessels at Customs stations.

* * * * *

(c) *Customs stations designated.*

(1) The Secretary of Homeland Security is authorized to establish, rearrange, or consolidate, and to discontinue Customs stations as operational needs may require.

(2) The Customs stations and the ports of entry having supervision thereof are listed below:

Customs station	Supervisory port of entry
Alaska	
Barrow	Fairbanks.
Dutch Harbor	Anchorage.
Eagle	Alcan.
Fort Yukon	Fairbanks.
Haines	Dalton Cache.
Hyder	Ketchikan.
Kaktovik (Barter Island)	Fairbanks.
Kenai (Nikiski)	Anchorage.
Northway	Alcan.
Pelican	Juneau.
Petersburg	Wrangell.
California	
Campo	Tecate.
Otay Mesa	San Diego.
San Ysidro	San Diego.
Colorado	
Colorado Springs	Denver.
Delaware	
Lewes	Philadelphia, PA.
Florida	
Fort Pierce	West Palm Beach.
Green Cove Springs	Jacksonville.
Port St. Joe	Panama City.
Indiana	
Fort Wayne	Indianapolis.
Maine	
Bucksport	Belfast.
Coburn Gore	Jackman.
Daaquam	Jackman.
Easton	Fort Fairfield.
Estcourt	Fort Kent.
Forest City	Houlton.
Hamlin	Van Buren.
Maryland	
Salisbury	Baltimore.
Massachusetts	
Provincetown	Plymouth.
Michigan	
Alpena	Saginaw-Bay City-Flint.
Detour	Sault Ste. Marie.
Escanaba	Sault Ste. Marie.
Grand Haven	Muskegon.
Houghton	Sault Ste. Marie.
Marquette	Sault Ste. Marie.
Rogers City	Saginaw-Bay City-Flint.
Minnesota	
Crane Lake	Duluth, MN-Superior, WI.
Ely	Duluth, MN-Superior, WI.
Lancaster	Noyes.
Oak Island	Warroad.
Mississippi	
Biloxi	Mobile, AL.
Montana	
Wild Horse	Great Falls.
Willow Creek	Great Falls.
New Jersey	
Atlantic City	Philadelphia-Chester, PA and Wilmington, DE.
Port Norris	Philadelphia-Chester, PA and Wilmington, DE.
Tuckerton	Philadelphia-Chester, PA and Wilmington, DE.
New York	
Cannons Corners	Champlain-Rouses Point.
Churubusco	Trout River.
New Hampshire	
Pittsburg	Beecher Falls, VT.
Monticello	Houlton, ME.
Orient	Houlton, ME.
Ste. Aurelie	Jackman, ME.
St. Pamphile	Jackman, ME.
New Mexico	
Antelope Wells (Mail: Hachita, NM).	Columbus, NM.
North Dakota	
Grand Forks	Pembina.
Minot	Pembina.
Ohio	
Akron	Cleveland.
Fairport Harbor	Ashtabula/Conneaut.
Lorain	Sandusky.
Marblehead-Lakeside	Sandusky.
Put-in-Bay	Sandusky.
Oklahoma	
Muskogee	Tulsa.
Texas	
Amistad Dam	Del Rio.
Boquillas	Presidio.
Falcon Dam	Roma.
Fort Hancock	Fabens.
Los Ebanos	Rio Grande City.
Marathon	El Paso.
Vermont	
Beebe Plaine	Derby Line.
Canaan	Beecher Falls.
East Richford	Richford.
Newport	Derby Line.
North Troy	Derby Line.
West Berkshire	Richford.

* * * * *

Alejandro N. Mayorkas,

Secretary.

[FR Doc. 2023–25280 Filed 11–15–23; 8:45 am]

BILLING CODE 9111–14–P

SELECTIVE SERVICE SYSTEM

32 CFR Part 1665

RIN 3240–AA04

Social Security Number Fraud Prevention Act of 2017 Implementation

AGENCY: United States Selective Service System.

ACTION: Direct Final Rule; request for comments.

SUMMARY: SSS is adding a section to its Privacy Act regulations to implement restrictions on the use of Social Security numbers in documents mailed by SSS.

These restrictions are required by the Social Security Number Fraud Prevention Act of 2017. The rule is intended to help reduce the potential risk of identity theft from fraudulent or other unauthorized acquisition of Social Security numbers from any SSS mailings.

DATES: The rule is effective November 13, 2023. Comments, if any, are requested by December 13, 2023.

ADDRESSES: You may submit comments identified by docket number and/or Regulatory Information Number (RIN) number and title by email to *federalregisterliaison@sss.gov,* or by mail to: Selective Service System, Federal Register Liaison, 1515 Wilson Boulevard, Suite 500, Arlington, VA 22209.

Instructions: All submissions received must include the Agency's name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Cramer, Selective Service System, Office of the General Counsel, 703–605–4069, *kcramer@sss.gov.*

SUPPLEMENTARY INFORMATION: The Social Security Number Fraud Prevention Act of 2017, Public Law 115–59, 131 Stat. 1152 (Sept. 15, 2017), codified at 42 U.S.C. 405 note, restricts Federal agencies from including Social Security numbers (SSNs) of individuals on documents sent by mail unless the head of the agency determines that including the SSN on the mailing is necessary. The Act requires agency heads to issue regulations within five years of the Act, specifying the circumstances under which including an SSN on a document sent by mail is necessary. The Act requires that the regulations include instructions for the partial redaction of SSNs where feasible and requires that SSNs not be visible on the outside of any package sent by mail.

To implement these requirements, SSS is amending its existing Privacy Act regulations, 32 CFR part 1665, adding a new § 1665.9 to accommodate the rule. The rule prohibits including an individual's SSN on any document that SSS sends by mail unless it is necessary, as determined by the Director of Selective Service (or other Agency official whom the Director of Selective Service may designate). If so, the rule requires that the SSN be truncated to display no more than the last four digits or, if such truncation is not feasible, the document may include additional SSN digits or the full SSN, as needed, but only under certain circumstances, *i.e.:* if required by law (*e.g.,* statute, court order, or other legal mandate); to identify a specific individual where no adequate substitute is available; or to fulfill some other compelling SSS business need. In all cases, the rule prohibits any SSN, truncated or not, from being visible on the outside of any SSS mailing.

Consistent with the language of the Act, and with the legislative intent and examples discussed in the House report (H.R. Rep. No. 115–150, pt. 1) accompanying the Act, the rule is limited to printed documents or correspondence mailed by SSS, including printed documents or correspondence mailed by a contractor acting on SSS's behalf. The rule does not apply to emails or other documents, correspondence, or communications transmitted by electronic means (*e.g.,* via web portals). The rule is also not intended to apply to mailings, if any, by candidates for SSS board and other volunteer positions (*e.g.,* State Resource Volunteers).

Administrative Procedure Act

The Agency finds good cause to publish this as a Direct Final Rule because the notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest because this rule expands protections to the public. The Agency is exempt from the prior public notice and comment requirements of the Administrative Procedure Act in accordance with 5 U.S.C. 553(b)(B). There is also no need to delay the effective date of the rule by 30 days, as normally required for substantive rules. See 5 U.S.C. 553(d). Instead, there is good cause to make the rule effective immediately, as it is merely procedural and reflects a statutory requirement that is already in effect (*i.e.,* documents mailed by the Agency may not include an SSN unless the Agency head determines it is necessary). Nonetheless, SSS will accept comments, if any, on the rule from interested parties, as provided in the **ADDRESSES** section of this document. SSS will consider such comments, if any, and may modify the rule on the basis of such comments, or as the Agency may otherwise deem necessary or appropriate.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule is not a significant regulatory action subject to review by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) under Executive Order 12866, section 6(a).

Executive Order 13132

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have any federalism implications, as described above.

Regulatory Flexibility Act

SSS hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The factual basis for this certification is that the rule governs only the circumstances under which SSS includes SSNs in documents mailed by SSS. The rule does not apply to mailings by small entities, other than any contractors who may be engaged to send mailings on SSS's behalf. Even in those cases, the economic impact would fall on SSS, not on the contractor, to determine to what extent, if any, a mailing needs to include an SSN in whole or part, and to pay mailing costs. In any event, SSS does not expect the volume of such mailings, if any, to be significant. Accordingly, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement analyzing and estimating anticipated costs and benefits before issuing any rule that may result in the expenditure by state, local, and Tribal Governments, in the aggregate, or

by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. See 2 U.S.C. 1532. The Act further requires that the agency publish a summary of such a statement with the agency's proposed and final rules. No statement or summary is required, since the rule will not result in the above-stated expenditure by state, local, and Tribal Governments, or by the private sector.

Section 1 of Executive Order 12785 requires the agency to submit a description of the extent of its prior consultation with representatives of affected state, local, and tribal governments, together with the agency's position, to OMB to support the need for any regulation that is not required by statute, if the direct compliance costs incurred by such governments will not be funded by the Federal Government (*i.e.,* an unfunded mandate). The Executive order does not apply, since the rule is required by statute and, in any event, imposes no mandate or compliance obligations, unfunded or otherwise, on any state, local, or Tribal Government.

Congressional Review Act

A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a major rule under 5 U.S.C. 801.

Paperwork Reduction Act

This rule contains no information collection, recordkeeping, or disclosure provisions that would constitute information collection activities subject to the OMB clearance requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

List of Subjects in 32 CFR Part 1665

Personally identifiable information, Privacy, Social security.

For the reasons stated in the preamble, SSS amends part 1665, title 32 of the Code of Federal Regulations, as set forth below:

PART 1665—PRIVACY ACT PROCEDURES

■ 1. Revise the authority citation for part 1665 to read as follows:

Authority: 5 U.S.C. 552a; Pub L. 115–59, 131 Stat. 1152, and 5 U.S.C. 301.

■ 2. Add § 1665.9 to read as follows:

§ 1665.9 SSS Compliance with the Social Security Fraud Prevention Act of 2017 to limit the use of Social Security numbers on documents mailed by the Selective Service System (SSS).

(a) A document that SSS sends by mail shall not include the Social Security number (SSN) of an individual, except where the Director of Selective Service (or other Agency official whom the Director of Selective Service may designate) determines that it is necessary. If so, the SSN must be truncated to the extent feasible, as follows—

(1) The document shall include no more than the last four digits of the SSN; or

(2) If the document needs to include more digits, then only where they are:

(i) Required by law (including, but not limited to, a statute, court order, or other legal mandate);

(ii) Needed to identify a specific individual when no adequate substitute is available; or

(iii) Needed to fulfill some other compelling SSS business need.

(b) No portion of an SSN may be visible on the outside of any SSS mailing.

(c) For purposes of this section, ''mail'' and ''mailing'' means printed documents or correspondence, and does not include emails or any other documents, correspondence, or communications in electronic form.

(d) The requirements of this section shall apply to mail sent by SSS, including mailings by a contractor on SSS's behalf, on or after November 13, 2023.

Daniel A. Lauretano, Sr.,

General Counsel.

[FR Doc. 2023–25036 Filed 11–15–23; 8:45 am]

BILLING CODE 8015–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0906]

RIN 1625–AA11

Safety Zone; Pacific Ocean, Oahu, Hawaii

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the re-entry of a space vehicle from the Starship Super Heavy launch by Space Exploration Technologies Corporation (Space X). The temporary safety zone is located within the Coast Guard District Fourteen area of responsibility, approximately 129 nautical miles offshore of Oahu, Hawaii. The purpose of this rule is to ensure the safety of vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled event. This action is necessary to provide for the safety of vessels and waterway users from the potential hazards created by reentry vehicle splashdowns and recovery operations in our exclusive economic zone. It is also necessary to provide for the safe recovery of reentry vehicles, and any personnel involved in reentry services, after the splashdown. This rule implements a special activities provision of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. Foreign-flagged vessels are encouraged to remain outside the safety zones. This rule prohibits U.S. flagged vessels from being in the safety zones unless authorized by the Commander of the Fourteenth Coast Guard District or a designated representative.

DATES: This rule is effective from 12:01 a.m. on November 17, 2023, through 11:59 p.m. on November 20, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0906 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Jessica Hull, District 14, Waterways Management Division, U.S. Coast Guard; telephone 808–535–3407, email *Jessica.L.Hull@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
EEZ Exclusive economic zone
FAA Federal Aviation Administration
FL Florida
FR Federal Register
MSIB Marine Safety Information Bulletin
NASA National Aeronautics and Space Administration
NM Nautical Mile
NPRM Notice of proposed rulemaking
RNA Regulated Navigation Area
§ Section
U.S. United States
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the

Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. Space Exploration Technologies Corporation (Space X) is a U.S. company. The SpaceX Starship Super Heavy mission was approved and scheduled less than 30 days before the need for the safety zone to be in place starting on November 17, 2023. Publishing an NPRM would be impracticable and contrary to the public interest since the missions would begin before completion of the rulemaking process, thereby inhibiting the Coast Guard's ability to protect against the hazards associated with re-entry of the capsule. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because the temporary safety zone must be established on November 17, 2023, to mitigate safety concerns during the capsule re-entry mission.

III. Legal Authority and Need for Rule

On January 1, 2021, the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) (Authorization Act) was enacted. Its section 8343 (134 Stat. 4710) calls for the Coast Guard to conduct a 2-year pilot program to establish and implement a process to establish safety zones to address special activities in the exclusive economic zone (EEZ). These special activities include space activities carried out by United States citizens. The Fourteenth District Commander and Captain of the Port Honolulu have determined that potential hazards associated with the Space X Starship spacecraft mission present a safety concern for anyone within the perimeter of the safety zone. The safety zone will only be activate for a reasonable time before the mission and deactivated once the area is no longer hazardous. The purpose of this rule is to ensure the safety of vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled event. The Coast Guard is issuing this rule under authority of section 8343 of the Authorization Act and 46 U.S.C. 70034.

IV. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone approximately 126 nautical miles north of Oahu, Hawaii for the re-entry of a SpaceX capsule. The coordinates are based on the projected re-entry locations as determined from telemetry data and modeling by Space X.

(1) Re-entry site:

Point 1	24°02′38″ N 157°33′43″ W
Point 2	24°08′49″ N 157°02′49″ W
Point 3	23°32′10″ N 156°53′17″ W
Point 4	23°25′48″ N 157°25′34″ W

The coordinates for the safety zones are based on the furthest north, east, south, and west points of the reentry vehicles splashdown and are determined from data and modeling by SpaceX and NASA. The coordinates take into account the trajectories of the reentry vehicles coming out of orbit and the potential risk to the public. The specific coordinates for the temporary safety zone is presented in the regulatory text at the end of this document.

To the extent feasible, 24 hours before a reentry vehicle splashdown and recovery operations, the District Commander, Captain of the Port Sector Honolulu, or a designated representative will inform the public of the activation of the temporary safety zones by Broadcast Notice to Mariners (BNM) on VHF–FM channel 16.

The District Commander, Captain of the Port Sector Honolulu, or designated representative will inform the public that the safety zone would remain activated (subject to enforcement) until announced by BNM on VHF–FM channel 16 that the safety zone is no longer subject to enforcement.

When the safety zone is activated, the District Commander, Captain of the Port Sector Honolulu, or a designated representative will be able to restrict U.S.-flagged vessel movement including but not limited to transiting, anchoring, or mooring within the safety zone to protect vessels from hazards associated with space activities. The activated safety zone will ensure the protection of vessels and waterway users from the potential hazards created by reentry vehicle splashdowns and recovery operations. This includes protection during the recovery of a reentry vehicle, and the protection of personnel involved in reentry services and space support vessels.[1]

After a reentry vehicle splashdown, the District Commander, Captain of the Port Sector Honolulu, or a designated representative will grant general permission to come no closer than three nautical miles within the activated safety zone from any reentry vehicle or space support vessel engaged in the recovery operations.

Once a reentry vehicle services are removed from the water and secured onboard a space support vessel, the District Commander, Captain of the Port Sector Honolulu, or designated representative would issue a BNM on VHF–FM channel 16 announcing the activated safety zone is no longer subject to enforcement.

When the safety zone is activated, the COTP or a designated representative will be able to restrict U.S.-flagged vessel movement including but not limited to transiting, anchoring, or mooring within the safety zone to protect vessels from hazards associated with capsule re-entry.[2] Because the safety zones are within the U.S. EEZ, only U.S.-flagged vessels would be subject to enforcement. However, all foreign-flagged vessels are encouraged to remain outside the safety zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and scope of the temporary safety zone. The safety zone will be established for approximately three and one half hours. After the launch has been completed, the Coast Guard will notify waterway

[1] *Space Support Vessel* means any vessel engaged in the support of space activities. These vessels are typically approximately 170 feet in length, have a forward wheelhouse, and are equipped with a helicopter pad and lifting crane.

[2] *Reentry Services* means (1) activities involved in the preparation of a reentry vehicle and payload, crew (including crew training), government astronaut, or space flight participant, if any, for reentry; and (2) the conduct of a reentry.

users and vessels that the safety zone is no longer in effect. The safety zone will ensure the protection of vessels and waterway users from the potential hazards created by the re-entry of the SpaceX capsule.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a safety zone through the duration of a space vehicle reentry. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T14–0906 to read as follows:

§ 165.T14–0906 Safety Zone; Pacific Ocean, Oahu, Hawaii.

(a) *Location.* The Coast Guard is establishing a safety zone in the U.S. exclusive economic zone (EEZ) for the re-entry of a capsule launched by SpaceX. The temporary zone is located within the Captain of the Port Sector Honolulu area of responsibility 129 nautical miles offshore of Oahu, Hawaii.

(1) *Re-entry site.* All waters of the Pacific Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at Point 1, thence to Point 2, thence to Point 3, thence to Point 4, connecting back to the beginning point.

TABLE 1 TO PARAGRAPH (a)(1)

Point 1	24°02′38″ N	157°33′43″ W
Point 2	24°08′49″ N	157°02′49″ W
Point 3	23°32′10″ N	156°53′17″ W
Point 4	23°25′48″ N	157°25′34″ W

(2) [Reserved]

(b) *Definitions.* As used in this section—

Designated representative means a Coast Guard Captain of the Port (COTP) Sector Honolulu; Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating a Coast Guard vessel; and other officers designated by the Captain of the Port Sector Honolulu or assisting the Captain of the Port Sector

Honolulu in the enforcement of the safety zones.

District Commander means Commander of the Fourteenth Coast Guard District.

Reentry services means:

(i) Activities involved in the preparation of a reentry vehicle and payload, crew (including crew training), government astronaut, or space flight participant, if any, for reentry; and

(ii) The conduct of a reentry.

Reentry vehicle means a vehicle designed to return from Earth orbit or outer space to Earth, or a reusable launch vehicle designed to return from Earth orbit or outer space to Earth, substantially intact.

Space support vessel means any vessel engaged in the support of space activities.

Splashdown means the landing of a reentry vehicle into a body of water.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, U.S.-flagged vessels may not enter the safety zone described in paragraph (a) of this section unless authorized by the District Commander or a designated representative. All foreign-flagged vessels are requested and encouraged to remain outside the safety zone.

(2) To seek permission to enter, transit through, anchor in or remain within the safety zone contact Sector Honolulu Command Center by telephone at (808) 842–2600 or the District Commander's representative via VHF–FM radio on channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the District Commander or a designated representative.

(3) The COTP Honolulu or a designated representative may restrict vessel movement including but not limited to transiting, anchoring, or mooring within the safety zone to protect vessels from hazards associated with rocket recoveries. These restrictions are temporary in nature and will only be enacted and enforced prior to and just after the recovery missions.

(d) *Enforcement period.* (1) To the extent possible, twenty-four hours before a reentry vehicle splashdown, reentry vehicle splashdown, the District Commander, Captain of the Port Sector Honolulu or designated representative will inform the public of the activation of the safety zone described in paragraph (a) of this section by Broadcast Notice to Mariners on VHF–FM channel 16. The safety zone described in paragraph (a) will remain activated until announced by Broadcast Notice to Mariners on VHF–FM channel 16, and/or Marine Safety Information Bulletin (as appropriate) that the safety zone is no longer subject to enforcement.

(2) After a reentry vehicle splashdown, the District Commander, Captain of the Port Sector Honolulu, or a designated representative will grant general permission to come no closer than three nautical miles of any reentry vehicle or space support vessel engaged in the recovery operations, within the activated safety zone described in paragraph (a) of this section.

(3) Once a reentry vehicle or its remnants are removed from the water and secured onboard a space support vessel, the District Commander, Captain of the Port Sector Honolulu, or designated representative will issue a Broadcast Notice to Mariners on VHF–FM channel 16 announcing the activated safety zone is no longer subject to enforcement.

(e) *Effective period.* This section is effective from 12:01 a.m. on November 17, 2023, through 11:59 p.m. on November 20, 2023.

Blake L. Novak,

Captain, U.S. Coast Guard, Fourteenth Coast Guard District.

[FR Doc. 2023–25429 Filed 11–15–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1, 11, and 41

[Docket No. PTO–C–2023–0010]

RIN 0651–AD67

Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule.

SUMMARY: The U.S. Patent and Trademark Office (USPTO or Office) is amending the rules of practice in patent cases and the rules regarding the representation of others before the USPTO by creating a separate design patent practitioner bar whereby admitted design patent practitioners would practice in design patent proceedings only. Prior to this rulemaking, there was only one patent bar that applied to those who practice in patent matters before the Office, including in utility, plant, and design patents. The creation of a design patent practitioner bar does not impact the ability of those already registered to practice in any patent matters before the USPTO to continue to practice in any patent matters, including design patent matters, before the Office. Furthermore, it does not impact the ability of applicants for registration who meet the criteria to practice in all patent matters from qualifying for and upon passing the current registration exam, practicing in any patent matters before the Office, including design patent matters. Expanding the admission criteria of the patent bar encourages broader participation and keeps up with the ever-evolving technology and related teachings that qualify someone to practice before the USPTO. The Manual of Patent Examining Procedure will be updated in accordance with this final rule in due course.

DATES: This rule is effective January 2, 2024.

FOR FURTHER INFORMATION CONTACT: Will Covey, Deputy General Counsel for Enrollment and Discipline and Director of the Office of Enrollment and Discipline (OED), at 571–272–4097; and Scott C. Moore, Acting Vice Chief Administrative Patent Judge, Patent Trial and Appeal Board, at 571–272–9797.

SUPPLEMENTARY INFORMATION:

Purpose

The Director of the USPTO has statutory authority to require a showing by patent practitioners that they possess ''the necessary qualifications to render applicants or other persons valuable service, advice, and assistance in the presentation or prosecution of their applications or other business before the Office.'' 35 U.S.C. 2(b)(2)(D). Courts have determined that the USPTO Director bears the primary responsibility for protecting the public from unqualified practitioners. See *Hsuan-Yeh Chang* v. *Kappos,* 890 F. Supp. 2d 110, 116–17 (D.D.C. 2012) (''Title 35 vests the [Director of the USPTO], not the courts, with the responsibility to protect [US]PTO proceedings from unqualified practitioners.'') (quoting *Premysler* v. *Lehman,* 71 F.3d 387, 389 (Fed. Cir. 1995)), aff'd sub nom., *Hsuan-Yeh Chang* v. *Rea,* 530 F. App'x 958 (Fed. Cir. 2013).

Pursuant to that authority and responsibility, the USPTO promulgated regulations, administered by OED, that provide that registration to practice in patent matters before the USPTO requires a practitioner to demonstrate possession of ''the legal, scientific, and technical qualifications necessary for him or her to render applicants valuable service.'' See 37 CFR 11.7(a)(2)(ii). The

Office determines whether an applicant possesses the legal qualification by administering a registration examination, which applicants for registration must pass before being admitted to practice. See 37 CFR 11.7(b)(ii). To take the registration exam, applicants must first demonstrate they possess specific scientific and technical qualifications. The USPTO sets forth guidance for establishing possession of these scientific and technical qualifications in the General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases Before the United States Patent and Trademark Office (GRB), available at *www.uspto.gov/sites/default/files/documents/OED_GRB.pdf.* The GRB also contains the ''Application for Registration to Practice before the United States Patent and Trademark Office.''

The criteria for practicing before the Office are and continue to be based in part on a determination of the types of scientific and technical qualifications and legal knowledge that are essential for practitioners to possess. This helps ensure that only competent practitioners who understand the applicable rules and regulations and have the background necessary to describe inventions in a full and clear manner are permitted to practice.

Prior to this rule, there was only one patent bar that applied to those who practice in patent matters before the Office, including in utility, plant, and design patents. The same scientific and technical requirements for admission to practice applied regardless of the type of patent application (that is, whether the application is a utility patent application, a plant patent application, or a design patent application). To gather public input before undertaking a rulemaking that would expand to the patent bar, on October 18, 2022, the USPTO published a request for comments in which it requested comments on the scope and eligibility criteria of a design patent practitioner bar. *See* Expanding Admission Criteria for Registration To Practice in Patent Cases Before the United States Patent and Trademark Office (87 FR 63044). On January 19, 2023, the USPTO extended the response period until January 31, 2023. See Expanding Admission Criteria for Registration To Practice in Patent Cases Before the United States Patent and Trademark Office (88 FR 3394).

The Office received a number of comments in favor of the creation of a separate design patent practitioner bar which noted that a design patent practitioner bar would: (1) align the criteria for design patent practitioners with those of design patent examiners at the USPTO; (2) improve design patent practitioner quality and representation; (3) allow more under-represented groups to practice design patent law and aid more under-represented inventors in acquiring patents; (4) enable individuals with valuable knowledge of design to aid design patent prosecution; (5) lower the costs of obtaining design patents by promoting competition among practitioners; (6) ensure consistent, high-quality design patents via qualified practitioners; (7) enlarge the pool of available service providers, including those practitioners whose background may be more tailored to the needs of a design patent applicant; and (8) increase economic opportunities for design practitioners by allowing them to access a new market for the provision of their professional services. The Office received a few comments that were not supportive of the creation of a separate design patent practitioner bar. These included statements that the division of the bar would cause confusion within the public, increase the cost of identifying appropriate counsel, add significant administrative and policing costs to the USPTO, and increase the risk of potential malpractice and ethical concerns.

Of the options presented, the majority of those who were in favor of creating and implementing a design patent practitioner bar preferred that design patent practitioner bar applicants be required to take the current registration examination, with modified scientific and technical requirements. Those who were in favor of this option noted that if the modified scientific and technical requirements included design degrees, the patent quality of design patents would increase because individuals with design degrees would be better able to prepare and prosecute design patent applications. Additionally, commenters noted that this option could increase the pool of potential applicants, which could lead to beneficial procompetitive effects. Lastly, this option would mirror the hiring practices of the USPTO for design patent examiners in that the same degrees would enable the practice of design patent examination in the Office and in prosecution before the Office.

Proposed Rule: Comments and Responses

On May 16, 2023, after considering all public input, the USPTO published a notice of proposed rulemaking, at 88 FR 31209, in which it proposed implementing a design patent practitioner bar. The notice of proposed rulemaking provided for a 90-day comment period.

The USPTO received nine unique comments from three organizations and six individuals. These comments are publicly available at the Federal eRulemaking Portal at *www.regulations.gov.* The Office received comments both generally supporting and objecting to the creation and implementation of a design patent practitioner bar. A summary of the comments and the USPTO's responses are provided below.

Comment 1: Three commenters opposed the proposal to create and implement a design patent practitioner bar, stating that a design patent practitioner would lack the training and experience to provide fully competent counsel concerning the differences between utility and design patent protection, have a bias favoring pursuit of design patent protection which could work against the client's interest, and that such a bar would create confusion amongst the public.

Response 1: All practitioners, including design patent practitioners, are required to provide competent representation to their clients. ''Competent representation requires the legal, scientific, and technical knowledge, skill, thoroughness and preparation reasonably necessary for the representation.'' See 37 CFR 11.101. In addition, all practitioners are required to be familiar with the Office's rules and regulations, as demonstrated by applicants taking and passing the registration examination. Confusion by the public is avoided in part by allowing design patent practitioners to indicate their designation as a ''design patent attorney'' or ''design patent agent,'' and requiring such practitioners to indicate ''design'' when they are signing USPTO documents.

Based on the support of stakeholders and commenters, this rulemaking implements a design patent practitioner bar wherein design patent practitioner bar applicants would be required to take the current registration examination, with modified scientific and technical requirements. Applicants to the design patent practitioner bar should have a bachelor's, master's, or doctorate of philosophy degree in any of the following areas from an accredited college or university: industrial design, product design, architecture, applied arts, graphic design, fine/studio arts, or art teacher education, or a degree equivalent to one of these listed degrees. Accepting degrees equivalent to those design degrees listed above is in line with the current practice of accepting degrees that are equivalent to those

listed in the GRB under Category A. These listed degrees are currently acceptable for those applying for design patent examiner positions with the Office. To ensure applicants to the design patent practitioner bar have the requisite knowledge of USPTO rules and regulations, the USPTO also requires them to take and pass the current registration examination. Applicants are also required to undergo and pass a moral character evaluation. The evaluation would be the same evaluation that is conducted for all patent bar applicants and is described in the GRB.

As mentioned above, admitted design patent practitioners may practice in design patent matters only. Patent practitioners admitted in the past, present, and future who have fulfilled the scientific and technical requirements as enumerated in the GRB in Categories A through C will be authorized to practice in all patent matters, including in utility, plant, and design patents.

Comment 2: One commenter suggested that a study of the implementation of a design patent practitioner bar, its impact on applicants/clients, and its overall effect on an efficient and reliable patent system be conducted.

Response 2: The USPTO issued a Request for Comments on this issue on October 18, 2022, requesting input on the creation and implementation of a design patent practitioner bar. See 87 FR 63044. Expanding the admission criteria of the patent bar would encourage broader participation and keep up with the ever-evolving technology and related teachings that qualify someone to practice before the USPTO. Based on the responses received, and the noted support of a design patent practitioner bar, the USPTO is proceeding with its implementation.

Comment 3: Two commenters requested clarification regarding whether the USPTO will accept candidates with coursework and/or work experience, as currently accepted for USPTO employment.

Response 3: The USPTO will accept degrees and evidence of equivalence to one of the listed degrees. Like the analysis for practice in all patent matters, the USPTO will evaluate each applicant for equivalency on a case-by-case basis.

Comment 4: Two commenters expressed concern that design patent practitioners may claim, or that clients may inappropriately believe, that design patent practitioners have specialized skills, training, or approval beyond traditional patent practitioners, providing them with expertise in design. Another commenter expressed concern that design patent practitioners should indicate that they are qualified to practice in design patent matters only.

Response 4: As per 37 CFR 1.32, ''[a]n attorney or agent registered under § 11.6(d) may only act as a practitioner in design patent applications or other design patent matters or design patent proceedings.'' Per ethics rule, 37 CFR 11.101, all practitioners, including design patent practitioners, are required to provide competent representation to their clients. This includes properly informing their clients of practice limitations.

Comment 5: One commenter expressed concern about design patent practitioners receiving a registration number and stated it would be beneficial to place a letter designation alongside the number.

Response 5: Patent Center does not support alphabetic indicators alongside registration numbers. However, design patent practitioners will receive a particular registration number series to distinguish them from those practitioners who are authorized to practice in all patent matters.

Comment 6: One commenter suggested that the USPTO remove all degree requirements for attorneys to sit for the registration examination.

Response 6: Courts have determined that the USPTO Director bears the primary responsibility for protecting the public from unqualified practitioners. See *Hsuan-Yeh Chang* v. *Kappos,* 890 F. Supp. 2d 110, 116–17 (D.D.C. 2012) (''Title 35 vests the [Director of the USPTO], not the courts, with the responsibility to protect [US]PTO proceedings from unqualified practitioners.'') (quoting *Premysler* v. *Lehman,* 71 F.3d 387, 389 (Fed. Cir. 1995)), aff'd sub nom., *Hsuan-Yeh Chang* v. *Rea,* 530 F. App'x 958 (Fed. Cir. 2013). Pursuant to that authority and responsibility, the USPTO promulgated regulations, administered by OED, that provide that registration to practice in patent matters before the USPTO requires a practitioner to demonstrate possession of ''the legal, scientific, and technical qualifications necessary for him or her to render applicants valuable service.'' See 37 CFR 11.7(a)(2)(ii). The USPTO sets forth guidance for establishing possession of these scientific and technical qualifications in the GRB. As these regulations and guidance have been long-standing, they are entitled to great weight. See *Alaska Dep't of Envtl. Conservation* v. *EPA,* 540 U.S. 461, 487 (2004) (recognizing that the Court ''will normally accord particular deference to longstanding agency interpretations'' (quoting *Barnhart* v. *Walton,* 535 U.S. 212, 220 (2002))); *Bragdon* v. *Abbott,* 524 U.S. 624, 644–45 (1998); *NLRB* v. *Hendricks Cnty. Rural Elec. Membership Corp.,* 454 U.S. 170, 189–90 (1981); *Menkes* v. *U.S. Dep't of Homeland Sec.,* 637 F.3d 319, 332 (D.C. Cir. 2011) (''It is highly significant here that the agency's 'interpretation is one of long standing.' '' (quoting *Walton,* 535 U.S. at 221)); *Estate of Landers* v. *Leavitt,* 545 F.3d 98, 107 (2d Cir. 2008) (finding that agency's ''longstanding'' interpretation was ''entitled to a great deal of persuasive weight''); *Council Tree Commc'ns, Inc.* v. *FCC,* 503 F.3d 284, 289 (3d Cir. 2007) (''[C]ourts give 'considerable weight' to a 'consistent and longstanding interpretation by the agency' responsible for administering a statute.'' (quoting *Int'l Union of Elec. Radio & Mach. Workers* v. *Westinghouse Electric Corp.,* 631 F.2d 1094, 1106 (3d Cir. 1980)).

Comment 7: One commenter suggested that instead of having design patent bar applicants take the current registration examination, applicants take an entirely new and separate design bar examination. Such applicants would then be the only ones entitled to practice in design patent matters.

Response 7: This suggestion has not been adopted. As previously indicated by other commenters, design bar practitioners need to be familiar with the practices and procedures of patent preparation and prosecution before the USPTO. This is what the current registration examination tests. Restricting the ability to practice in design patent matters from those who meet the criteria for registration to practice in all patent matters would take away a right from those already qualified and be unfair to those who may qualify in the future.

Discussion of Specific Rules

The USPTO amends § 1.4(d)(1) to add the requirement that a design patent practitioner indicate their design patent practitioner status by placing the word ''design'' (in any format) adjacent to their handwritten signature.

The USPTO amends § 1.4(d)(2)(ii) to add the requirement that a design patent practitioner indicate their design patent practitioner status by placing the word ''design'' (in any format) adjacent to the last forward slash of their S-signature.

The USPTO amends § 1.32 to update the definition of ''practitioner'' in light of the amendments to § 11.6(d).

A power of attorney naming the practitioners associated with a customer number filed in an application may only

include practitioners who are authorized to practice in that application. If a design practitioner is associated with a customer number, that customer number cannot be used to establish power of attorney in a utility or plant application. This applies even if a practitioner that is authorized to practice before the Office in all patent matters is also associated with that same customer number.

The USPTO amends § 11.1 to add a definition for ''design patent practitioner.''

The USPTO amends § 11.1 to amend paragraph (1) under the definition of ''practitioner'' to refer to § 11.6.

The USPTO amends § 11.1 to amend the definition of ''register or roster'' to include design patent practitioners.

The USPTO amends § 11.5 to amend paragraph (b)(1) to add ''all'' in view of new paragraph (b)(2), so that it is clear that (b)(1) defines the matters that a patent practitioner who is authorized to practice in all patent matters can practice; to remove ''public use'' proceedings, which are no longer held, and insert ''derivation'' proceedings; re-designate paragraph (b)(2) as paragraph (b)(3); and insert a new paragraph (b)(2), which defines practice before the Office in design patent matters.

The USPTO amends § 11.6 to re-designate paragraph (d) as paragraph (e), and insert a new paragraph (d) to clarify the parameters under which attorneys and agents may be registered as design patent practitioners.

The USPTO amends § 11.8(b) to require design patent practitioners to submit an oath or declaration under the same parameters as other registered practitioners.

The USPTO amends § 11.10(b) to restrict former employees of the USPTO from serving as design patent practitioners, commensurate with the restrictions placed on other registered practitioners.

The USPTO amends § 11.16(c) to clarify that only a practitioner registered under § 11.6(a) or (b) may serve as a Patent Faculty Clinic Supervisor in the USPTO Law School Clinic Certification Program.

The USPTO amends § 11.704 to state that a registered practitioner under § 11.6(a) who is an attorney may use the designation ''Patents,'' ''Patent Attorney,'' ''Patent Lawyer,'' ''Registered Patent Attorney,'' or a substantially similar designation; a registered practitioner under § 11.6(b) who is not an attorney may use the designation ''Patents,'' ''Patent Agent,'' ''Registered Patent Agent,'' or a substantially similar designation; a registered practitioner under § 11.6(d) who is an attorney may use the designation ''Design Patent Attorney''; and a registered practitioner under § 11.6(d) who is not an attorney (*i.e.,* who is an agent) may use the designation ''Design Patent Agent.''

The USPTO amends § 41.106 by replacing the term ''registered patent practitioner'' with ''registered practitioner.'' This amendment is intended solely to conform the terminology of this section to that used elsewhere in part 41 and is not intended to alter the substantive scope of § 41.106. For avoidance of doubt, the USPTO clarifies that the term ''registered practitioner,'' as used in parts 41 and 42, and the term ''USPTO patent practitioner,'' as used in § 42.57, encompasses ''design patent practitioners,'' as defined in § 11.1.

Rulemaking Requirements

A. Regulatory Flexibility Act: For the reasons set forth in this rulemaking, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO, has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This rule amends the rules regarding the representation of others before the USPTO to create a separate design patent practitioner bar in which admitted design patent practitioners practice in design patent proceedings only. The creation of a design patent practitioner bar does not impact the ability of those already registered to practice in any patent matters, including design patent matters, before the USPTO. Furthermore, it does not impact the ability of applicants who meet the scientific and technical criteria as described in Categories A through C in the GRB, including qualifying for and passing the current registration exam and passing the moral character evaluation, to practice in any patent matters before the Office.

The Regulatory Flexibility Act of 1980 (RFA) requires Federal agencies to consider the potential impact of regulations on small entities during the development of their rules. See 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (March 29, 1996). The term ''small entities'' is comprised of small businesses, not-for-profit organizations that are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. An ''individual'' is not defined by the RFA as a small entity and costs to an individual from a rule are not considered for RFA purposes. In addition, the courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities. Consequently, any indirect impacts from a rule to a small entity are not considered as costs for RFA purposes.

This rulemaking creates a separate design patent practitioner bar that only impacts individuals who apply for recognition to practice before the USPTO in design patent proceedings and does not directly impact any small businesses. Additionally, the changes do not add requirements or costs beyond those that currently exist for applicants or members to the USPTO practitioner bar. The changes only expand the applicants that can represent certain matters before the USPTO. Applicants to the design patent practitioner bar are expected to pay the same application and examination fee as applicants who want to practice in all patent matters and are subject to existing requirements and procedures during the application process (for example, the same application and supporting documentation would be required of all applicants). Accordingly, the changes are expected to be of minimal or no additional burden to those practicing before the Office.

The Office acknowledges that the creation of a design patent practitioner bar allows more practitioners to be recognized to practice before the USPTO, although they would be limited to design patent proceedings only. The Office considers these to be indirect impacts that are not considered to be costs for RFA purposes. The Office has not received any comments of data regarding the costs for RFA purposes.

For the reasons discussed above, this rulemaking will not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of E.O. 12866 (Sept. 30, 1993), as amended by Executive Order 14094 (April 6, 2023).

C. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with E.O. 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits;

(4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

D. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 13132 (Aug. 4, 1999).

E. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under E.O. 13175 (Nov. 6, 2000).

F. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under E.O. 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under E.O. 13211 (May 18, 2001).

G. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden, as set forth in sections 3(a) and 3(b)(2) of E.O. 12988 (Feb. 5, 1996).

H. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under E.O. 13045 (Apr. 21, 1997).

I. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under E.O. 12630 (Mar. 15, 1988).

J. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a ''major rule'' as defined in 5 U.S.C. 804(2).

K. Unfunded Mandates Reform Act of 1995: The changes in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

L. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

M. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

N. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking involves information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The collections of information involved in this rulemaking have been reviewed and previously approved by OMB under OMB control numbers 0651–0012 (Admission to Practice and Roster of Registered Patent Attorneys and Agents Admitted to Practice Before the USPTO) and 0651–0017 (Practitioner Conduct and Discipline). These information collections are updated alongside this final rulemaking, to reflect any updated forms included within these information collections. Any increased respondent and burden numbers associated with the introduction of the design patent practitioner bar options are included in that update.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information has a currently valid OMB control number.

O. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 11

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

37 CFR Part 41

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the USPTO amends 37 CFR parts 1, 11, and 41 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Amend § 1.4 by revising paragraphs (d)(1) introductory text and (d)(2)(ii) to read as follows:

§ 1.4 Nature of correspondence and signature requirements.

* * * * *

(d)(1) *Handwritten signature.* A design patent practitioner must indicate their design patent practitioner status by

placing the word ''design'' (in any format) adjacent to their handwritten signature. Each piece of correspondence, except as provided in paragraphs (d)(2) through (4), (e), and (f) of this section, filed in an application, patent file, or other proceeding in the Office that requires a person's signature, must:

* * * * *

(2) * * *

(ii) A patent practitioner (§ 1.32(a)(1)), signing pursuant to § 1.33(b)(1) or (2), must supply their registration number either as part of the S-signature or immediately below or adjacent to the S-signature. The hash (#) character may only be used as part of the S-signature when appearing before a practitioner's registration number; otherwise, the hash character may not be used in an S-signature. A design patent practitioner must additionally indicate their design patent practitioner status by placing the word ''design'' (in any format) adjacent to the last forward slash of their S-signature.

* * * * *

■ 3. Amend § 1.32 by revising paragraph (a)(1) to read as follows:

§ 1.32 Power of attorney.

(a) * * *

(1) *Patent practitioner* means a registered patent attorney or registered patent agent under § 11.6. An attorney or agent registered under § 11.6(d) may only act as a practitioner in design patent applications or other design patent matters or design patent proceedings.

* * * * *

PART 11—REPRESENTATION OF OTHERS BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

■ 4. The authority citation for part 11 continues to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 2(b)(2), 32, 41; Sec. 1, Pub. L. 113–227, 128 Stat. 2114.

■ 5. Amend § 11.1 by:
■ a. Adding in alphabetical order a definition for ''Design patent practitioner''; and
■ b. Revising the definitions of ''Practitioner'' and ''Roster or register''.

The addition and revisions read as follows:

§ 11.1 Definitions.

* * * * *

Design patent practitioner means a practitioner who is registered under § 11.6(d).

* * * * *

Practitioner means:

(1) An attorney or agent registered to practice before the Office in patent matters under § 11.6;

(2) An individual authorized under 5 U.S.C. 500(b), or otherwise as provided by § 11.14(a) through (c), to practice before the Office in trademark matters or other non-patent matters;

(3) An individual authorized to practice before the Office in patent matters under § 11.9(a) or (b); or

(4) An individual authorized to practice before the Office under § 11.16(d).

* * * * *

Roster or *register* means a list of individuals who have been registered as a patent attorney, patent agent, or design patent practitioner.

* * * * *

■ 6. Amend § 11.5 by:
■ a. Revising paragraph (b)(1),
■ b. Re-designating paragraph (b)(2) as (b)(3), and
■ c. Adding new paragraph (b)(2).

The revisions and addition read as follows:

§ 11.5 Register of attorneys and agents in patent matters; practice before the Office.

* * * * *

(b) * * *

(1) *Practice before the Office in all patent matters.* Practice before the Office in patent matters includes, but is not limited to, preparing or prosecuting any patent application; consulting with or giving advice to a client in contemplation of filing a patent application or other document with the Office; drafting the specification or claims of a patent application; drafting an amendment or reply to a communication from the Office that may require written argument to establish the patentability of a claimed invention; drafting a reply to a communication from the Office regarding a patent application; and drafting a communication for an interference, derivation, and/or reexamination proceeding, a petition, an appeal to or any other proceeding before the Patent Trial and Appeal Board, or any other patent proceeding. Registration to practice before the Office in patent matters authorizes the performance of those services that are reasonably necessary and incident to the preparation and prosecution of patent applications or other proceedings before the Office involving a patent application or patent in which the practitioner is authorized to participate. The services include:

(i) Considering the advisability of relying upon alternative forms of protection which may be available under State law, and

(ii) Drafting an assignment or causing an assignment to be executed for the patent owner in contemplation of filing or prosecution of a patent application for the patent owner, where the practitioner represents the patent owner after a patent issues in a proceeding before the Office, and when drafting the assignment the practitioner does no more than replicate the terms of a previously existing oral or written obligation of assignment from one person or party to another person or party.

(2) *Practice before the Office in design patent matters.* (i) Practice before the Office in design patent matters includes, but is not limited to, preparing or prosecuting a design patent application; consulting with or giving advice to a client in contemplation of filing a design patent application or other document relating to a design patent application with the Office; drafting the specification or claim of a design patent application; drafting an amendment or reply to a communication from the Office that may require written argument to establish the patentability of a claimed design invention; drafting a reply to a communication from the Office regarding a design patent application; and drafting a communication for an interference, derivation, and/or reexamination proceeding, a petition, an appeal to or any other design patent proceeding before the Patent Trial and Appeal Board, or any other design patent proceeding.

(ii) Design patent registration to practice before the Office in design patent matters authorizes the performance of those services that are reasonably necessary and incident to the preparation and prosecution of design patent applications or other proceedings before the Office involving a design patent application or design patent in which the practitioner is authorized to participate. The services include:

(A) Considering the advisability of relying upon alternative forms of protection which may be available under State law, and

(B) Drafting an assignment or causing an assignment to be executed for the design patent owner in contemplation of filing or prosecution of a design patent application for the design patent owner, where the design patent practitioner represents the design patent owner after a design patent issues in a proceeding before the Office, and when drafting the assignment the design patent practitioner does no more than replicate the terms of a previously existing oral or

written obligation of assignment from one person or party to another person or party.

* * * * *

■ 7. Amend § 11.6 by re-designating paragraph (d) as (e) and adding a new paragraph (d).

The addition reads as follows:

§ 11.6 Registration of attorneys and agents.

* * * * *

(d) *Design patent practitioners.* Any citizen of the United States who is an attorney and who fulfills the requirements of this part may be registered as a design patent attorney to practice before the Office in design patent proceedings. Any citizen of the United States who is not an attorney, and who fulfills the requirements of this part may be registered as a design patent agent to practice before the Office in design patent proceedings.

* * * * *

■ 8. Amend § 11.8 by revising paragraph (b) to read as follows:

§ 11.8 Oath and registration fee.

* * * * *

(b) An individual shall not be registered as an attorney under § 11.6(a), registered as an agent under § 11.6(b) or (c), registered as a design patent practitioner under § 11.6(d), or granted limited recognition under § 11.9(b) unless, within two years of the mailing date of a notice of passing the registration examination or of a waiver of the examination, the individual files with the OED Director a completed Data Sheet, an oath or declaration prescribed by the USPTO Director, and the registration fee set forth in § 1.21(a)(2) of this subchapter. An individual seeking registration as an attorney under § 11.6(a) must provide a certificate of good standing of the bar of the highest court of a State that is no more than six months old.

* * * * *

■ 9. Amend § 11.10 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to read as follows:

§ 11.10 Restrictions on practice in patent matters; former and current Office employees; government employees.

* * * * *

(b) * * *

(1) To not knowingly act as an agent, attorney, or design patent practitioner for or otherwise represent any other person:

* * * * *

(2) To not knowingly act within two years after terminating employment by the Office as agent, attorney, or design patent practitioner for, or otherwise represent any other person:

* * * * *

■ 10. Amend § 11.16 by revising paragraph (c)(1)(i) to read as follows:

§ 11.16 Requirements for admission to the USPTO Law School Clinic Certification Program.

* * * * *

(c) * * *

(1) * * *

(i) Be registered under § 11.6(a) or (b) as a patent practitioner in active status and good standing with OED;

* * * * *

■ 11. Amend § 11.704 by revising paragraph (b) to read as follows:

§ 11.704 Communication of fields of practice and specialization.

* * * * *

(b) A registered practitioner under § 11.6(a) who is an attorney may use the designation ''Patents,'' ''Patent Attorney,'' ''Patent Lawyer,'' ''Registered Patent Attorney,'' or a substantially similar designation. A registered practitioner under § 11.6(b) who is not an attorney may use the designation ''Patents,'' ''Patent Agent,'' ''Registered Patent Agent,'' or a substantially similar designation. A registered practitioner under § 11.6(d) who is an attorney may use the designation ''Design Patent Attorney.'' A registered practitioner under § 11.6(d) who is not an attorney may use the designation ''Design Patent Agent.'' Unless authorized by § 11.14(b), a registered patent agent or design patent agent shall not hold themself out as being qualified or authorized to practice before the Office in trademark matters or before a court.

* * * * *

PART 41—PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 12. The authority citation for part 41 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135, and Pub. L. 112–29.

■ 13. Amend § 41.106 by revising paragraph (f)(4) to read as follows:

§ 41.106 Filing and service.

* * * * *

(f) * * *

(4) A certificate made by a person other than a registered practitioner must be in the form of an affidavit.

Kathi Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023–25234 Filed 11–15–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2020–0432; FRL–10121–02–R2]

Approval and Promulgation of Air Quality Implementation Plans; New Jersey; Regional Haze State Implementation Plan for the Second Implementation Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the regional haze Staet implementation plan (SIP) revision submitted by New Jersey on March 26, 2020, as satisfying applicable requirements under the Clean Air Act (CAA) and EPA's Regional Haze Rule (RHR) for the program's second implementation period. New Jersey's SIP submission addresses the requirement that states must periodically revise their long-term strategies for making reasonable progress towards the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility, including regional haze, in mandatory Class I Federal areas. The SIP submission also addresses other applicable requirements for the second implementation period of the regional haze program.

DATES: This final rule is effective on December 18, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R02–OAR–2020–0432. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are

available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nicholas Ferreira, Air Programs Branch, Environmental Protection Agency, Region 2, 290 Broadway, 25th Floor, New York, New York 10007–1866, telephone number: (212) 637–3127, email address: *ferreira.nicholas@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background
II. Evaluation of Comments
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I. Background

On March 26, 2020, the New Jersey Department of Environmental Protection (NJDEP) submitted a revision to its SIP to address regional haze for the second implementation period. NJDEP supplemented its SIP submission on September 8, 2020, and April 1, 2021. NJDEP made this SIP submission to satisfy the requirements of the CAA's regional haze program pursuant to CAA sections 169A and 169B and 40 CFR 51.308.

On August 19, 2022, the EPA published a Notice of Proposed Rulemaking (NPRM) in which the EPA proposed to approve New Jersey's March 26, 2020, SIP submission, as supplemented on September 8, 2020, and April 1, 2021, as satisfying the regional haze requirements for the second implementation period contained in the CAA and 40 CFR 51.308. *See* 87 FR 51016. The EPA is now determining that the New Jersey regional haze SIP submission for the second implementation period meets the applicable statutory and regulatory requirements and is thus approving New Jersey's submission into its SIP.

II. Evaluation of Comments

In response to the NPRM, the EPA received eight comments, seven of which were unique, during the 30-day public comment period and is providing responses to the comments that were received. The specific comments may be viewed under Docket ID Number EPA–R02–OAR–2020–0432 on the *https://www.regulations.gov* website.

Comment: Several commentors, including MANE–VU, the Tennessee Department of Environment & Conservation, and the National Park Service (NPS), support EPA's proposal to approve New Jersey's regional haze Staet implementation plan (SIP). One commenter, MANE–VU, also states that it supports EPA's thorough approach in reviewing New Jersey's SIP, including its response to each MANE–VU Ask.

Response: EPA appreciates and agrees with the commentors.

Comment: Several commentors, including the Tennessee Department of Environment & Conservation, Virginia Department of Environmental Quality, and North Carolina Division of Air Quality, acknowledge EPA's assessment and agree with EPA's determination that the Reasonable Progress Goals (RPGs) cannot include strategies for upwind states that those upwind states have not adopted.

Response: As noted in the NPRM, § 51.308(f)(3)(i) specifies that RPGs must reflect ''enforceable emissions limitations, compliance schedules, and other measures *required under paragraph (f)(2)* of this section'' (emphasis added). RPGs are intended to provide a snapshot of projected visibility conditions at the end of the implementation period, assuming all measures that are necessary to make reasonable progress at a given class I area are being implemented. The emission reduction measures that must be reflected in RPGs include adopted regulations and measures that both the downwind and upwind states have identified as necessary and that will be implemented by 2028. However, EPA interprets this provision to exclude emission reduction measures that downwind states believe are necessary to make reasonable progress but that upwind states have not, at the time of plan submission, determined are necessary pursuant to § 51.308(f)(2). This ensures that RPGs include only those measures that are reasonably certain to be implemented.

New Jersey's 2028 RPGs include measures for upwind states that, as of now, have not been determined to be necessary to make reasonable progress by those upwind states and are not currently included in their long-term strategies. Therefore, those RPGs in the New Jersey SIP do not represent implementation of the measures required under § 51.308(f)(2) and, as a result, do not accurately represent RPGs for Brigantine Wilderness. New Jersey's 2028 most impaired base case of 18.16 deciviews reflects the visibility conditions that are projected to be achieved based on states' existing measures. As such, EPA considers the 2028 modeled base case value of 18.16 deciviews to be a more appropriate, conservative estimate of the RPG for the 20% most impaired visibility days as it does not inappropriately rely on highly uncertain upwind emissions reductions.

Comment: The commentor, NPS, expresses concern over the use of MANE–VU's contribution threshold to identify the Class 1 areas New Jersey impacts beyond its boundaries and believes this threshold is not adequately protective of cumulative visibility impacts at Class 1 areas outside of the Staet. The commentor also states that it supports EPA's recognition that New Jersey emission sources contribute to visibility impairment for Class I areas beyond the Staet's boundaries, including at Shenandoah National Park in Virginia.

Response: In the NPRM, EPA did not expressly determine and explicitly state that New Jersey significantly contributes to visibility impairment for Class I areas beyond its boundaries, including at Shenandoah National Park in Virginia.

Regarding the analysis and determinations concerning New Jersey's contribution to visibility impairment at out-of-state Class I areas, the MANE–VU technical work focuses on the magnitude of visibility impacts from certain New Jersey emissions on its Class I area and other nearby Class I areas. Nevertheless, as explained in the NPRM, the analyses this rulemaking is based on did not account for all emissions and all components of visibility impairment (*e.g.,* primary PM emissions, and impairment from fine PM, elemental carbon, and organic carbon). In addition, as stated in the NPRM, ''Q/d'' analyses [1] with a relatively simplistic accounting for wind trajectories and CALPUFF being applied to a very limited set of electric generating units (EGUs) and major industrial sources of sulfur dioxide (SO_2) and nitrogen oxides (NO_X) are not scientifically rigorous tools capable of evaluating contribution to visibility impairment from *all* emissions in a Staet. Furthermore, we note in the NPRM that the 2 percent or greater sulfate-plus-nitrate threshold used to determine whether New Jersey emissions contribute to visibility impairment at a particular Class I area may be higher than what EPA believes is an ''extremely low triggering threshold'' intended by the statute and regulations.

In sum, as discussed in the NPRM, based on the information provided in the SIP submission, emissions from New Jersey do contribute to visibility impairment at Brigantine Wilderness

[1] ''Q/d'' is emissions (Q) in tons per year, typically of one or a combination of visibility impairing pollutants, divided by distance to a class I area (d) in kilometers. The resulting ratio is commonly used as a metric to assess a source's potential visibility impacts on a particular class I area.

and have relatively minor contributions to other out-of-state Class I areas. However, as we indicated in the NPRM, due to the low triggering threshold intended by the CAA and the RHR and the lack of rigorous modeling analyses, EPA does not necessarily agree with New Jersey's conclusion that, based on a 2% contribution threshold, it does not contribute to visibility impairment at any Class I areas outside the Staet. While New Jersey noted that the contributions from several states outside the MANE–VU region are significantly larger than its own, we again clarify that each Staet is obligated under the CAA and the RHR to address regional haze visibility impairment resulting from emissions from within the State, irrespective of whether another Staet's contribution is greater. See ''Clarifications Regarding Regional Haze State Implementation Plans for the Second implementation Period,'' dated July 8, 2021 (''2021 Clarifications Memo'').[2]

Comment: The commentor, National Parks Conservation Association (NPCA), states that EPA's final action must make clear that reliance on the MANE–VU analysis alone is inadequate to satisfy the Regional Haze Rule. The commentor expresses concern that (1) the MANE–VU 3.0 Mm-1 threshold for defining sources to evaluate for additional controls to achieve reasonable progress towards the national visibility goal and (2) the two percent threshold New Jersey employed based on MANE–VU are unreasonably high.

Response: As explained in the NPRM, EPA does not necessarily agree that the 3.0 inverse megameters (Mm^{-1}) visibility impact is a reasonable threshold for source selection. The RHR recognizes that, due to the nature of regional haze visibility impairment, numerous and sometimes relatively small sources may need to be selected and evaluated for implementation of control measures to make reasonable progress. See 2021 Clarifications Memo at 4. As explained in the 2021 Clarifications Memo, while states have discretion to choose any source selection threshold that is reasonable, ''[a] state that relies on a visibility (or proxy for visibility impact) threshold to select sources for four-factor analysis should set the threshold at a level that captures a meaningful portion of the state's total contribution to visibility impairment to Class I areas.'' See 2021 Memo at 3. In this case, the 3.0 Mm^{-1} threshold identified only one source in New Jersey (and only 22 across the entire MANE–VU region), indicating that it may in some cases be unreasonably high. Since MANE–VU's threshold identified only one source in New Jersey for four-factor analysis, we do not in this case necessarily agree that a 3.0 Mm^{-1} threshold for selecting sources for four-factor analysis results in a set of sources the evaluation of which has the potential to meaningfully reduce the Staet's contribution to visibility impairment.

In this particular instance, we proposed to find that New Jersey's additional information and explanation indicated that the State had in fact examined a reasonable set of sources, including sources flagged by the federal land managers (FLMs), and reasonably concluded that four-factor analyses for its top-impacting sources were not necessary because the outcome would be that no further emission reductions would be reasonable. EPA based the proposed finding on the State's examination of its largest operating EGUs and its industrial commercial institutional (ICI) boilers, at the time of SIP submission, and on the emissions from and controls that apply to those sources, as well as on New Jersey's existing SIP-approved NO_X and SO_2 rules that effectively control emissions from the largest contributing stationary-source sectors.[3]

Comment: The commentor, NPCA, asserts that, contrary to the CAA's requirement, SIP measures, including stationary source emission limitations, must be practically enforceable and approved into the SIP. Additionally, the commentor notes EPA's proposal explains that for MANE–VU's Ask 4, the State's reliance and use of this Ask, which includes unspecified provisions that either are or will be in stationary source permits, is approvable ''as being part of the region's strategy for making reasonable progress.'' NPCA states that EPA must not approve this element of the proposed SIP because the permit provisions in construction and operating permits neither are nor will be in the SIP.

Response: EPA's approval of New Jersey's regional haze SIP is based on the fact the submission satisfies the applicable regulatory requirements for the second planning period in 40 CFR 51.308(f), (g), and (i). The applicable regulatory requirements include that states must evaluate and determine the emission reduction measures which are necessary to make reasonable progress by considering the four statutory factors, and that the measures that are necessary for reasonable progress must be in the SIP. EPA's NPRM explains that MANE–VU's Asks 2 and 3 engage with these requirements. EPA's proposal further explains that the measures in the State's SIP, and the related explanations it provided in its SIP submission, satisfy those Asks and therefore the applicable regulatory requirements. EPA's approval is therefore based on its determination that New Jersey's response to Asks 2 and 3 satisfy the reasonable progress requirements. To the extent that MANE–VU and the State regard the measures in Asks 1 and 4 through 6 as being part of the long term strategy for making reasonable progress, it was reasonable for New Jersey to address those Asks in its SIP submission.

As articulated in EPA's NPRM, Ask 4 requests that MANE–VU states pursue updating permits, enforceable agreements, and/or rules to lock-in lower emission rates for sources larger than 250 million British Thermal Units (MMBtu) per hour that have switched to lower emitting fuels. New Jersey's federally approved SIP for NO_X reasonably available control technology (RACT) limits the capability of a subject facility to switch to higher emitting fuels.[4] Furthermore, New Jersey's federally approved sulfur regulations in their SIP, provide that any source that combusts solid fuel and that is constructed, installed, reconstructed or modified, is also subject to New Jersey's state-of-the-art requirements,[5] lowest achievable emission rate requirements,[6] and best available control technology requirements at 40 CFR 52.21. In addition, modified units in New Jersey are required to amend their permits through the New Source Review (NSR) process if they plan to switch back to coal or a fuel that will increase emissions. A change in fuel would be a modification.[7] New Jersey's operating

[2] Clarifications Regarding Regional Haze State Implementation Plans for the Second Implementation Period. The EPA Office of Air Quality Planning and Standards, Research Triangle Park (July 8, 2021). *https://www.epa.gov/system/files/documents/2021-07/clarificationsregarding-regional-haze-state-implementationplans-for-the-second-implementation-period.pdf.*

[3] See April 2021 Supplemental Information for New Jersey's March 2020 Regional Haze SIP at 4–7.

[4] See N.J.A.C. 7:27–19.20 ''Fuel switching.''

[5] See N.J.A.C. 7:27–8.12 ''State of the art'' and N.J.A.C. 7:27–22.35 ''Advances in the art of air pollution control.''

[6] See N.J.A.C. 7:27–18 ''Control and Prohibition of Air Pollution from New or Altered Sources Affecting Ambient Air Quality (Emission Offset Rules).''

[7] See N.J.A.C. 7:27–22.1, defining ''Modify'' or ''modification'' as ''means any physical change in, or change in the method of operation of, existing equipment or control apparatus that increases the amount of actual emissions of any air contaminant emitted by that equipment or control apparatus or that results in the emission of any air contaminant not previously emitted. This term shall not include

permits regulations require that an application to modify the permit be submitted prior to the change in fuel.[8] Given the permitting and regulatory requirements outlined above, the EPA finds that New Jersey reasonably determined it had satisfied Ask 4.

Comment: Sierra Club and NPCA comment that EPA must thoroughly consider environmental justice concerns, for which the New Jersey SIP revision fails to adequately account. The energy and non-air quality environmental impacts of compliance factor directs states to consider the broader environmental implications of their regional haze plans, by requiring an analysis of the ''non-air quality environmental impacts of compliance,'' including environmental justice. In addition, the commenters assert that EPA failed to consider environmental justice concerns in several New Jersey communities identified by EPA's EJ Screen ranking in the ''90+ percentile for air toxics cancer risk, air toxics respiratory health impacts, and ozone exposure.'' Commenters also state that neither the SIP submittal nor EPA's proposal explain how the SIP complies with Title VI of the Civil Rights Act of 1964.

Response: The regional haze statutory provisions do not explicitly address considerations of environmental justice, and neither do the regulatory requirements of the second planning period in 40 CFR 51.308(f), (g), and (i). However, the lack of explicit direction does not preclude the State's SIP submission. As explained in ''EPA Legal Tools to Advance Environmental Justice,'' [9] the CAA provides states with the discretion to consider environmental justice in developing rules and measures related to regional haze. While a Staet may consider environmental justice under the reasonable progress factors, neither the statute nor the regulation requires states to conduct an environmental justice analysis for EPA to approve a SIP submission.

In this instance, New Jersey explained that it ''determined that reasonable progress is being made with the implementation of the Asks and other additional measures to improve visibility for the second planning period.'' [10] In its submittal, the State also noted that it has an advisory body, the Environmental Justice Advisory Council (EJAC), that is committed to the basic tenet set forth by the ''Environmental Justice Movement that all communities, regardless of their racial, ethnic, or economic composition, are entitled to equal protection from the consequences of environmental hazards.'' New Jersey's submittal also states that EJAC has a workgroup that focuses on air issues. In addition, the State's submittal indicates that New Jersey Executive Order No. 23,[11] signed on April 20, 2018, by Governor Murphy, directs NJDEP, with support from other agencies, to develop guidance on how all Staet departments can incorporate environmental justice considerations into their actions.

Commenters have provided additional information from an EJ Screen analysis that the State did not consider as part of its regional haze decision making. Without agreeing with the particular relevance or accuracy of this information, EPA acknowledges the EJ Screen information provided as part of the comment, which identifies certain demographic and environmental information regarding areas across New Jersey. The focus of the SIP at issue here, the regional haze SIP for New Jersey, is sulfate and nitrate emissions. This action addresses one EGU facility with three units and two industrial/institutional sources of air pollution impacting Class I areas. As discussed in the NPRM and in this notice of final rulemaking, EPA has evaluated New Jersey's SIP submission against the statutory and regulatory regional haze requirements and determined that it satisfies those minimum requirements. Furthermore, the CAA and applicable implementing regulations neither prohibit nor require such an evaluation of environmental justice with a SIP.

In addition to the above-discussed environmental justice related comments, the commenters also reference Title VI of the Civil Rights Act of 1964 (Title VI). EPA has previously addressed comments pertaining to Title VI and submitted on attainment planning SIP actions. *See, e.g.,* 87 FR 60494, 60530 (Oct. 5, 2022); 77 FR 65294 (Oct. 26, 2012). Most recently, EPA acknowledged in the October 5, 2022, proposed action that EPA has not issued national guidance or regulations concerning consideration of Title VI in the context of the SIP program. EPA indicated in the October 5, 2022, proposed action that guidance concerning implementation of CAA section 110(a)(2)(E) and Title VI is forthcoming.

Comment: The commentor, NPCA, asserts that there are two statements in section III.C. ''Long-Term Strategy for Regional Haze,'' [12] of the proposal that are inconsistent with the statutory requirements for reasonable progress. The commentor states that EPA must correct and clarify these inaccurate and confusing statements in its final action. The commentor notes that where a Staet uses visibility impacts (or supposedly minimal or insufficient visibility improvements) to reject emission controls at air pollution sources, that SIP submittal will be at odds with the plain language of the Act. The commentor also states that EPA must clarify in its final action that states must not rely on visibility to exclude emission reducing measures from a source that would otherwise be required to do so under the four statutory factors.

Response: EPA agrees with the commentor that visibility should not be used to summarily reject controls that are reasonable given the four statutory factors and notes that New Jersey did not use visibility impacts to reject emission controls at air pollution sources in its SIP submission. However, the EPA has also explained that states have flexibility under the CAA and RHR to reasonably consider visibility benefits as an optional factor alongside the four statutory factors, so long as such consideration does undermine or nullify the role of those statutory factors.[13]

III. Final Action

EPA is approving New Jersey's March 26, 2020, SIP submission, supplemented on September 8, 2020, and April 1, 2021, as satisfying the regional haze requirements for the second implementation period contained in 40 CFR 51.308(f).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve Staet choices, provided that they meet

normal repair and maintenance. A modification may be incorporated into an operating permit through a significant modification, a minor modification, or a seven-day-notice change.''

[8] See N.J.A.C. 7:27–22 ''Operating Permits.''

[9] See EPA Legal Tools to Advance Environmental Justice, May 2022, available at *https://www.epa.gov/system/files/documents/2022-05/EJ%20Legal%20Tools%20May%202022%20FINAL.pdf* at 35–36.

[10] See Appendix K of docket EPA–R02–OAR–2020–0432.

[11] *https://nj.gov/infobank/eo/056murphy/pdf/E.O.-23.pdf.*

[12] See 87 FR 51020–23.

[13] See, *e.g.,* Responses to Comments on Protection of Visibility: Amendments to Requirements for State Plans; Proposed Rule (81 FR 26942, May 4, 2016), Docket Number EPA–HQ–OAR–2015–0531, U.S. Environmental Protection Agency at 186; 2019 Guidance at 36–37.

the criteria of the Clean Air Act. Accordingly, this action merely approves Staet law as meeting federal requirements and does not impose additional requirements beyond those imposed by Staet law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a Staet program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and it will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The NJDEP did not evaluate EJ considerations by means of an extensive EJ analysis as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. Nevertheless, NJDEP did reference existing EJ programs within its SIP submittal, as described above in the section titled, ''Evaluation of Comments.'' EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 16, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Lisa Garcia,

Regional Administrator, Region 2.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart FF—New Jersey

■ 2. In § 52.1570, the table in paragraph (e) is amended by adding an entry for ''Regional Haze Plan from 2018–2028'' at the end of the table to read as follows:

§ 52.1570 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEW JERSEY NONREGULATORY AND QUASI-REGULATORY PROVISIONS

SIP element	Applicable geographic or nonattainment area	New Jersey submittal date	EPA approval date	Explanation
*	*	*	*	*
Regional Haze Plan from 2018–2028.	State-wide	March 26, 2020 as supplemented on September 8, 2020 and April 1, 2021.	11/16/2023, [insert **Federal Register** citation].	• Full approval. • New Jersey has met the Regional Haze Rule requirements for the 2nd implementation period.

[FR Doc. 2023–25239 Filed 11–15–23; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[GN Docket No. 16–142; FCC 23–53; FR ID 184482]

Authorizing Permissive Use of the ''Next Generation'' Broadcast Television Standard

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection requirements associated with the Commission's rules in a Report and Order on authorizing permissive use of the ''Next Generation'' Broadcast Television Standard. This document is consistent with the Commission's Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: The amendments to 47 CFR 73.3801(f) and (i), 73.6029(f) and (i), and 74.782(g) and (j) are published at 88 FR 45347, July 17, 2023 are effective as of November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Evan Baranoff, Policy Division, Media Bureau, at 202–418–7142, or via email at *evan.baranoff@ffc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on November 7, 2023, OMB approved the information collection requirements contained in §§ 73.3801, 73.6029, and 74.782 of the Commission's rules. The OMB Control Number is 3060–1254. The Commission publishes this document as an announcement of the effective date of these rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 3–317, 45 L Street NE, Washington, DC 20554. Please include the OMB Control Number, 3060–1254, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval on November 7, 2023, for the information collection requirements contained in §§ 73.3801, 73.6029, and 74.782 of the Commission's rules.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1254.

OMB Approval Date: November 7, 2023.

OMB Expiration Date: November 30, 2026.

Title: Next Gen TV/ATSC 3.0 Local Simulcasting Rules; 47 CFR 73.3801 (full-power TV), 73.6029 (Class A TV), and 74.782 (low-power TV) and FCC Form 2100 (Next Gen TV License Application).

Form Number: FCC Form 2100 (Next Gen TV License Application).

Respondents: Business or other for-profit entities, state, local, or tribal government and not for profit institutions.

Number of Respondents and Responses: 1,222 respondents; 11,260 responses.

Estimated Time per Response: 0.017–8 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement; Third party disclosure.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1, 4, 7, 301, 303, 307, 308, 309, 316, 319, 325(b), 336, 338, 399b, 403, 614, and 615 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 157, 301, 303, 307, 308, 309, 316, 319, 325(b), 336, 338, 399b, 403, 534, and 535.

Total Annual Burden: 3,802 hours.

Total Annual Cost: $147,000.

Needs and Uses: On June 23, 2023, the Commission released a Third Report and Order (Third R&O), FCC 23–53, in GN Docket No. 16–142. In this Third R&O, the Commission makes changes to its Next Gen TV rules designed to preserve over-the-air (OTA) television viewers' access to multicast streams during television broadcasters' transition to ATSC 3.0.

Multicast Licensing. The Commission generally adopts its proposal in the Next Gen TV Multicast Licensing FNPRM to allow a Next Gen TV station to seek modification of its license to include certain of its non-primary video programming streams (multicast streams) that are aired on ''host'' stations during a transitional period. In adopting this proposal, the Commission follows the same licensing framework, and to a large extent the same regulatory regime, established for the simulcast of primary video programming streams on ''host'' station facilities.

Form 2100. The Commission adopts the Next Gen TV Multicast Licensing FNPRM's proposal to modify its Next Gen TV license application form (FCC Form 2100) to accommodate multicast licensing by collecting information similar to that already collected in the interim STA process. The Commission requires certain additional information as an addendum to Form 2100 if stations seek to include hosted multicast streams within their license. It also clarifies and slightly modifies the requirements of its rules governing Form 2100 to reflect the possibility of reliance on multiple hosts.

Specifically, applicants must prepare an Exhibit identifying each proposed hosted stream and provide the following information about each stream, as broadcast:

- the host station;
- channel number (RF and virtual);
- network affiliation (or type of programming if unaffiliated);
- resolution (*e.g.,* 1080i, 720p, 480p, or 480i);
- the predicted percentage of population within the noise limited service contour served by the station's original ATSC 1.0 signal that will be served by the host, with a contour overlay map identifying areas of service loss and, in the case of 1.0 streams, coverage of the originating station's community of license; and
- whether the stream will be simulcast, and if so, the ''paired'' stream in the other service.

Finally, the Exhibit must either state that the applicant will be airing the same programming that it is airing in 1.0

at the time of the application or identify the station that has aired or is airing the same or a similar programming lineup at the same resolutions on the same type of facility (individual or shared), as well as that station's lineup (with resolutions). This Exhibit must be placed on the applicant's public website or in the applicant's online public inspection file if the station does not have a dedicated website, with a link provided in the application. This information is consistent both with that currently collected in STA applications and the approach identified in the Next Gen TV *Multicast Licensing FNPRM.* As with broadcast licenses generally, modifications to this license application or its accompanying exhibit (with respect to the primary or multicast streams) must be preceded by the filing and approval of a new application. Changes to the affiliation or content of a stream, or the elimination of a stream, however, do not implicate the concerns raised in this proceeding if they would not result in the use of additional capacity and if information about the change is easily available to the public. Therefore, in order to streamline this process for both broadcasters and the Commission, such changes may be implemented without prior Commission approval. They need only be reflected in a timely update to the Exhibit that the applicant makes available on its public website or in the applicant's online public inspection file and in an email notice to the Chief of the Media Bureau's Video Division. The new information collection requirements are contained in §§ 73.3801(f) and (i), 73.6029(f) and (i), and 74.782(g) and (j) of the Commission's rules.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2023–25305 Filed 11–15–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 386 and 387

[Docket No. FMCSA–2016–0102]

RIN 2126–AC10

Broker and Freight Forwarder Financial Responsibility

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA amends the regulations pertaining to financial responsibility requirements for brokers of property and freight forwarders in five separate areas: assets ''readily available''; immediate suspension of broker/freight forwarder operating authority; surety or trust responsibilities in cases of broker/freight forwarder financial failure or insolvency; enforcement authority; and entities eligible to provide trust funds for brokers and freight forwarders, which are filed using Form BMC–85, Broker's or Freight Forwarder's Trust Fund Agreement under 49 U.S.C. 13906 or Notice of Cancellation of the Agreement.

DATES:

Effective date: This regulation is effective January 16, 2024.

Expiration dates: Section 387.307T, which contains the current regulations on broker of property surety bonds or trust funds, expires as of January 16, 2025.

Section 387.307, which contains the revised regulations on broker of property surety bonds or trust funds, is stayed until January 16, 2025.

Compliance dates: Brokers, surety providers, and financial institutions must comply with the provisions regarding immediate suspension, financial failure or insolvency, and enforcement authority on January 16, 2025.

Brokers, surety providers, and financial institutions must comply with the provisions regarding assets readily available and entities eligible to provide trust funds for Form BMC–85 trust fund filings on January 16, 2026.

Petition submittal date: Petitions for reconsideration of this final rule must be submitted to the FMCSA Administrator no later than December 18, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey L. Secrist, Chief, Registration, Licensing, and Insurance Division, Office of Registration, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 385–2367, *Jeff.Secrist@dot.gov.* If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this final rule as follows:

I. Availability of Rulemaking Documents
II. Executive Summary
  A. Summary of Major Provisions
  B. Costs and Benefits
III. Abbreviations
IV. Legal Basis for the Rulemaking
V. Discussion of Proposed Rulemaking and Comments
  A. Proposed Rulemaking
  B. Comments and Responses
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    2. Immediate Suspension of Broker/Freight Forwarder Operating Authority
    3. Surety or Trust Responsibility in Case of Broker/Freight Forwarder Financial Failure or Insolvency
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    5. Entities Eligible To Provide Trust Funds for Form BMC–85 Trust Fund Filings
    6. Proposed Changes to the Regulatory Text
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VII. Section-by-Section Analysis
VIII. Severability
IX. Regulatory Analyses
  A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 14094 (Modernizing Regulatory Review), and DOT Regulatory Policies and Procedures
  B. Congressional Review Act
  C. Regulatory Flexibility Act (Small Entities)
  D. Assistance for Small Entities
  E. Unfunded Mandates Reform Act of 1995
  F. Paperwork Reduction Act (Collection of Information)
  G. E.O. 13132 (Federalism)
  H. Privacy
  I. E.O. 13175 (Indian Tribal Governments)
  J. National Environmental Policy Act of 1969

I. Availability of Rulemaking Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2016-0102/document* and choose the document to review. To view comments, click this final rule, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations at U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Executive Summary

A. Summary of Major Provisions

This final rule modifies the following five regulatory areas relating to broker and freight forwarder financial responsibility:

Assets Readily Available. In the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112–141, 126 Stat. 405, 822, MAP–21), Congress mandated that broker/freight forwarder trust funds consist of ''assets readily available to pay claims without resort to personal guarantees or collection of pledged accounts receivable,'' (49 U.S.C. 13906(b)(1)(C), (c)(1)(D)). The Agency adopts a definition of *assets readily available* that both implements the statutory requirement and is reasonable for the Agency to administer. The final rule sets out a list of the acceptable asset types a BMC–85 trust may contain. FMCSA has determined that these asset types are readily available because they are stable in value and can be easily liquidated within 7 calendar days of an event that triggers a payment from the trust.

Immediate Suspension of Broker/Freight Forwarder Operating Authority. Pursuant to this final rule, when a broker or freight forwarder's available financial security falls below $75,000, FMCSA may suspend its operating authority registration. A broker's or freight forwarder's ''available financial security'' may fall below $75,000 because a broker or freight forwarder consents to a drawdown, or if a broker or freight forwarder does not respond to a valid notice of claim from a surety or trust provider, or if a claim against the broker or freight forwarder is converted to a judgment. If the available financial security falls below $75,000 and the broker or freight forwarder does not replenish funds within 7 calendar days after notice from FMCSA, the Agency will issue a notification of suspension of operating authority to the broker or freight forwarder. The Agency intends to use its forthcoming Unified Registration System (URS) platform to receive information from surety providers, trustees, brokers, and freight forwarders and to administer FMCSA's responsibilities regarding immediate suspension of operating authority registration.

Surety or trust responsibilities in cases of broker/freight forwarder financial failure or insolvency. FMCSA defines *financial failure or insolvency* as any payment made or other default pursuant to § 387.307(e)(1), the regulatory provision that addresses the situations under which a broker or freight forwarder's operating authority may be immediately suspended, which the broker or freight forwarder does not cure in accordance with § 387.307(e)(5) or (6). This rule requires that if the surety/trustee becomes aware that a broker or freight forwarder is experiencing financial failure or insolvency, it must notify FMCSA and initiate cancelation of the financial responsibility. FMCSA will then publish a notice of failure in the FMCSA Register.[1]

If the broker or freight forwarder subsequently cures the default, and the surety company or financial institution reinstates the bond or trust or the broker or freight forwarder obtains a new bond or trust, FMCSA will lift the suspension notice and update the FMCSA Register.

As with the immediate suspension provision, FMCSA intends to use the forthcoming URS platform to receive information and carry out its own responsibilities under this provision.

Enforcement Authority. With this rule, FMCSA implements the requirement in MAP–21 for suspension of a surety or trust fund provider's authority in certain circumstances. The Agency will first provide notice of the suspension to the surety/trust fund provider, followed by 30 calendar days for the surety or trust fund provider to respond before a final Agency decision is issued. The Agency also adds monetary penalties and a statutorily mandated suspension in 49 Code of Federal Regulations (CFR) part 386, appendix B, for violations of the new requirements.

Entities Eligible to Provide Trust Funds for BMC–85 Filings. In this rule, FMCSA removes loan and finance companies from the list of providers eligible to serve as BMC–85 trustees, because this type of institution is not subject to the rigorous Federal regulations applicable to chartered depository institutions or to the state regulations applicable to insurance companies. Loan and finance companies will now be prohibited from offering BMC–85 trusts unless they obtain certification to operate as another type of financial institution that remains on the list of eligible providers in § 387.307(c).

B. Costs and Benefits

Brokers and freight forwarders, surety bond and trust fund providers, and the Federal Government will incur costs for compliance and implementation. The quantified costs of the rule include notification costs related to a drawdown on a surety bond or trust fund, and immediate suspension proceedings, FMCSA costs to hire new personnel, and costs associated with the development and maintenance of the BMC–84/85 Filing and Management Information Technology (IT) System. As shown in Table 1, FMCSA estimates that the 10-year cost of the rule will total $5.5 million on an undiscounted basis, $3.9 million discounted at 7 percent, and $4.7 million discounted at 3 percent (all in 2022 dollars). The annualized cost of the rule will be $559,971 discounted at 7 percent and $556,786 discounted at 3 percent. Ninety-eight percent of the costs will be incurred by the Federal Government.

TABLE 1—TOTAL COST OF THE RULE

Year	Undiscounted				Discounted	
	Brokers and freight forwarders	Financial responsibility providers	Federal govt.	Total [a]	Discounted at 7%	Discounted at 3%
2025	$2,500	$3,700	$706,700	$712,900	$666,300	$692,100
2026	2,700	4,000	526,800	533,500	466,000	502,900
2027	2,900	4,400	526,800	534,100	436,000	488,800
2028	3,200	4,800	526,900	534,900	408,100	475,300
2029	3,500	5,200	527,000	535,700	381,900	462,100
2030	3,800	5,700	527,100	536,600	357,600	449,400
2031	4,200	6,300	527,200	537,700	334,900	437,200
2032	4,600	6,800	527,300	538,700	313,500	425,300
2033	5,000	7,500	527,400	539,900	293,700	413,800

[1] The FMCSA Register is available at: *https://li-public.fmcsa.dot.gov/LIVIEW/pkg_menu.prc_menu.*

TABLE 1—TOTAL COST OF THE RULE—Continued

Year	Undiscounted				Discounted	
	Brokers and freight forwarders	Financial responsibility providers	Federal govt.	Total [a]	Discounted at 7%	Discounted at 3%
2034	5,500	8,200	527,500	541,200	275,100	402,700
Total	38,000	56,500	5,450,700	5,545,200	3,933,100	4,749,600
Annualized					559,971	556,786

[a] Total cost values may not equal the sum of the components due to rounding (the totals shown in this column are the rounded sum of unrounded components).

This rule will result in benefits to motor carriers. FMCSA is aware that some brokers choose to withhold payment to motor carriers for services rendered. Motor carriers can then submit claims to the financial responsibility provider to receive payment. If the financial responsibility provider has received claims against an individual broker that exceed $75,000, the financial responsibility provider will often submit the claims to a court in an interpleader action [2] to determine how to allocate the broker bond or trust fund. The interpleader process can be costly and time consuming for motor carriers, and generally results in motor carrier claims being paid pro rata, depending on the number of claims against the broker bond or trust fund. FMCSA believes that most brokers operate with integrity and uphold the contracts made with motor carriers and shippers. However, a minority of brokers with unscrupulous business practices can create unnecessary financial hardship for unsuspecting motor carriers.

FMCSA is relying on available data from which to draw an estimated percentage of how many brokers fail to pay motor carriers. The Agency's best estimate is that approximately 1.3 percent of brokers (totaling approximately 429 in 2022) [3] will experience a drawdown on their surety bond or trust fund within a given year, with average claim amounts of approximately $1,900 per claim submitted. Of these brokers, 18 percent may receive total claims in excess of $75,000, potentially leading to interpleader proceedings. Because this data is limited in scope, FMCSA cannot quantify benefits resulting from this rule. It is FMCSA's intent that the provisions in this rule will mitigate the need to initiate interpleader proceedings and alleviate the concern caused by broker non-payment of claims.

III. Abbreviations

ANPRM Advance Notice of Proposed Rulemaking
ATA American Trucking Associations
ATA–MSC ATA Moving and Storage Conference
CFR Code of Federal Regulations
DOT Department of Transportation
E.O. Executive Order
FDIC Federal Deposit Insurance Corporation
FMCSA Federal Motor Carrier Safety Administration
FR Federal Register
ILC Irrevocable Letters of Credit
ITSA International Trade Surety Association
MAP–21 The Moving Ahead for Progress in the 21st Century Act
NAICS North American Industry Classification System
NCCDB National Consumer Complaint Database
NCUA National Credit Union Association
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
OOIDA Owner-Operator Independent Drivers Association
PFA Pacific Financial Association, Inc. and PFA Transportation Insurance & Surety Services
SBA Small Business Administration
SFAA The Surety & Fidelity Association of America
TIA Transportation Intermediaries Association
UMRA The Unfunded Mandates Reform Act of 1995
URS Unified Registration System
U.S.C. United States Code

IV. Legal Basis for the Rulemaking

In 2012, Congress enacted MAP–21 (Pub. L. 112–141, 126 Stat. 405, 822), section 32918, which contained requirements for the financial security of brokers and freight forwarders in amendments to 49 U.S.C. 13906(b) and (c). Section 32918(b) of MAP–21 (note to 49 U.S.C. 13906) directed the Secretary to issue regulations to implement and enforce the requirements under subsections (b) and (c) of section 13906. Authority to carry out and enforce these provisions has been delegated to the Administrator of FMCSA (49 CFR 1.87(a)(5)).

Title 49 CFR 387.403T(c), concerning freight forwarder surety bonds and trust funds, provides that the requirements applicable to broker of property surety bonds and trust funds in § 387.307 also apply to the surety bond or trust fund required of freight forwarders. Therefore, any time this rule and this preamble refer to brokers, the same requirements are also applicable to freight forwarders.

V. Discussion of Proposed Rulemaking and Comments

A. Proposed Rulemaking

On January 5, 2023, FMCSA published an NPRM titled ''Broker and Freight Forwarder Financial Responsibility'' in the **Federal Register** (Docket No. FMCSA–2016–0102, 88 FR 830). The NPRM proposed amending the regulations in five separate areas: assets readily available; immediate suspension of broker/freight forwarder operating authority; surety or trust responsibilities in cases of broker/freight forwarder financial failure or insolvency; enforcement authority; and entities eligible to provide trust funds for Form BMC–85 trust fund filings.

B. Comments and Responses

FMCSA solicited comments for a total of 90 days. On March 8, 2023, FMCSA announced that it would be holding a listening session on this rulemaking and other broker related matters in conjunction with the Mid-America Trucking Show in Louisville, KY on March 31, 2023, and the Agency extended the public comment period until April 6, 2023 (88 FR 14439).[4]

[2] ''By definition, interpleader is a suit to determine a right to property held by a disinterested third party who is in doubt about ownership and who deposits the property with the court so that interested parties can litigate ownership.'' *Scottrade, Inc.* v. *Davenport,* No. CV–11–03–BLG–RFC, 2011 WL 153999, at *1 (D. Mont. Apr. 21, 2011).

[3] See Table 4 of the Regulatory Impact Analysis (RIA) which is available in the Docket for this rulemaking for further detail.

[4] The public listening session was recorded and is available at: *https://www.youtube.com/watch?v=*

By April 6, the deadline for submitting responses to the NPRM, FMCSA received 340 unique comments, including Air & Expedited Motor Carriers Association (AEMCA), Airforwarders Association (AfA), the American Trucking Associations Moving and Storage Conference (ATA–MSC), Auto Haulers Association of America (AHAA), American Home Furnishings Alliance (AHFA), Apex Capital Corp, Avalon Risk Management Insurance Agency LLC (Avalon), Alliance for the Safe, Efficient and Competitive Truck Transportation (ASECTT), International Trade Surety Association (ITSA), Liberty National Financial Corporation (Liberty), National Association of Small Trucking Companies (NASTC), National Owner Operators Association, Owner-Operator Independent Drivers Association (OOIDA), Pacific Financial Association, Inc. and PFA Transportation Insurance & Surety Services (PFA), Pinnacle Financial Partners/Pinnacle Bank, Sompo International, Specialized Furniture Carriers, The Surety & Fidelity Association of America (SFAA), The Expedite Association of North America (TEANA), Transportation Intermediaries Association (TIA), Transportation & Logistics Council (T&LC), Transportation & Loss Prevention and Security Association (TLP&SA), approximately 30 private and family-owned businesses, and approximately 300 individuals.

1. Assets Readily Available

In the NPRM, FMCSA proposed a list of prohibited asset types. FMCSA also specified that the ability to liquidate an asset within 7 calendar days of the event that triggers a payment from the trust is necessary for that asset to be considered readily available.

Comments: FMCSA received feedback from private citizens, owner-operators, and trade associations on this proposed provision. The majority of commenters agreed that acceptable assets should be issued by banks insured by the Federal Deposit Insurance Corporation (FDIC) and have the capacity to be liquidated within 7 calendar days. However, most commenters disagreed with FMCSA's decision to publish only a list of prohibited assets. For example, the ATA–MSC, ITSA, TIA, and OOIDA each suggested that the Agency instead provide a list of acceptable assets, including those that would be acceptable under trusts. ATA–MSC stated that this would eliminate any ambiguity and set a standard for the Agency's expectations.

TIA expressed concern that fraudulent companies might ''seek a potential asset that isn't on the list and note that it is 'readily available' due to the fact it isn't included on the Agency's list of non-compliant assets.'' Similarly, PFA stated that including a list of prohibited assets could encourage financial institutions to create new asset classes in an attempt to circumvent the regulations.

PFA interpreted the proposed provision, in conjunction with other proposed provisions in the rule, as limiting allowable assets to cash and irrevocable letters of credit (ILC). OOIDA suggested that the only sufficient trust/surety funding sources should be cash and an ''unconditional FDIC-insured letter of credit.'' [5]

FMCSA Response: After considering the comments addressing this topic, FMCSA determined that prescribing a list of allowable assets, instead of prohibited assets, would benefit stakeholders by clearly articulating what assets the Agency deems acceptable. FMCSA proposed a list of prohibited assets in an attempt to strike a balance between the needs of brokers—particularly small businesses—and the goal of protecting motor carriers and shippers. However, FMCSA acknowledges that brokers may find it easier to comply with the regulations if they know the specific asset classes FMCSA deems acceptable.

FMCSA has therefore determined that cash, ILCs issued by a Federally insured depository institution, and Treasury bonds will constitute the acceptable categories of assets readily available. FMCSA considers this to be the broadest range of assets that meet the criteria set by Congress in MAP–21. Other asset classes such as real estate are not sufficiently liquid, while stocks, non-Treasury bonds, and other securities involve significant risk to the investor, and therefore none of these asset classes can be considered readily available. FMCSA also shares commenters' concerns about the potential use of assets that are not included in a list of prohibited assets, but which would nevertheless not meet the statutory mandate. FMCSA believes the listed asset classes will not require the Agency or trust fund providers to expend resources on continual monitoring and valuation to ensure the trusts remain compliant.

2. Immediate Suspension of Broker/Freight Forwarder's Operating Authority

FMCSA proposed suspending a broker/freight forwarder's operating authority when its available financial security falls below $75,000 and the broker or freight forwarder fails to replenish funds within 7 calendar days. This process would be triggered when there is a drawdown on the broker or freight forwarder's surety bond or trust fund, meaning when (1) a broker or freight forwarder consents to the drawdown and the instrument value drops below $75,000; (2) a broker or freight forwarder does not respond to adequate notice of a claim by a surety or trust fund provider, and the surety or trust provider pays the claim, and the instrument value drops below $75,000; or (3) a claim is reduced to a judgment, the surety or trust fund provider pays the judgment, and the instrument value drops below $75,000. A surety would be permitted to pay a claim either with the consent of the broker, when the broker fails to respond to a notice of claim within 14 calendar days, or when there is a judgment against the broker or freight forwarder.

Suggestions To Modify the Required Financial Security Amount

Comments: FMCSA received over 50 comments addressing this provision, including from brokers, owner-operators, and trade associations. Many commenters who identified as owner-operators and motor carriers expressed their full support for FMCSA's proposal to suspend a broker or freight forwarder's operating authority if they fail to meet the financial security requirements. A total of 20 individual commenters stated that the surety amount of $75,000 is too low and should be raised to meet inflation rates. The Agency received suggestions to raise the required amount to a minimum of $95,000, while others suggested $100,000, $250,000, or an amount reflecting the broker or freight forwarder's quarterly revenue. The commenters contend that such an increase would prevent fraudulent brokers while providing drivers and owner-operators assurance that they will be compensated for their services. These individuals also expressed the view that a higher surety minimum would improve the chances of receiving a higher percentage of pro rata payment when such situations arise. In their second comment, OOIDA mentioned that the MAP–21 legislation had previously raised the bond amount, which did not resolve the problem of unscrupulous brokers stealing

hgyKepEyoG0. A transcript is available at: *https://www.regulations.gov/document/FMCSA-2016-0102-0434.*

[5] Docket No. FMCSA–2016–0102–0178 at p. 2. FMCSA interprets this to mean an ILC.

transportation services that exceeded the bond minimum.

Five commenters, including those who identified as brokers and small business owners, stated that $75,000 is too high and should not be implemented for small businesses. These commenters stated this minimum will make it challenging for them to start a brokerage company or to remain in business. One commenter proposed reducing the required amount to $5,000.

FMCSA Response: As part of MAP–21, Congress raised the minimum required financial responsibility amount from $25,000 to $75,000 for household goods brokers and from $10,000 to $75,000 for all other brokers of property. The statute states that brokers ''shall provide financial security of $75,000 for purposes of this subsection, regardless of the number of branch offices or sales agents of the broker'' (49 U.S.C. 13906(b)(3)). In the NPRM, FMCSA did not propose changing the financial responsibility requirements, and therefore views these comments as outside the scope of the proposed rule.

Timing of When the Available Financial Security Falls Below the Required Minimum

Comments: Many stakeholders commented on FMCSA's proposal regarding when an entity's available financial security will be considered to have fallen below $75,000. ITSA supported the triggering event being an actual drawdown of funds which results in a security balance lower than $75,000. Many other commenters expressed concerns about FMCSA's proposal or opposed it entirely.

Avalon and TIA both stated that FMCSA's use of the word ''or'' in proposed § 387.307(e) suggested that sureties ''are free to make an independent determination on valid claims and make payments irrespective of the current regulations which require the claimants to obtain a judgment.'' [6] Both commenters proposed adding language to the regulation that permits immediate suspension when a broker or freight forwarder fails to adhere to the terms of its contract with the surety or financial institution.

PFA opposed the concept of a drawdown, stating that ''[m]aking a payment from the surety bond or trust fund without regard to other possible claims is in direct contradiction to 49 U.S.C. 13906 9(b)(6) [sic] and violates the Fair Claim Practices of several state Departments of Insurance.'' [7] PFA largely agreed with the language proposed by Avalon and TIA, with minor changes. Liberty National Financial Corporation (Liberty) also opposed limiting the definition to an actual drawdown, stating, ''[f]rom a practical standpoint, if a broker creates an 'inevitable' (versus 'actual') drawdown against its BMC–85 trust fund, that broker should just as well be cancelled . . . because, when legitimate claims are coming in, there is no practical distinction between a broker who cannot pay, and a broker who will not pay, and a broker who gives the run-around, and the broker who goes incommunicado. . . .'' [8]

FMCSA Response: After considering all the comments on this issue, FMCSA has determined that a bond or trust fund should be considered to have fallen below $75,000 when either an actual drawdown occurs, or when the surety provider or financial institution receives legitimate claims that have not been adequately addressed by the broker and will inevitably result in the bond or trust fund falling below that amount. Expanding the criteria in this manner will allay concerns from surety providers and financial institutions about their ability to quickly notify FMCSA of brokers warranting suspension while still adhering to the 60-day period for public advertisement and subsequent 30-day period for paying claims specified in 49 U.S.C. 13906(b)(6). This is because surety providers and financial institutions will not be required to actually make a payment from the bond or trust fund before notifying FMCSA that the assets have fallen below $75,000, and will thus be able to continue aggregating claims throughout the statutory claims period.

FMCSA did not include the language requested by Avalon, TIA, and PFA that would consider available financial security to fall below the minimum required amount when the broker or freight forwarder fails to adhere to the terms of its contract with the surety or financial institution, as it could potentially create due process concerns. FMCSA does not have authority to adjudicate such contract disputes, which may occur for reasons having nothing to do with the required financial security.

Notification Processes and Requirements

Comments: The Agency received numerous comments from trade organizations requesting specifics on when and how they will be notified if the status of a broker's financial security changes. OOIDA suggested providing a clearer definition of ''adequate notice'' and encouraged the Agency to strengthen its final rule by providing details on how the Agency will provide notice that a broker's financial security has fallen below the required amount. An individual commenter asked how the Agency plans to receive notification that a broker's financial security status no longer meets the required financial standards.

FMCSA Response: In response to these comments, FMCSA added provisions to the regulation delineating the process for surety providers or financial institutions to notify FMCSA of changes to a broker's or freight forwarder's financial security status. Such notification must be made in writing, by electronic means, within 2 business days of either a payment from the bond or trust that causes the available financial security to fall below $75,000 or a determination by the surety provider or financial institution that such payment will be inevitable once the 60-day period for submission of claims has elapsed.

FMCSA intends that surety providers and financial institutions will use the URS platform, which is currently under development, to provide FMCSA with relevant information. Brokers will be able to submit responses using the same platform.

Timeframe To Respond to a Claim

Comments: An anonymous commenter raised concerns regarding the proposed 7-day timeframe for immediate suspension and suggested allowing adequate time to respond to a claim but did not provide any suggestions. Another commenter suggested 24 hours. OOIDA proposed a timeframe of 5 to 10 calendar days and ATA–MSC suggested a timeframe of 2 weeks. The latter explained this timeline would provide enough time for internal investigations to take place and prevent disruptions from occurring in the supply chain.

Avalon advised that 5 business days would allow enough time for the trust or surety to ''request immediate suspension'' if the broker fails to respond to a claim. They recommended that suspension upon financial failure be triggered in the event a broker fails to resolve ''a specified number of undisputed claims representing a percentage of the security after 30 days.'' [9]

FMCSA Response: In the final rule, FMCSA is adopting a timeframe for brokers and freight forwarders to

[6] Docket No. FMCSA–2016–0102–0150 at pp. 3–4.

[7] Docket No. FMCSA–2016–0102–0146 at p. 2.

[8] Docket No. FMCSA–2016–0102–0148 at p. 3.

[9] Docket No. FMCSA–2016–0102 at p. 6.

respond to a claim. After considering the suggestions proposed by the various commenters, FMCSA determined that 7 business days is appropriate. This timeframe provides an adequate interval for a broker or freight forwarder to respond. In response to ATA–MSC's concern that an internal investigation may take up to 10 business days, FMCSA notes that this provision sets the timeframe for a broker or freight forwarder to submit an initial response when notified of a claim. It does not prescribe a timeframe for the surety provider or financial institution to investigate and make a determination on the validity of the claim. However, if the surety provider or financial institution ultimately determines that the claim is valid and will be paid, it must then comply with the 2-business day reporting timeline described above.

Need for Show Cause Remedies

Comments: A commenter on behalf of 13 stakeholders stressed the need to implement show cause remedies in the process leading up to a broker or freight forwarder's operating authority suspension. They contend that documented ''due process issues and procedural protections must be met,'' [10] allowing the broker or freight forwarder to either remedy or demonstrate reasons for their noncompliance. The commenter also pointed out that this process will provide a degree of fairness and protection to victims of identity theft or fraud, which the commenter identified as a rampant problem in the industry.

On the other hand, FMCSA received a request from the Surety & Fidelity Association of America (SFAA) to refine the language by clarifying that claimants would only be entitled to payment until the investigation period has elapsed.

FMCSA Response: FMCSA has strengthened due process protections for brokers in this final rule. After a surety provider or financial institution notifies FMCSA that a broker or freight forwarder's available financial security has fallen below $75,000, FMCSA will send written notification to the broker or freight forwarder and allow 7 business days for response. If the broker or freight forwarder presents evidence that the notification from the surety provider or financial institution was sent to FMCSA in error, the available financial security has been restored to the required minimum amount, or the pending claims have been satisfied without the use of surety bond or trust fund assets, FMCSA may find that immediate suspension is not warranted. FMCSA will also allow brokers or freight forwarders to cure a default after a suspension has been implemented.

Additional Requirements Requested

Comments: FMCSA received multiple comments requesting the adoption of additional requirements following the suspension of a broker's operating authority. ATA–MSC expressed its support for FMCSA's proposal, and suggested additional requirements, ''such as requiring these entities to take down websites and advertising as well notifying motor carriers and shippers with in-progress transportation services of the change in their authority status, particularly for brokers involved in household goods.'' [11]

The National Owner Operators Association, which represents 28,000 owner-operators, stated that brokers should be fined, barred, and sanctioned to prevent bad actors from operating.

An individual owner-operator who experienced an instance of inadequate payment from a broker suggested suspension of brokers for 30 days and decreasing their credit rating. Another commenter suggested imprisoning brokers who fail to pay.

FMCSA Response: FMCSA recognizes the adverse impact on motor carriers when brokers fail to pay for services rendered and appreciates that some motor carriers would like to see more severe sanctions put in place for such brokers. Except for the suspension of operating authority adopted in this rule, these suggested penalties exceed the Agency's statutory authorities.

Inconsistencies or General Concerns With the Suspension Provision

Comments: Many trade organizations pointed to some inconsistencies in the broader scope of the immediate suspension provision and raised concerns that it relies on the broker to self-disclose bankruptcy or insolvency as evidence of financial failure.

Avalon stated that the rulemaking will not prevent brokers from accumulating claims and exceeding their financial security, which will not improve the status quo for drivers and owner-operators. Liberty advised that the proposed procedure will not resolve the broader issue of nonpayment, as it will be challenging to trigger a broker or freight forwarder's financial failure status, which may not result in the immediate suspension of their operating authority. Liberty added that ''trust funds will continue to be expended on a ''first come, serve served'' basis and leave everyone else in the cold.'' [12] TIA shared concerns that ''the proposed change might be worse than the existing rules in place.'' [13]

Additionally, OOIDA inquired about the purpose of this statutory provision ''[i]f the broker is not considered insolvent upon evidence that is has stopped paying motor carriers.'' [14] SFAA shared that concern ''that the broker will continue conducting operations even during the solicitation period, which will result in increased claims and a corresponding reduction in pro rata recovery for all claimants.'' [15]

FMCSA Response: FMCSA recognizes that relying only on filings made pursuant to Title 11, United States Code or an equivalent state insolvency proceeding as evidence of financial failure or insolvency could prevent surety companies and financial institutions from reporting in a timely manner when a broker or freight forwarder is accumulating claims. The changes FMCSA made in the final rule to the reporting requirements for immediate suspensions, as discussed above, and to the definition of *financial failure or insolvency,* discussed below, will ensure that surety providers and financial institutions can initiate the immediate suspension process more quickly once certain conditions are met. This will help reduce the risk that brokers and freight forwarders can continue accumulating claims for an extended period. These changes also ensure that surety providers and financial institutions can continue to utilize the payment provisions of either 49 U.S.C. 13906(b)(2) or (6), as applicable.

Brokers who file bankruptcy proceedings are also covered by the anti-discrimination provisions in 11 U.S.C. 525. Accordingly, FMCSA made changes in the final rule to specify that the immediate suspension procedures do not apply when a broker or freight forwarder has filed a proceeding pursuant to Title 11, United States Code, in addition to changes in the definition of *financial failure or insolvency,* as discussed below. FMCSA believes these changes remove the potential for conflicts between the Bankruptcy Code and the regulatory requirements.

3. Surety or Trust Responsibility in Case of Financial Failure or Insolvency

In the NPRM, FMCSA proposed to define the terms *financial failure and*

[10] Docket No. FMCSA–2016–0102–0147 at p. 2.

[11] Docket No. FMCSA–2016–0102–0136 at p. 5.

[12] Docket No. FMCSA–2016–0102–0148 at p. 3.

[13] Docket No. FMCSA–2016–0102–0150 at p. 4.

[14] Docket No. FMCSA–2016–0102–0178 at p. 4.

[15] Docket No. FMCSA–2016–0102–0151 at p. 5.

insolvency and *publicly advertise,* in accordance with 49 U.S.C. 13906(b)(6) and (c)(7), as well as procedures relating to the cancellation of a surety bond or trust as the result of a broker's financial failure or insolvency.

Definition of Financial Failure or Insolvency

Comments: ITSA supported the proposed definitions of financial failure and insolvency and the proposed regulatory text for § 387.307(f). However, many other commenters opposed FMCSA's proposal to define *financial failure or insolvency* as bankruptcy or state insolvency proceeding. These commenters, who included Avalon, TIA, PFA, Liberty, and SFAA, stated that FMCSA's proposal would likely worsen the problem, as a significant period often elapses between the time a broker ceases paying motor carriers and the time a bankruptcy or insolvency proceeding commences. Further, in some instances a broker will simply move on and never make such a filing, and the surety or financial institution would be prevented from initiating the Form BMC–84 or BMC–85 cancellation process despite knowing that the broker is not paying motor carriers.

Surety and trust providers expressed a need for some flexibility in making determinations about the solvency of brokers they work with. PFA noted that financial failures typically involve a broker disputing claims on invalid or unreasonable grounds, acknowledging claims but not paying them while continuing to aggregate additional claims, or booking many loads and then exiting the market without paying motor carriers. Similarly, SFAA stated, ''[o]ften, when a broker's business is failing, the surety will receive a sudden spike in claims against the bond and will not receive any response from the broker.'' [16]

Liberty stated that ''BMC–85 Trustees are claims managers—not merely claims payers. We are intermediaries, liaisons, and problem solvers between claimants and brokers.'' [17] Liberty believes trustees have expertise necessary to determine whether a broker is in financial failure and/or insolvent.

Commenters were also concerned that the use of a bankruptcy proceeding as evidence of financial failure or insolvency would violate the anti-discrimination provisions of 11 U.S.C. 525, which provides that a governmental unit may not, among other actions, deny, revoke, suspend, or refuse to renew a license, permit, charter, franchise, or other similar grant to a person solely because the person has been a debtor under Title 11 or a bankrupt or debtor under the Bankruptcy Act.

FMCSA Response: FMCSA appreciates commenters expressing detailed perspectives on this issue. After considering the comments, FMCSA has determined that, while it is necessary to establish an objective standard for determining financial failure or insolvency, the proposed definition would limit surety providers' or financial institutions' ability to protect motor carriers from brokers who delay or refuse to initiate formal bankruptcy or insolvency proceedings. Thus, FMCSA has modified the definition of *financial failure or insolvency* to allow surety providers or financial institutions flexibility to exercise their judgment and expertise in making such a determination. FMCSA also removed the use of a filing pursuant to Title 11, United States Code from the definition.

Under the final rule, surety providers or financial institutions may cite financial failure or insolvency of the broker or freight forwarder as grounds for cancellation of a Form BMC–84 surety bond or BMC–85 trust agreement when the surety provider or financial institution either makes a payment against the bond or trust fund that is not cured in accordance with § 387.307(e)(5) or (6) or expects to make a payment after aggregating multiple claims. FMCSA intends to receive this information via the URS.

Failure To Report Insolvent Brokers

Comments: A commenter inquired what type of action the Agency will take if a trust company refuses to report an insolvent broker or advertise for claims.

FMCSA Response: FMCSA has the authority to seek specific penalties for violations of the relevant statutes and regulations under 13906(b)(7) and (c)(8). While any action FMCSA may take would depend on the specific facts and circumstances involved in a violation, nothing in this rule is intended to, nor would it, limit the scope of FMCSA's enforcement authority.

Cancellation Notice

Comments: OOIDA commented on FMCSA's proposal to publish cancellation notices in the FMCSA Register. It noted that the FMCSA Register is not ''searchable or inherently accessible'' and requested that such notice be published on FMCSA's SAFER web page and the ''Licensing and Insurance'' web page of the broker bond in question. OOIDA additionally suggested that the Agency change its Licensing and Insurance web page to provide a link to a page on the surety's or trustee's website showing how many pending claims exist on a given bond.

FMCSA Response: The FMCSA Register [18] provides to the public a daily summary of motor carrier applications for operating authority registration, as well as decisions and notices the Agency has issued regarding the status of entities operating authority. FMCSA acknowledges the concerns raised regarding the importance of cancellation notices being easily accessible to the public and, in response, has placed a link to the FMCSA Register in a more prominent location on the Agency's website [19] to make it more accessible.

FMCSA declines to include links to the sureties' or trustees' web pages, as they are not required to list pending claims on their websites. The FMCSA Register web page is a reliable resource which is updated daily to provide the public information related to operating authority registration.

Ex Parte Communication Concerning This Provision

Comment: On May 12, 2023 an individual informed FMCSA that the hypothetical situation described in their original comment [20] to the docket had in fact occurred.

FMCSA Response: FMCSA placed an ex parte memo [21] in the docket for this rulemaking to capture this information and updated the registration page to ensure that others are also aware of the situation. The Agency notes that this rulemaking is not enforceable until the compliance dates listed under the **DATES** section of this final rule.

4. Enforcement Authority

In the NPRM, FMCSA proposed to implement MAP–21's provision for suspension of a surety provider's eligibility to make filings with FMCSA by providing a notice of suspension to the surety/trust fund provider followed by 30 calendar days for the surety or trust fund provider to respond before a final decision is issued. FMCSA also proposed to add penalties in 49 CFR part 386, appendix B, for violations of the new requirements.

Comments: FMCSA received approximately 50 comments on the

[16] Docket No. FMCSA–2016–0102–0151 at p. 3.

[17] Docket No. FMCSA–2016–0102–0148 at p. 2.

[18] The FMCSA Register is accessible at *https://www.fmcsa.dot.gov/registration/daily-fmcsa-registration-decisions-letters-certificates-permits-and-licenses.*

[19] The FMCSA Register is available at *https://www.fmcsa.dot.gov/registration/daily-fmcsa-registration-decisions-letters-certificates-permits-and-licenses.*

[20] Docket No. FMCSA–2016–0102–0419.

[21] Docket No. FMCSA–2016–0102–0435.

Agency's enforcement authority over surety providers. Many of the comments received were out of scope as they addressed what the commenters perceived as a lack of provisions to combat fraud and implement transparency requirements. Two individual commenters opposed this provision urging that the Agency should not regulate the financial aspect of the trucking industry.

ATA–MSC and TIA agreed with the Agency's proposal and found the provisions reasonable. ITSA also agreed with and supported FMCSA's proposed language but suggested placing it in §§ 387.317 and 387.415, which concern FMCSA's authority to refuse to accept or to revoke surety bonds, insurance certificates, self-insurer qualifications, or other securities or agreements, instead of in § 387.307. However, if FMCSA were to keep the language in § 387.307, ITSA recommended ensuring that the citation to section 13906 of the United States Code include both subsections (b) and (c), which apply to brokers and freight forwarders, respectively.

FMCSA Response: In response to the comments about regulation of financial aspects of the trucking industry, FMCSA notes that this rulemaking stems from a Congressional mandate to implement certain provisions of MAP–21. FMCSA must, by law, regulate these aspects. In response to the comments about fraud and transparency, this rule aims to reduce fraud by limiting the time brokers can continue to accrue claims while experiencing financial failure or insolvency before their operating authority registration is suspended. These changes adopted in this rule will result in fewer motor carriers accepting loads from brokers who do not intend to pay.

Regarding ITSA's suggestion to alter the placement of the enforcement authority provision in the regulations, FMCSA believes that the proposed language fits within the scope of § 387.307 and therefore declines to make changes to other sections of part 387. FMCSA has revised the citation to section 13906 of the United States Code to include both subsections (b) and (c).

Request for More Detail

Comments: OOIDA expressed frustration that bad actors have been able to ''register, conduct transactions, and stay in business without fear of any recourse against their criminal activity'' [22] but agreed that these are necessary provisions to implement the MAP–21 requirements. It requested to see a more detailed plan demonstrating how FMCSA plans to take enforcement action.

FMCSA Response: FMCSA is dedicated to ensuring the integrity of the trucking sector and refers incidents of criminal conduct to appropriate authorities. Criminal enforcement is handled by the Office of Inspector General and the Department of Justice.

5. Entities Eligible To Provide Trust Funds for BMC–85 Filings

In the NPRM, FMCSA proposed prohibiting loan and finance companies from serving as BMC–85 trustees. FMCSA received support on this provision from driver and motor carrier trade organizations, which fully agree that loan and finance companies should not serve as BMC–85 trustees.

Assets That Can Be Used as Collateral

Comment: PFA stated that the NPRM did not address the difference between allowable assets that the trustor can use as collateral and the way in which a trust provider can invest cash provided as collateral. In response to the proposed removal of finance lenders from the list of qualified financial institutions in § 387.307(c), PFA stated that ''the only entity that will practically be able to generate a profit from issuing BMC–85s will be banks,'' [23] as insurance companies stopped taking collateral on this type of surety many years ago. Thus, any investment the trust provider made using the collateral would be overseen by State and Federal regulators.

FMCSA Response: FMCSA takes note of PFA's comment that banks will be the only type of financial institution that will be able to profit from offering BMC–85 trust funds and acknowledges that the final rule may result in some providers ceasing to offer this service. However, FMCSA believes this change is necessary because loan and finance companies are not subject to similar levels of oversight as the other entities described in § 387.307(c) and such oversight is necessary to ensure the stability of the BMC–85 trust instrument.

Concern About Small Businesses

Comments: The Agency received two comments from 1st Security Financial Corporation on FMCSA's proposed rule expressing its disagreement with disqualifying loan and finance companies as acceptable entities. The company explained this will force many small loan companies out of business and increase premiums on BMC–84 forms. 1st Security Financial Corporation added that the company abides by the MAP–21 agreement instructions by vetting brokers and publicly advertising insolvent ones, and it urged the Agency to reconsider the provision. PFA also agreed that the provision would eliminate many small businesses and reduce ''the experience of claims management in the industry'' and the number of claims that will be paid.

FMCSA Response: Consistent with the requirement for brokers and freight forwarders to maintain $75,000 in available assets, FMCSA determined that the definition of a financial institution should include only highly regulated depository institutions, insurance companies, or equivalent entities. This decision is intended to ensure that a broker's or freight forwarder's surety bond or trust fund assets remain stable, secure, and readily available.

Loan and finance companies are not depository institutions and therefore are not regulated by the Federal depository regulators, such as the Federal Reserve, Office of the Comptroller of the Currency, the FDIC, or the National Credit Union Administration (NCUA), or an equivalent State regulator.[24] They are also generally not subject to a level of State regulation comparable to insurance companies. As FMCSA is now limiting the allowable assets held in BMC–85 trusts to cash, ILCs issued by Federally insured depository institutions, and Treasury bonds, loan and finance companies are unlikely to be able to comply with these requirements. FMCSA believes the risks involved in allowing companies that are not part of highly regulated industries to administer BMC–85 trusts are incompatible with the requirement that the trust fund consist of assets ''readily available to pay claims without resort to personal guarantees or collection of pledged accounts receivable'' (49 U.S.C. 13906(b)(1)(C)).

While FMCSA recognizes that removing loan and finance companies from the list of eligible BMC–85 providers may cause some of these companies to leave the industry, ensuring that all BMC–85 trust funds are administered by highly regulated institutions is a priority for the Agency and is necessary to carry out the requirements of MAP–21. This rule change will also more closely align FMCSA's regulations with those of other

[22] Docket No. FMCSA–2016–0102–0178 at p. 5.

[23] Docket No. FMCSA–2016–0102–0146 at p. 2.

[24] See, *e.g., Introduction to Financial Services: The Regulatory Framework,* Congressional Research Service, January 5, 2023, available at *https://crsreports.congress.gov/product/pdf/IF/IF11065.*

DOT agencies. For instance, in DOT's regulations on aviation proceedings applicable to public charter security and depository agreements, a surety provider must be a bonding or surety company that is listed in Best's Insurance Reports (Fire and Casualty) with a general policyholders' rating of ''A'' or better and legally authorized to issue bonds of that type in the State in which the charter originates (14 CFR 380.34(c)(6)). A trustee must be either an FDIC-insured national bank complying with the provisions of 12 CFR 7.7010(a) or a State bank complying with applicable State laws that grant authority to issue such agreements (14 CFR 380.34(c)(7)).

In Chapter 3.3.1 of this final rule's RIA, FMCSA outlines the process and anticipated timeline for a loan and finance company to become an FDIC-insured depository institution in order to continue serving as a BMC–85 trustee. Based on that timeline, FMCSA has concluded that the 2-year implementation period for this rule is reasonable for loan and finance companies to achieve compliance if they wish to do so. Due to a lack of data on the cost of this process and the number of loan and finance companies currently serving as BMC–85 trustees, the Agency cannot determine how many loan and finance companies will choose to meet the additional requirements to remain eligible entities or, alternatively, will exit the market. Nothing in this rule prohibits loan and finance companies that wish to continue offering services to brokers and freight forwarders from taking the necessary steps to become an eligible financial institution.

6. Proposed Changes to the Regulatory Text

Comments: The Agency received additional requests from commenters to modify the regulatory text pertaining to § 387.307(a), (b), (e), and (f). Additionally, PFA suggested adding a paragraph to § 387.307 outlining penalties for suspended brokers.

ITSA recommended keeping the language in paragraph (b), which deals with evidence of financial security, as it currently exists or alternately moving it to paragraph (a), which currently concerns the security necessary. ITSA also pointed to a typographical error in the proposed rule mentioning the removal of paragraph (c)(8); it believes the Agency intended to remove paragraph (c)(7).

Avalon and PFA both proposed changes to paragraphs (e) and (f), which would allow surety providers and trustees to initiate the immediate suspension process more quickly for brokers and freight forwarders who are accruing claims.

OOIDA proposed extensive changes to the structure and organization of § 387.307, including:

- Security—(a)(1); (d);
- Cancellation of Security and Revocation of Registration—(f)(1)(B);
- Public Notice—(f)(3)(A);
- Sureties and Trustees: The financial failure or insolvency of a broker—(g)(5)(a); (g)(5)(b);
- Claim Processing: First review of claim—(h)(3)(A)(i); (h)(3)(A)(ii);
- Claim Processing: Second review of claims—(h)(5)(A); (h)(5)(C); and
- Notice—(h)(6).

FMCSA Response: FMCSA agrees with ITSA that it is important to retain the language previously in paragraph (b) regarding the manner in which brokers and freight forwarders must provide evidence of security and the content of security agreements. In the final rule, FMCSA has moved this language to paragraph (a).

ITSA also accurately identified that FMCSA intended to remove paragraph (c)(7), not paragraph (c)(8). This typographical error has been corrected in the final rule.

FMCSA made several changes to the text of § 387.307(e) and (f) in response to comments received. FMCSA believes the text of the final rule both addresses commenters' concerns and implements the desire of Congress to expeditiously suspend brokers who are accruing claims against their surety bonds or trust funds.

While FMCSA appreciates the time and effort OOIDA spent in proposing changes to § 387.307, the Agency believes the structure and content of the regulatory changes implemented by this final rule is clear, well-organized, and fully addresses the intended scope of the rulemaking. The manner in which OOIDA has suggested restructuring this section goes beyond the changes FMCSA proposed in the NPRM, and FMCSA prefers to retain the current structure of the regulation to the extent possible.

In addition to the structural changes, OOIDA also proposes to set out in precise detail the procedures surety providers and trustees must follow when processing claims, including the responses required of brokers. As discussed above, the changes FMCSA made to paragraphs (e) and (f) of the final rule are designed to set certain parameters around claim processing, but the Agency does not believe the process needs to be regulated at the level of detail OOIDA suggests. OOIDA also proposed requiring all surety providers and trustees to maintain a public web page for each surety bond or trust fund, which would contain specified types of information, and to notify FMCSA of the correct URL address of the web page and any changes to that address. However, MAP–21 did not require FMCSA to implement this type of requirement, and the Agency believes administering such a provision would be unduly burdensome on sureties, trust fund providers, and Agency personnel. FMCSA therefore declines to make the changes OOIDA suggested.

7. Implementation Timeline

Comments: FMCSA received feedback on the 3-year implementation timeline proposed in the NPRM. ITSA disagreed that the industry needs that much time to comply with the regulatory changes, as brokers covered by a loan or finance company ''can easily transition to a surety company or other form of approved financial institution.'' They proposed that FMCSA consider 3 months as a reasonable timeframe. TIA agreed that a 3-year period would be too long and suggested 12 months instead.

FMCSA Response: FMCSA acknowledges the comments it received regarding the implementation period pertaining to this rule. After careful consideration, the Agency determined that reducing the 3-year implementation period would be beneficial to stakeholders while still providing the industry sufficient time to comply with the financial requirements. The Agency has decided to reduce the implementation period from 3 years to 1 year for the immediate suspension, financial failure or insolvency, and enforcement authority provisions of this rulemaking. FMCSA also reduces the implementation period from 3 years to 2 years for the assets readily available and entities eligible to provide trust funds for Form BMC–85 trust fund filings provisions.

8. Out of Scope Comments

Business Practices

Comments: FMCSA received more than 150 comments concerning issues beyond the scope of the NPRM. Most of these comments concerned common operational procedures or business practices and relationships between brokers and motor carriers.

These commenters stated that brokers often behave in various fraudulent ways and are not currently sufficiently regulated by DOT or FMCSA. In particular, commenters mentioned those who operate under fake/stolen business information, as multiple businesses with different operating authority numbers. Many commenters mentioned

broker actions the commenters viewed as predatory and, accordingly, favored FMCSA setting limits on rates brokers could charge. Multiple commenters at the March 2023 listening session mentioned charge backs and claims from brokers after loads were delivered.

A common complaint in the public comments was ''double-brokering'' of loads. This term is commonly used to refer to a situation where a motor carrier accepts a load from a broker and then transfers the load without the shipper's or original broker's knowledge to another motor carrier who actually delivers the load. In many instances, the motor carrier who completes the load does not receive payment for their services, as the original broker pays the motor carrier with whom it has contracted and believes the transaction is complete, but that motor carrier does not pay the second motor carrier with whom it has subcontracted.

FMCSA Response: FMCSA appreciates commenters for bringing these issues to the Agency's awareness and hopes the commenters will stay engaged, including by continuing to inform the Agency of such issues. However, these issues are outside of the scope of this rulemaking, as they do not specifically pertain to the issues presented in the NPRM. FMCSA therefore declines to modify the final rule based upon these comments.

Regarding the accusations of fraud, FMCSA is aware of increasing concerns in this area and is actively examining approaches to address the problems, including potential rule changes in other areas. FMCSA and DOT are also looking at new tools and practices to better enforce existing regulations against companies engaging in fraud. The Agency encourages drivers affected by deceptive business practices or similar concerns to file a complaint against the company involved on the National Consumer Complaint Database (NCCDB) website.[25]

Other Out of Scope Comments

Comments: Other out of scope comments included many complaints about specific brokers or brokers being foreign-owned and operated. Many individuals commented concerning a planned Agency rulemaking regarding transparency in the broker industry.

FMCSA Response: FMCSA encourages these commenters to submit complaints regarding a specific broker or company to FMCSA via the NCCDB website as detailed earlier. FMCSA requests that commenters interested in the issue of br'oker transparency submit comments to that rulemaking when it is published.

[25] The NCCDB is available at *https://nccdb.fmcsa.dot.gov/nccdb/home.aspx#*.

VI. Discussion of the Final Rule

A. Assets Readily Available

As discussed above, FMCSA modified this final rule to provide an explicit list of acceptable asset types, rather than the list of prohibited assets included in the NPRM. This list of acceptable assets will provide clarity to brokers, freight forwarders, surety providers, and financial institutions about the specific assets that meet the criteria set by Congress in MAP–21, as they are both stable and able to be made liquid within 7 calendar days. The final rule will also prevent the use of new asset types that would not be specifically included on a list of prohibited assets but would not meet the criteria FMCSA used to determine whether an asset type is allowable. In this rule, acceptable assets to be included in a trust fund are limited to cash, irrevocable letters of credit issued by Federally insured depository institutions, and Treasury bonds.

Compliance with this provision will be required on January 16, 2026.

B. Immediate Suspension of Broker/Freight Forwarder Operating Authority

Many comments on this provision requested more detail on the circumstances and process leading up to a broker or freight forwarder's suspension. A broker or freight forwarder's operating authority will be suspended when their available financial security falls below $75,000 and the broker or freight forwarder fails to replenish funds within 7 calendar days. This final rule outlines information about the triggers and roles of surety or financial institutions and FMCSA, including how surety providers issuing a BMC–84 form or financial institutions issuing a BMC–85 Form must notify FMCSA when a broker's financial responsibility falls below the required minimum and is not replenished in a timely manner. Compliance for this provision will be required on January 16, 2025.

C. Surety or Trust Responsibilities in Cases of Broker/Freight Forwarder Financial Failure or Insolvency

FMCSA defines the terms *financial failure and insolvency* as any payment made or other default pursuant to § 387.307(e)(1) not cured in accordance with § 387.307(e)(5) or (6) but does not include, in and of itself, a broker filing for bankruptcy protection pursuant to Title 11 of the United States Code. This final rule outlines the procedures and responsibilities for a surety company or financial institution and for FMCSA once the company or financial institution has become aware that a broker or freight forwarder has experienced financial failure or insolvency. Compliance with this provision will be required on January 16, 2025.

D. Enforcement Authority

As proposed in the NPRM, FMCSA implements the MAP–21 requirement for suspension of a surety provider's authority and to add penalties in 49 CFR part 386, appendix B, for violations of the new requirements. This final rule includes a new paragraph (g)(24) which specifies the monetary penalty for which a surety company or financial institution found to be in violation of 49 U.S.C. 13906 or § 387.307 will be liable, as well as the mandatory 3-year ineligibility period for providing broker financial security. This final rule does not remove any of the authority that FMCSA or other Federal entities already have in place to enforce compliance from brokers, sureties, and financial institutions. Compliance for this provision will be required on January 16, 2025.

E. Entities Eligible To Provide Trust Funds for Form BMC–85 Trust Fund Filings

As proposed in the NPRM, FMCSA removes the provision allowing loan and finance companies to serve as BMC–85 trustees. Compliance for this provision will be required on January 16, 2026.

VII. Section-by-Section Analysis

This section includes a summary of the changes to 49 CFR parts 386 and 387. The regulatory changes are discussed in numerical order.

Appendix B to Part 386—Penalty Schedule: Violations and Monetary Penalties

In Appendix B to part 386, a new paragraph (g)(24) is added to clearly state the monetary penalty for which a surety company or financial institution found in violation of 49 U.S.C. 13906 or § 387.307 may be liable.

Sections 387.307 and 387.307T

Due to the delayed compliance date(s) in this final rule, FMCSA moves the existing language in § 387.307 to § 387.307T. This temporary section will expire January 16, 2025. FMCSA also corrects a typographical error in the existing text of the section now designated as § 387.307(d)(2)(i)T.

New § 387.307 modifies the existing language as follows and is suspended until January 16, 2025.

Section 387.307 Property Broker Surety Bond or Trust Fund

In § 387.307(b), FMCSA provides a list of acceptable assets for BMC–85 trust funds. Existing paragraph (c)(7) is removed and existing paragraph (c)(8) would be renumbered as paragraph (c)(7). New paragraphs (e), (f), and (g) are added.

Paragraph (e) sets out the triggers and procedures for immediate suspension of a broker. The paragraph establishes the role of the surety provider or financial institution, FMCSA, and the broker.

Paragraph (f) sets out procedures and responsibilities for a surety company or a financial institution and FMCSA following financial failure or insolvency of a broker. A financial failure or insolvency of a broker is defined as any payment made or other default pursuant to § 387.307(e)(1) not cured in accordance with § 387.307(e)(5) or (6).

Paragraph (g) sets out procedures concerning suspension of a surety company or financial institution's eligibility to file evidence of financial responsibility with FMCSA and FMCSA's role in that action. Penalties for violation of the requirements of this section or subsection (b) of Title 49, section 13906 U.S.C. are established.

Section 387.307T Property Broker Surety Bond or Trust Fund

This section is moved from existing § 387.307. A new introductory paragraph is inserted to reflect the expiration date of the temporary section. No other changes are made to this section. This temporary section will expire January 16, 2025.

VIII. Severability

The purpose of this rule is to implement, based on FMCSA's statutory authorities described in section V (Legal Basis for the Rulemaking), regulatory requirements for the financial security of brokers and freight forwarders. A judicial decision invalidating some of these measures would not necessarily require rejection of the entire rule. While many the provisions of this rule are integrated, and the Agency anticipates the separate provisions will function most effectively operating together, FMCSA nonetheless finds that each major provision of the rule is severable from the others and would operate effectively even in the event some provisions were deemed invalid. For example, if a court vacated FMCSA's decision to remove loan and finance companies from the list of allowable BMC–85 providers, that removal would not change FMCSA's determination regarding *assets readily available,* nor would it affect the validity of the rule's other provisions, which should be allowed to remain in effect. Likewise, if a court were to set aside FMCSA's definition of financial failure or insolvency, other provisions of the rule could be separately implemented and thus would remain valid.

IX. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 14094 (Modernizing Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impact of this final rule under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and E.O. 14094 (88 FR 21879, Apr. 11, 2023), Modernizing Regulatory Review. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) determined that this final rulemaking is not a significant regulatory action under section 3(f) of E.O. 12866, as supplemented by E.O. 13563 and E.O. 14094, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. Accordingly, OMB has not reviewed it under that E.O.

A regulatory impact analysis is available in the docket. That document:

- Identifies the problem targeted by this rulemaking, including a statement of the need for the action.
- Defines the scope and parameters of the analysis.
- Defines the baseline.
- Defines and evaluates the costs and benefits of the action.

Copies of the full analysis are available in the docket or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Summary of Estimated Costs

Brokers and freight forwarders, surety bond and trust fund providers, and the Federal Government will incur costs for compliance and implementation. The quantified costs of the final rule include notification costs related to a drawdown on a surety bond or trust fund, and immediate suspension proceedings, FMCSA costs to hire new personnel, and costs associated with the development and maintenance of the BMC–84/85 Filing and Management IT System. FMCSA estimates that the 10-year cost of the proposed rule will total $5.5 million on an undiscounted basis, $3.9 million discounted at 7 percent, and $4.7 million discounted at 3 percent (all in 2022 dollars). The annualized cost of the rule will be $559,971 discounted at 7 percent and $556,786 at 3 percent. Ninety-eight percent of the costs will be incurred by the Federal Government.

Summary of Estimated Benefits

This final rule will result in benefits to motor carriers resulting from a decrease in the claims against brokers that go unpaid. FMCSA expects that result for several reasons. First, FMCSA will immediately suspend brokers that do not respond following a drawdown on their financial security. Such brokers will no longer be able to accrue liabilities that they do not plan, or lack the ability, to pay. This will be accomplished through the BMC–84/85 Filing Management System FMCSA intends to implement and maintain as part of the larger URS, which is currently under development. Surety bond and trust fund providers will submit claim data and notice of a drawdown on a broker bond or trust fund in the system, provide notice of broker insolvency or financial failure, and provide notice if a broker satisfies all pending claims and is no longer experiencing financial failure or insolvency. Notices of a drawdown or financial failure will automatically alert FMCSA and trigger the system to generate a letter outlining requirements that must be met for brokers to maintain operating authority. Brokers will be able to provide written evidence of a restored financial instrument through the system. Motor carriers will be able to query the system to determine if a broker has active operating authority registration before accepting a load.

As described above, the BMC–84/85 Filing Management System within the URS will efficiently exchange information between motor carriers, brokers, financial responsibility providers, and FMCSA, thereby reducing the information asymmetry concerns associated with broker and motor carrier transactions. However, given a lack of data, FMCSA is unable to quantify benefits resulting from this rule, and instead qualitatively discusses benefits directly related to three provisions in the regulatory impact analysis.

FMCSA cannot directly estimate an impact on safety resulting from this rule. OOIDA [26] contends that broker

[26] Docket No. FMCSA–2016–0102–0076.

non-payment of claims causes smaller motor carriers to defer maintenance on their vehicles or ''run harder until they make up the shortfall,'' both resulting in unsafe driving practices.[27] TIA contends that ''small carriers and owner-operators often operate on thin financial margins and need the revenue from every load to maintain their equipment so that it meets roadworthiness and safety requirements. If they are not paid, necessary maintenance and repairs may be put off or ignored because of the reduced cash flow.'' With this final rule, motor carriers will have more information to avoid contracting with unscrupulous brokers and will also receive more timely payment for work completed, without use of interpleader proceedings. Both of these outcomes will lead to an increase in safety if motor carriers choose to use these resources to further their safety focus.

B. Congressional Review Act

This rule is not a *major rule* as defined under the Congressional Review Act (5 U.S.C. 801–808).'' [28]

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980, Public Law 96–354, 94 Stat. 1164 (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121, 110 Stat. 857, Mar. 29, 1996) and the Small Business Jobs Act of 2010 (Public Law 111–240, 124 Stat. 2504, Sept. 27, 2010), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses.

Accordingly, FMCSA prepared an Initial Regulatory Flexibility Analysis (IRFA) for the NPRM and a Final Regulatory Flexibility Analysis (FRFA) for the final rule. This rule will affect financial responsibility providers, brokers, and freight forwarders.

FMCSA does not know the asset make-up of brokers, and therefore cannot anticipate based on current asset portfolios how many brokers will be unable to fund the type of assets that will be required in BMC–85 trust funds going forward. FMCSA estimates that a maximum of 17 percent of brokers could be forced out of the market. However, FMCSA anticipates that most, if not all, of the brokers who utilize BMC–85 trust funds will increase their capitalization during the 2-year compliance period such that they will meet the assets readily available requirements.

FMCSA does not have data on the number of loan and finance companies currently serving as BMC–85 trustees. FMCSA has no quantifiable data or information on what decisions these loan and finance companies will make (*i.e.,* remain an eligible entity or exit the market) nor reliable cost data relating to those decisions. Therefore, FMCSA has not determined whether this final rule will have a significant economic impact on a substantial number of small entities.

A FRFA must contain the following:

(1) A statement of the need for, and objectives of, the rule;

(2) A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4) A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(5) A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(6) A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected;

(7) For a covered agency, as defined in section 609(d)(2) of the Regulatory Flexibility Act, a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

1. *A statement of the need for, and objectives of, the rule.*

MAP–21, section 32918, amended 49 U.S.C. 13906 and provided new requirements for the financial security of brokers and freight forwarders. Congress mandated that FMCSA conduct rulemaking to implement the statutory changes. The objective of this rulemaking is to complete the implementation of Congress's directive and to help ensure that motor carriers are paid for the services they provide for brokers and freight forwarders.

2. A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

There were no public comments submitted in response to the IRFA. However, the Agency received approximately 342 unique comments in response to the NPRM. FMCSA received some comments concerning small businesses, specifically regarding the required financial security amount and entities eligible to provide trust funds for BMC–85 Filings. These comments are addressed in Section VI. B. of this final rule.

3. The response of the agency to any comments filed by the chief counsel for advocacy of the SBA in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

The Chief Counsel for Advocacy of the SBA did not file comments in response to the proposed rule.

4. A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

Small entity is defined in 5 U.S.C. 601. Section 601(3) defines a *small entity* as having the same meaning as *small business concern* under Section 3 of the Small Business Act. This includes any small business concern that is independently owned and operated and is not dominant in its field of operation.

[27] TIA also references potential safety benefits of this rulemaking, available at Docket No. FMCSA–2016–0102–0032.

[28] A *major rule* means any rule that OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, geographic regions, Federal, State, or local government agencies; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 802(4)).

Section 601(4), likewise includes within the definition of *small entities* not-for-profit enterprises that are independently owned and operated and are not dominant in their fields of operation. Additionally, Section 601(5) defines *small entities* as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000.

This final rule will affect financial responsibility providers, brokers, and freight forwarders.

The financial responsibility providers that would be affected by this final rule operate under many different North American Industry Classification System [29] (NAICS) codes with differing size standards. Additionally, the financial responsibility providers that would be affected by the rule are a subset of the entities within these codes. Many of the entities operating under these NAICS codes have various functions that do not include providing financial responsibility to brokers or freight forwarders. In providing a wide range of NAICS codes in the finance and insurance sectors, FMCSA believes it captures financial responsibility providers who perform various other functions. Table 15 below, the SBA size standard for finance and insurance, ranges from $15 million in revenue per year for insurance agencies and brokerages, to $859 million in assets per year for commercial banking.

Brokers and freight forwarders operate in the transportation sector under the NAICS code 48851. As shown in Table 15, the SBA size standard for freight transportation arrangement is $20.0 million in revenue.

TABLE 2—SBA SIZE STANDARDS FOR SELECTED INDUSTRIES

[in millions of 2023$]

NAICS code	NAICS industry description	SBA size standard
	Subsector 522—Credit Intermediation and Related Activities	
52211	Commercial Banking	$850.
52229	All Other Nondepository Credit Intermediation	$47.0.
	Subsector 523—Securities, Commodity Contracts, and Other Financial Investments and Related Activities	
52315	Investment Banking and Securities Intermediation	$47.0.
52316	Commodity Contracts Intermediation	$47.0.
52321	Securities and Commodity Exchanges	$47.0.
52391	Miscellaneous Intermediation	$47.0.
	Subsector 524—Insurance Carriers and Related Activities	
524126	Direct Property and Casualty Insurance Carriers	1,500 employees.
524127	Direct Title Insurance Carriers	$47.0.
524128	Other Direct Insurance (except life, health, and medical) Carriers	$47.0.
52413	Reinsurance Carriers	$47.0.
52421	Insurance Agencies and Brokerages	$15.0.
524292	Third Party Administration of Insurance and Pension Funds	$45.5.
	Subsector 488—Support Activities for Transportation	
48851	Freight Transportation Arrangement	$20.0.

FMCSA examined data from the 2017 Economic Census, the most recent Census for which data was available, to determine the percentage of firms that have revenue at or below SBA's thresholds within each of the NAICS industries.[30] Boundaries for the revenue categories used in the Economic Census do not precisely coincide with the SBA thresholds. Instead, the SBA threshold generally falls between two different revenue categories. However, FMCSA was able to make reasonable estimates as to the percent of small entities within each NAICS industry group.

The commercial banking industry group has a revenue size standard of $850 million. The largest Economic Census revenue category is $100 million or more. As such, FMCSA could not determine the percent of entities within this NAICS industry group that would be considered small, and conservatively estimates that all commercial banking entities are small entities as defined by the SBA.

For Other Nondepository Credit Intermediation, the $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of Other Nondepository Credit Intermediates with revenue less than these amounts were 50 percent and 54 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of these entities that are small will be closer to 50 percent and is using that figure.

The Securities Brokerage industry group focuses on underwriting securities issues and/or making markets for securities and commodities. The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of Securities Brokerages with revenue less than these amounts were 97 percent and 98 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of securities brokerages that are small will be closer to 97 percent and is using that figure. Note that the SBA size standards published on March 17, 2023, use the 2022 NAICS

[29] More information about NAICS is available at: *http://www.census.gov/naics/* (accessed June 29, 2022).

[30] U.S. Census Bureau. *2017 Economic Census.* Available at: *https://data.census.gov/cedsci/table?q=EC1700&n=48-49&tid=ECNSIZE2017.EC1700SIZEREVEST&hidePreview=true* (accessed Apr. 20, 2022).

codes. A key difference from the 2017 NAICS is that Investment Banking and Securities Dealing (52311) and Securities Brokerage (52312) have been combined into a single industry, Investment Banking and Securities Intermediation (52315). Although these two industries are now combined within NAICS and the SBA size standards, we do not wish to capture Investment Banking businesses in the number of affected entities. The estimates in Table 3 exclude these entities, as was the case in the NPRM RIA.

The Commodity Contracts Dealing industry group focuses on acting as agents between buyers and sellers of securities and commodities (52313). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of commodity contracts dealers with revenue less than these amounts were 75 percent and 81 percent. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of commodity contracts dealers that are small will be closer to 75 percent and is using that figure.

The Commodity Contracts Brokerage industry group focuses on providing securities and commodity exchange services (52314). The SBA size standard for this industry group is $41.5 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of commodity contracts brokers with revenue less than these amounts were 84 percent and 86 percent. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of commodity contracts brokers that are small will be closer to 84 percent and is using that figure. Note that in the 2022 NAICS, Commodities Contract Dealing (52313) and Commodities Contracts Brokerages (52314) were combined into one industry—Commodity Contracts Intermediation (52316). Both industries previously had identical size standards. FMCSA made the assumption that in the new combined size standard, both industries still maintained identical size standards with each other.

The Securities and Commodity Exchanges industry group provides marketplaces and mechanisms for the purpose of facilitating the buying and selling of stocks, stock options, bonds, or commodity contracts (52321). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. There are 13 total firms that operated for the entire year under the securities and commodity exchanges industry group, but the Census has redacted the number of firms with revenue less than $100 million. The Census reports that there are 4 firms with revenue of $100 million or greater, which leads FMCSA to estimate that there are nine firms with revenue below $100 million. FMCSA conservatively estimates that all nine firms with revenue below $100 million (69 percent of the industry group) are considered small.

The Miscellaneous Intermediation industry group primarily engages in acting as principals in buying or selling of financial contracts (52391). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of miscellaneous intermediation firms with revenue less than these amounts were 97 percent and 99.6 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of miscellaneous intermediates that are small will be closer to 97 percent and is using that figure.

The Direct Property and Casualty Insurance Carriers industry group primarily engages in initially underwriting insurance policies (524126). The SBA size standard for this industry group is 1,500 employees. The 1,500 employees SBA threshold falls within the highest employment category of 250 employees or more. The low bound estimate assumes all firms in this category are above the SBA threshold and thus can be considered small. The high bound estimate assumes all firms in this category are below the SBA threshold and can be considered small. The estimated percentages of direct property and casualty insurance carrier firms with employment less than the SBA threshold is between 92 percent and 100 percent. FMCSA has assumed that the percent of direct property and casualty insurers that are small will be closer to 92 percent and is using that figure, as the agency believes there exist some non-small direct property and casualty insurance carriers and thus 92 percent is a more plausible assumption than estimating that the industry consists of 100 percent small firms.

The Direct Title Insurance Carriers industry group primarily engages in initially underwriting title insurance policies (524127). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of direct title insurers with revenue less than these amounts were 66 percent and 67 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of direct title insurers that are small will be closer to 66 percent and is using that figure.

The Other Direct Insurance Carriers industry group primarily engages in initially underwriting insurance policies (524128). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of other direct insurance carriers with revenue less than these amounts were 58 percent and 63 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of other direct insurance carriers that are small will be closer to 58 percent and is using that figure.

The Reinsurance Carriers industry group primarily engages in assuming all or part of the risk associated with insurance policies originally underwritten by a different provider (52413). The SBA size standard for this industry group is $47.0 million. The $47.0 million SBA threshold falls between two Economic Census revenue categories, $10 million and $100 million. The percentages of reinsurance carriers with revenue less than these amounts were 49 percent and 60 percent, respectively. The SBA threshold is not near either of these revenue categories, therefore FMCSA conservatively estimates that the percent of reinsurance carrier firms that are small will be closer to 60 percent and is using that figure.

The Insurance Agencies and Brokerages industry group primarily engages in selling insurance (52421). The SBA size standard for this industry group is $15 million. The $15 million SBA threshold falls between two Economic Census revenue categories, $10 million and $25 million. The percentages of insurance agencies and brokerages with revenue less than these amounts were 99 percent and 100 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of insurance agencies and brokerages that are small will be

closer to 99 percent and is using that figure.

The Third Party Administration of Insurance and Pension Funds industry group primarily engages in providing third-party administrative services of insurance (524292). The SBA size standard for this industry group is $45.5 million. The $45.5 million SBA threshold falls between two Economic Census revenue categories, $25 million and $100 million. The percentages of firms with revenue less than these amounts were 92 percent and 97 percent, respectively. Because the SBA threshold is closer to the lower of these two boundaries, FMCSA has assumed that the percent of firms that are small will be closer to 92 percent and is using that figure.

The Freight Transportation Arrangement industry group primarily engages in arranging the transportation of freight between shippers and motor carriers (48851). The SBA size standard for this industry group is $20.0 million. The $20.0 million SBA threshold falls between two Economic Census revenue categories, $10 million and $25 million. The percentages of firms with revenue less than these amounts were 93 percent and 97 percent, respectively. Because the SBA threshold is closer to the higher of these two boundaries, FMCSA has assumed that the percent of firms that are small will be closer to 97 percent and is using that figure. Table 3 below shows the complete estimates of the number of small entities within the NAICS industry groups that may be affected by this rule. FMCSA notes that there are approximately 36,000 financial responsibility providers, which is a small subset of the firms identified in the commercial industry groups below.

TABLE 3—ESTIMATES OF NUMBERS OF SMALL ENTITIES

NAICS code	Description	Total number of firms	Number of small entities	% of all firms
52211	Commercial Banking	4,804	4,804	100
52229	All Other Nondepository Credit Intermediation	10,411	5,255	50
52312	Securities Brokerage	6,009	5,832	97
52313	Commodity Contracts Dealing	493	368	75
52314	Commodity Contracts Brokerage	728	608	84
52321	Securities and Commodity Exchanges	13	9	69
52391	Miscellaneous Intermediation	6,912	6,715	97
524126	Direct Property and Casualty Insurance Carriers	2,079	1,912	92
524127	Direct Title Insurance Carriers	662	438	66
524128	Other Direct Insurance (except life, health, and medical) Carriers	285	166	58
52413	Reinsurance Carriers	129	77	60
52421	Insurance Agencies and Brokerages	106,260	105,056	99
524292	Third Party Administration of Insurance and Pension Funds	2,498	2,306	92
48851	Freight Transportation Arrangement	13,252	12,889	97

5. A description of the proposed reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to requirements and the type of professional skills necessary for preparation of the report or record.

Small financial responsibility providers and brokers will be required to provide notification to FMCSA of specific activity on a broker bond or trust fund. FMCSA anticipates that these notifications can be completed by office clerks.

Though this rulemaking does not modify existing, or create any new, paperwork impacts within the 3-year timeframe, FMCSA acknowledges that due to the impacts of compliance with this rulemaking there will likely be changes to the information collection requirements associated with this rulemaking at a future date due to the requirements set forth in this rulemaking.

6. A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact of small entities was rejected.

FMCSA made its best effort to draft a rule that would minimize any significant economic impact on small entities.

After reviewing comments to the NPRM, FMCSA understands that brokers may find it easier to comply with the regulations if they know the specific asset classes FMCSA deems acceptable. FMCSA, therefore, determined that cash, ILCs issued by institutions insured by the FDIC or NCUA, and Treasury bonds will constitute the acceptable categories of assets readily available. No other asset types, including but not limited to real estate, stocks, bonds, and other securities, will be considered acceptable. The list of acceptable assets provides the broadest range of assets that meet the criteria set by Congress in MAP–21 while also providing more clarity to small businesses than the proposed list of prohibited assets in the NPRM did.

Most commenters and agency stakeholders support prohibiting loan and finance companies from serving as financial institutions for the broker market. These entities are not regulated to the same extent as other financial institutions at the state or Federal level. For example, they may not undergo safety and soundness examinations that score institutions in various areas, such as capital adequacy or asset quality. This decision is intended to ensure that a small broker's or freight forwarder's surety bond or trust fund assets remain stable, secure, and readily available.

In Chapter 3.3.1 of the final rule's RIA, FMCSA has outlined the process and anticipated timeline for a loan and finance company to become an FDIC-insured depository institution in order to continue serving as a BMC–85 trustee. FMCSA has learned through this knowledge and public comments that the 2-year implementation period is reasonable for loan and finance companies to achieve compliance if they wish to do so.

FMCSA has no data on the number of loan and finance companies currently serving as BMC–85 trustees but understands that the top five BMC–85 trustees currently serve about 93 percent

of the BMC–85 market, while 97 percent of the BMC–85 trustees serve five or fewer brokers. Based on this data, it is safe to assume that providing financial responsibility to brokers is not the main line of business for most trust fund providers. FMCSA also has no quantifiable data or information on what decisions these loan and finance companies will make (*i.e.,* remain an eligible entity or exit the market) nor reliable cost data relating to those decisions.

FMCSA proposed a 3-year compliance date in the NPRM to allow ample time for small entities to meet the requirements of the rule. The comments received from small entities and stakeholders indicate that a three-year compliance date is unnecessarily long. After careful consideration of comments to the NPRM, the Agency determined that reducing the 3-year implementation period to 2 years will be beneficial to stakeholders while still allowing sufficient time for small businesses to comply with the financial requirements, considering their available resources.

The compliance date for the immediate suspension, financial failure or insolvency, and enforcement authority provisions is one year because the Agency believes that these provisions are the most urgently needed to protect motor carriers, shippers, and other parties in the transportation industry from brokers and freight forwarders who are financially unable or unwilling to meet their obligations and from surety providers or financial institutions that do not properly report such brokers to FMCSA. The compliance date for the other provisions (assets readily available and entities eligible to serve as trust providers) is 2 years because the Agency believes and that small businesses will need more time to come into compliance with them. The Agency believes this compliance date is the best way to minimize the economic impact of the rule's implementation on small entities.

FMCSA does not know the asset make-up of brokers, and therefore cannot anticipate how many brokers will be unable to fund the type of assets that we will require in BMC–85 trust funds given their current portfolio. FMCSA estimates that a maximum of 17 percent of brokers could be forced out of the market. FMCSA anticipates that most, if not all, of the brokers who utilize the BMC–85 trust funds will increase their capitalization during the 2-year compliance period. FMCSA believes the 2-year compliance period will allow most brokers to meet the assets readily available requirements.

In the event that a broker does not meet the assets readily available requirement, FMCSA anticipates that at least some of the freight brokerage business will then be shifted, or transferred, to other brokers that maintain their operating authority. FMCSA does not anticipate a substantial disruption to the freight brokerage market resulting from this final rule.

FMCSA has already implemented Congress's directive to set the minimum financial security required of $75,000 and is not altering the amount in this final rule. FMCSA is not aware of any further significant alternatives that would meet the intent of our statutory requirements.

7. Description of steps taken by a covered agency to minimize costs of credit for small entities.

FMCSA is not a covered agency as defined in section 609(d)(2) of the Regulatory Flexibility Act and has taken no steps to minimize the additional cost of credit for small entities.

C. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FMCSA wants to assist small entities in understanding this final rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see *https://www.sba.gov/about-sba/oversight-advocacy/office-national-ombudsman*) and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their discretionary regulatory actions. The Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $192 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2022 levels) or more in any 1 year. Though this final rule would not result in such an expenditure, and the analytical requirements of UMRA do not apply as a result, the Agency discusses the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This final rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Though this rulemaking does not modify existing, or create any new, paperwork impacts within the 3-year timeframe, FMCSA acknowledges that due to the impacts of compliance with this rulemaking there will likely be changes to the information collection requirements associated with this rulemaking at a future date due to the requirements set forth in this rulemaking. When those potential changes are identified, FMCSA will publish a notice in the **Federal Register** soliciting comment on those changes.

G. E.O. 13132 (Federalism)

A rule has implications for federalism under section 1(a) of E.O. 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

FMCSA has determined that this rule will not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy

The Consolidated Appropriations Act, 2005,[31] requires the Agency to assess the privacy impact of a regulation that will affect the privacy of individuals. This rule would not require the collection of personally identifiable

[31] Public Law 108–447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a (Dec. 4, 2014).

information (PII). The supporting Privacy Impact Analysis (PIA), available for review in the docket, gives a full and complete explanation of FMCSA practices for protecting PII in general and specifically in relation to this final rule.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002,[32] requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology will collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a PIA.

In addition, the Agency submitted a Privacy Threshold Assessment (PTA) to evaluate the risks and effects the proposed rulemaking might have on collecting, storing, and sharing personally identifiable information. The DOT Privacy Office has determined that this rulemaking does not create privacy risk.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

J. National Environmental Policy Act of 1969

FMCSA analyzed this rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680), Appendix 2, paragraphs (6.k) and (6.q). The categorical exclusions (CEs) in paragraphs (6.k) and (6.q) cover broker activities and implementation of record preservation. The requirements in this rule are covered by these CEs and do not have any effect on the quality of the environment.

List of Subjects

49 CFR Part 386

Administrative practice and procedure, Brokers, Freight forwarders, Hazardous materials transportation, Highway safety, Motor carriers, Motor vehicle safety, Penalties.

49 CFR Part 387

Buses, Freight, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Intergovernmental relations, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

For the reasons set forth in the preamble, FMCSA amends 49 CFR parts 386 and 387 as follows:

PART 386—RULES OF PRACTICE FOR FMCSA PROCEEDINGS

■ 1. The authority citation continues to read as follows:

Authority: 49 U.S.C. 113; chapters 5, 51, 131–141, 145–149, 311, 313, and 315; Sec. 204, Pub. L. 104–88, 109 Stat. 803, 941 (49 U.S.C. 701 note); Sec. 32402, Pub. L. 112–141, 126 Stat. 405, 795 (49 U.S.C. 31306a); Sec. 701 Pub. L. 114–74, 129 Stat. 599 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.87.

■ 2. Amend Appendix B by adding paragraph (g)(24) to read as follows:

Appendix B to Part 386—Penalty Schedule: Violations and Monetary Penalties

* * * * *

(g) * * *

(24) Beginning on January 16, 2025, a surety company or financial institution for a broker or freight forwarder pursuant to §§ 387.307 or 387.403T that violates subsection (b) or (c) of Title 49 of the United States Code, Section 13906 or § 387.307:—

(i) Is liable to the United States for a penalty of $12,882 for each violation; and

(ii) Will be ineligible to provide broker financial security for three years.

* * * * *

PART 387—MINIMUM LEVELS OF FINANCIAL RESPONSIBILITY FOR MOTOR CARRIERS

■ 3. The authority citation continues to read as follows:

Authority: 49 U.S.C. 13101, 13301, 13906, 13908, 14701, 31138, and 31139; sec. 204(a), Pub. L. 104–88, 109 Stat. 803, 941; and 49 CFR 1.87.

■ 4. Redesignate § 387.307 as § 387.307T.

■ 5. Add a new § 387.307, to read as follows:

§ 387.307 Property broker surety bond or trust fund.

This section is effective January 16, 2025.

(a) *Security.* A broker must have a surety bond or trust fund of $75,000 in effect. FMCSA will not register a broker until a surety bond or trust fund for the full limits of liability prescribed herein is in effect. The broker registration shall remain in effect only as long as a surety bond or trust fund remains in effect and shall ensure the financial responsibility of the broker. Evidence of a surety bond must be filed using FMCSA's prescribed Form BMC–84. Evidence of a trust fund with a financial institution must be filed using FMCSA's prescribed Form BMC–85. The surety bond or the trust fund shall ensure the financial responsibility of the broker by providing for payments to shippers or motor carriers if the broker fails to carry out its contracts, agreements, or arrangements for the supplying of transportation by authorized motor carriers.

(b) *Acceptable assets.* Beginning on January 16, 2026, trust funds under this section must contain assets aggregating to $75,000 that can be liquidated to cash within 7 calendar days. As of this date, acceptable assets included in any trust fund filed under this section are limited to cash, irrevocable letters of credit issued by a federally insured depository institution, and Treasury bonds.

(c) *Financial institution.* When used in this section and in forms prescribed under this section, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, shall mean each agent, agency, branch or office within the United States of any person, as defined by the ICC Termination Act, doing business in one or more of the capacities:

(1) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h));

(2) A commercial bank or trust company;

(3) An agency or branch of a foreign bank in the United States;

(4) An insured depository institution (as defined in section 3(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1813(c)(2));

(5) A thrift institution (savings bank, building and loan association, credit union, industrial bank or other);

(6) An insurance company;

(7) Until January 16, 2026, a loan or finance company; or

[32] Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002).

(8) A person subject to supervision by any State or Federal bank supervisory authority.

(d) *Forms and Procedures.* (1) Forms for broker surety bonds and trust agreements. Form BMC–84 broker surety bond will be filed with FMCSA for the full security limits under paragraph (a) of this section; or Form BMC–85 broker trust fund agreement will be filed with FMCSA for the full security limits under paragraph (a) of this section.

(2) Broker surety bonds and trust fund agreements in effect continuously. Surety bonds and trust fund agreements shall specify that coverage thereunder will remain in effect continuously until terminated as herein provided in paragraphs (d)(2)(i) and (d)(2)(ii) of this section.

(i) *Cancellation notice.* The surety bond and the trust fund agreement may be cancelled only upon 30 days' written notice to FMCSA, on prescribed Form BMC–36, by the principal or surety for the surety bond, and on prescribed Form BMC–85, by the trustor/broker or trustee for the trust fund agreement. The notice period commences upon the actual receipt of the notice at FMCSA's Washington, DC office.

(ii) *Termination by replacement.* Broker surety bonds or trust fund agreements which have been accepted by FMCSA under these rules may be replaced by other surety bonds or trust fund agreements, and the liability of the retiring surety or trustee under such surety bond or trust fund agreements shall be considered as having terminated as of the effective date of the replacement surety bond or trust fund agreement. However, such termination shall not affect the liability of the surety or the trustee hereunder for the payment of any damages arising as the result of contracts, agreements or arrangements made by the broker for the supplying of transportation prior to the date such termination becomes effective.

(e) *Immediate suspension.* (1) A surety company issuing a Form BMC–84 or a financial institution issuing a Form BMC–85 must notify FMCSA in writing, by electronic means, when the surety company or financial institution:

(i) Makes a payment, with the consent of the broker, from the surety bond or trust fund for a claim by a shipper or motor carrier that causes the surety bond or trust fund to fall below $75,000;

(ii) Makes a payment in any case in which the broker does not respond within 7 business days to address the validity of the claim, and the surety provider or financial institution determines that the claim is valid, and the payment causes the surety bond or trust fund to fall below $75,000;

(iii) Makes a payment due to a judgment against the broker that causes the surety bond or trust fund to fall below $75,000; or

(iv) Determines that the broker is experiencing financial failure or insolvency and that the surety company or financial institution will be required to pay one or more claims pursuant to 49 U.S.C. 13906(b)(6) in an amount that will cause the surety bond or trust fund to fall below $75,000. The surety company or financial institution may make this determination when:

(A) It receives one or more claims that, if paid, would reduce the balance of the trust fund or surety bond below the required minimum;

(B) It has notified the broker of such claims and provided 7 business days for the broker to respond to the determination; and

(C) Either the broker fails to respond within the time period provided in paragraph (e)(1)(D)(ii) of this section, or provides a response and the surety company or financial institution nevertheless determines that the claim is legitimate and that the surety company or financial institution expects to make one or more payments on the claim from the bond or trust fund.

(2) Paragraph (e)(1) of this section does not apply when a broker has filed to initiate a proceeding pursuant to Title 11 of the United States Code.

(3) The notification to FMCSA must include the broker's MC number or USDOT number, a description of the reason for the notification, and either:

(i) Evidence of the date a payment was made under paragraphs (e)(1)(i) through (iii) of this section and amount of such payment, or

(ii) A list of currently pending claims, amounts, and evidence that the surety company or financial institution complied with the notification requirements in paragraph (e)(1)(D) of this section.

(4) The notification to FMCSA must be made within 2 business days of a payment or determination.

(5) Upon notification by the surety company or financial institution in accordance with paragraphs (e)(1) through (4) of this section, FMCSA will provide written notice to the broker that its operating authority registration issued pursuant to part 365 of this chapter will be suspended within 7 business days of the date of the notice unless the broker provides written evidence to FMCSA that the notification was sent in error, the surety bond or trust fund has been restored to the $75,000 amount required by this section, or the pending claims have been satisfied without the use of surety bond or trust fund assets.

(6) If the broker fails to respond to the notice within 7 business days, FMCSA will enter a suspension of the broker's authority and provide written notice to the broker that the suspension is in effect. A broker whose authority has been suspended may request FMCSA to lift the suspension by providing written evidence that the notification was sent in error; the surety bond or trust fund has been restored to the $75,000 amount required by this section; or the pending claims have been satisfied without the use of surety bond or trust fund assets. FMCSA will consider such evidence and provide written notice to the broker of its determination.

(f) *Financial failure or insolvency of the broker.* (1) For purposes of this section, a *financial failure or insolvency* of a broker is defined as any payment made or other default pursuant to § 387.307(e)(1) not cured in accordance with § 387.307(e)(5) or (6).

(2) For purposes of this provision, a filing related to the broker pursuant to Title 11 of the United States Code does not constitute financial failure or insolvency.

(3) If a surety company or financial institution makes a determination as described in paragraph (f)(1) of this section, such surety company or financial institution shall initiate cancellation of the Form BMC–84 or Form BMC–85 pursuant to paragraph (d)(2)(i) of this section.

(4) Upon notification by the surety company or financial institution, FMCSA will provide written notice of the cancellation in the FMCSA Register on its public website. The surety or financial institution must accept claims against the BMC–84 surety bond or BMC–85 trust fund for 60 calendar days (extended to the next business day if the final day of the period falls on a weekend or Federal holiday) following FMCSA's public notification of the financial failure or insolvency in the FMCSA Register.

(5) If a surety company or financial institution notifies FMCSA of its determination pursuant to paragraph (e)(1)(iv) that a broker is experiencing financial failure or insolvency and the broker subsequently satisfies all pending claims that would have reduced the surety bond or trust fund below $75,000, the surety company or financial institution must immediately notify FMCSA that the broker is no longer experiencing financial failure or insolvency. Upon receiving evidence from the broker that the surety company or financial institution has terminated

the cancellation process and reinstituted the bond or trust, or that the broker has obtained a new bond or trust from another eligible surety company or financial institution, FMCSA will promptly provide written notice in the FMCSA Register on its public website that the financial failure or insolvency has been cured.

(g) *Suspension of surety company or financial institution.* (1) If a surety company or financial institution violates the requirements of this section or 49 U.S.C. 13906(b) or (c), FMCSA shall suspend the authorization of such surety company or financial institution to have its instruments filed as evidence of financial responsibility pursuant to § 387.307 for 3 years.

(2) If FMCSA initiates a suspension action pursuant to paragraph (g)(1) of this section it shall provide written notice to the surety company or financial institution, provide 30 calendar days (extended to the next business day if the final day of the period falls on a weekend or Federal holiday) for the surety company or financial institution to provide evidence contesting such proposed suspension, and then render a final decision in writing.

■ 6. Amend newly redesignated § 387.307T by:

■ a. Adding introductory text; and

■ b. Revising paragraph (d)(2)(i).

The addition and revision read as follows:

§ 387.307T Property broker surety bond or trust fund.

This section will remain in effect until January 16, 2025.

* * * * *

(d) * * *

(2) * * *

(i) *Cancellation notice.* The surety bond and the trust fund agreement may be cancelled only upon 30 days' written notice to the FMCSA, on prescribed Form BMC 36, by the principal or surety for the surety bond, and on prescribed Form BMC 85, by the trustor/broker or trustee for the trust fund agreement.

* * * * *

Issued under authority delegated in 49 CFR 1.87.

Robin Hutcheson,

Administrator.

[FR Doc. 2023–25312 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 221214–0271]

RIN 0648–BL52

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Revolution Wind Offshore Wind Farm Project Offshore Rhode Island; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to a final rule. The document being corrected is the regulations governing the Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Revolution Wind Offshore Wind Farm Project Offshore Rhode Island, published on October 20, 2023.

DATES: Effective on November 20, 2023.

FOR FURTHER INFORMATION CONTACT: Carter Esch, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

NMFS published a final rule in the **Federal Register** on October 20, 2023 (88 FR 72562) announcing the promulgation of regulations governing the incidental take of marine mammals incidental to Revolution Wind, LLC's (Revolution Wind), construction of the Revolution Wind Offshore Wind Energy Project in Federal and State waters offshore Rhode Island, specifically within the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS) Lease Area OCS–A–0486 and along two export cable routes to sea-to-shore transition points, valid for 5 years from the date of effectiveness.

The regulations, which allow for the issuance of a Letter of Authorization to Revolution Wind for the incidental take of marine mammals during the specified activities within the specified geographical region during the effective dates of the regulations, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking. NMFS refers the reader to the final rule (88 FR 72562, October 20, 2023) for background information concerning the regulations. The regulations contained a codification error requiring correction. Specifically, 50 CFR 217.274(b)(8) was promulgated twice (*i.e.,* two different measures were both designated as 217.274(b)(8), necessitating renumbering), and, therefore, a correction is necessary to properly number 50 CFR 217.274(b).

Correction

■ Effective November 20, 2023, in rule document 2023–22056 at 88 FR 72659 in the issue of October 20, 2023, on page 72662, in the first column, in amendatory instruction 2, paragraph (b) is corrected to read as follows:

§ 217.274 [Corrected]

(b) *Vessel strike avoidance measures.* LOA Holder must comply with the following vessel strike avoidance measures, unless an emergency situation presents a threat to the health, safety, or life of a person or when a vessel, actively engaged in emergency rescue or response duties, including vessel-in-distress or environmental crisis response, requires speeds in excess of 10 kn (11.5 miles per hour (mph)) to fulfill those responsibilities, while in the specified geographical region:

(1) Prior to the start of the Project's activities involving vessels, LOA Holder must receive a protected species training that covers, at a minimum, identification of marine mammals that have the potential to occur where vessels would be operating; detection observation methods in both good weather conditions (*i.e.,* clear visibility, low winds, low sea states) and bad weather conditions (*i.e.,* fog, high winds, high sea states, with glare); sighting communication protocols; all vessel speed and approach limit mitigation requirements (*e.g.,* vessel strike avoidance measures); and information and resources available to the project personnel regarding the applicability of Federal laws and regulations for protected species. This training must be repeated for any new vessel personnel who join the Project. The dedicated visual observers must receive prior training on protected species detection and identification, vessel strike minimization procedures, how and when to communicate with the vessel captain, and reporting requirements in this subpart. Confirmation of the observers' training and understanding of the Incidental

Take Authorization (ITA) requirements must be documented on a training course log sheet and reported to NMFS;

(2) LOA Holder's vessels, regardless of their vessel's size, must maintain a vigilant watch for all marine mammals during all vessel operations and slow down, stop their vessel, or alter course to avoid striking any marine mammal;

(3) LOA Holder's underway vessels (*e.g.,* transiting, surveying) operating at any speed must have a dedicated visual observer on duty on each vessel at all times to monitor for marine mammals primarily within a 180° direction of the forward path of the vessel (90° port to 90° starboard) located at an appropriate vantage point for ensuring vessels are maintaining appropriate separation distances. Visual observers must be equipped with alternative monitoring technology (*e.g.,* night vision devices, infrared cameras) for periods of low visibility (*e.g.,* darkness, rain, fog, *etc.*). The dedicated visual observer must receive prior training on protected species detection and identification, vessel strike minimization procedures, how and when to communicate with the vessel captain, use of visual monitoring and alternative monitoring equipment, and reporting requirements in this subpart. Visual observers may be third-party observers (*i.e.,* NMFS-approved PSOs as defined in § 217.275 (a)(1)) or trained crew members;

(4) LOA Holder must continuously monitor the U.S. Coast Guard VHF Channel 16 at the onset of transiting through the duration of transiting, over which notifications of North Atlantic right whale Slow Zones (DMAs and acoustically-triggered Slow Zones) are broadcasted. At the onset of transiting and at least once every 4 hours, vessel operators and/or trained crew member(s) must also monitor the LOA Holder's Project-Wide Situational Awareness System, WhaleAlert, and relevant NOAA information systems such as the Right Whale Sighting Advisory System (RWSAS) for the presence of North Atlantic right whales;

(5) All LOA Holder's vessels must transit at 10 knots (11.5 mph) or less within any active North Atlantic right whale Seasonal Management Area (SMA) and Slow Zone (*i.e.,* Dynamic Management Areas (DMA) or acoustically-triggered Slow Zones);

(6) Between November 1 and April 30, all vessels, regardless of size, must operate port to port (specifically from ports in Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Virginia, and Maryland), and within the Lease Area and Revolution Wind Export Cable (RWEC) corridor, at 10 knots (11.5 mph) or less, except for vessels transiting in Narragansett Bay or Long Island Sound;

(7) All LOA Holder's vessel(s) (including crew transfer vessels) are restricted from traveling over 10 knots (11.5 mph), unless traveling in a frequently traveled transit corridor (*e.g.,* crew transfer corridor) between port to the Lease Area while LOA Holder monitors the transit corridor to detect large whales (including North Atlantic right whales) in real-time with PAM prior to and during transits. This measure only applies when no other vessel speed restrictions are in place;

(8) All LOA Holder's vessels, regardless of size, must immediately reduce speed to 10 knots (11.5 mph) or less for at least 24 hours when a North Atlantic right whale is sighted at any distance by any project-related personnel or acoustically detected by any project-related PAM system. Each subsequent observation or acoustic detection in the Project area must trigger an additional 24-hour period of operating at 10 knots (11.5 mph) or less. If a North Atlantic right whale is reported via any of the monitoring systems (see (b)(4) of this section) within 10 kilometers (km; 6.2 miles (mi)) of a transiting vessel(s), that vessel must operate at 10 knots (11.5 mph)) or less for 24 hours following the reported detection;

(9) LOA Holder's vessels, regardless of size, must immediately reduce speed to 10 knots (11.5 mph) or less when any large whale (other than a North Atlantic right whale) is observed within 500 meters (m; 1,640 ft) of an underway vessel;

(10) If a large whale (other than a North Atlantic right whale) is detected via the transit corridor PAM system, all vessels must travel at 10 knots (11.5 mph) until the whale can be confirmed visually beyond 500 m of the vessel or 24 hours has passed;

(11) LOA Holder's vessels must maintain a minimum separation distance of 500 m (1,640 ft) from North Atlantic right whales. If underway, all vessels must steer a course away from any sighted North Atlantic right whale at 10 knots (11.5 mph) or less such that the 500-m minimum separation distance requirement is not violated. If a North Atlantic right whale is sighted within 500 m of an underway vessel, that vessel must reduce speed and shift the engine to neutral. Engines must not be engaged until the whale has moved outside of the vessel's path and beyond 500 m. If a whale is observed but cannot be confirmed as a species other than a North Atlantic right whale, the vessel operator must assume that it is a North Atlantic right whale and take the vessel strike avoidance measures described in this paragraph;

(12) LOA Holder's vessels must maintain a minimum separation distance of 100 m (328 ft) from sperm whales and non-North Atlantic right whale baleen whales. If one of these species is sighted within 100 m of a transiting vessel, LOA Holder's vessel must reduce speed and shift the engine to neutral. Engines must not be engaged until the whale has moved outside of the vessel's path and beyond 100 m (328 ft);

(13) LOA Holder's vessels must maintain a minimum separation distance of 50 m (164 ft) from all delphinid cetaceans and pinnipeds with an exception made for those that approach the vessel (*i.e.,* bow-riding dolphins). If a delphinid cetacean that is not bow riding or a pinniped is sighted within 50 m of a transiting vessel, LOA Holder's vessel operator must shift the engine to neutral, with an exception made for those that approach the vessel (*e.g.,* bow-riding dolphins). Engines must not be engaged until the animal(s) has moved outside of the vessel's path and beyond 50 m (164 ft);

(14) When a marine mammal(s) is sighted while LOA Holder's vessel(s) is transiting, the vessel must not divert or alter course to approach any marine mammal and must take action as necessary to avoid violating the relevant separation distances (*e.g.,* attempt to remain parallel to the animal's course, slow down, and avoid excessive speed or abrupt changes in direction until the animal has left the area). If a separation distance is triggered, any vessel underway must avoid abrupt changes in course direction and take appropriate action as specified in paragraphs (b)(11) through (13) of this section. This measure does not apply to any vessel towing gear or any situation where respecting the relevant separation distance would be unsafe (*i.e.,* any situation where the vessel is navigationally constrained);

(15) LOA Holder is required to abide by other speed and approach regulations. Nothing in this subpart exempts vessels from any other applicable marine mammal speed and approach regulations;

(16) LOA Holder must check, daily, for information regarding the establishment of mandatory or voluntary vessel strike avoidance areas (*i.e.,* DMAs, SMAs, Slow Zones) and any information regarding North Atlantic right whale sighting locations;

(17) LOA Holder must submit a North Atlantic Right Whale Vessel Strike Avoidance Plan to NMFS Office of Protected Resources for review and

approval at least 90 days prior to the planned start of vessel activity. The plan must provide details on the vessel-based observer and PAM protocols for transiting vessels. If a plan is not submitted or approved by NMFS prior to vessel operations, all project vessels transiting, year round, must travel at speeds of 10 knots (11.5 mph) or less. LOA Holder must comply with any approved North Atlantic Right Whale Vessel Strike Avoidance Plan; and

(18) Speed over ground will be used to measure all vessel speed restrictions.

Dated: November 13, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2023–25366 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230810–0190]

RTID 0648–XD514

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; White Hake Trimester Total Allowable Catch Area Closure for the Common Pool Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; area closure.

SUMMARY: This action closes the White Hake Trimester Total Allowable Catch Area to Northeast multispecies common pool vessels fishing with trawl gear, sink gillnet gear, and longline/hook gear, except Handgear A and Handgear B vessels, through December 31, 2023. The closure is required because the common pool fishery is projected to have caught 90 percent of its Trimester 2 quota for white hake. This closure is intended to prevent an overage of the common pool's quota for this stock.

DATES: This action is effective November 13, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Spencer Talmage, Fishery Policy Analyst, (978) 281–9232.

SUPPLEMENTARY INFORMATION: Federal regulations at § 648.82(n)(2)(ii) require the Regional Administrator to close a common pool Trimester Total Allowable Catch (TAC) Area for a stock when 90 percent of the Trimester TAC is projected to be caught. The closure applies to all common pool vessels fishing with gear capable of catching that stock, and remains in effect for the remainder of the trimester. During the closure, affected common pool vessels may not fish for, harvest, possess, or land regulated multispecies or ocean pout in or from the Trimester TAC Area for the stock.

The Trimester 2 TAC for white hake is 17,482 lb (pounds) (7.9 metric tons (mt)). Based on the best available data from this fishing year and the analyses described below, the common pool is estimated to have achieved 90 percent of the Trimester 2 TAC for white hake on or shortly after November 9, 2023.

NMFS closely monitors commercial fisheries landings on a weekly basis. Catch projections of white hake were run using data through November 7, 2023, which indicated that 87.7 percent (15,211.9 lb (6.9 mt)) of the Trimester 2 TAC was harvested. Given these projections and additional information, including that there have been up to four trips for which catch data are not yet available, NMFS estimates that 90 percent of the white hake Trimester 2 TAC has been harvested. As noted above, implementing regulations for the Northeast Multispecies FMP require the Regional Administrator to close an area when a trimester TAC is projected to reach the 90-percent trigger.

Effective November 13, 2023, the White Hake Trimester TAC Area is closed for the remainder of Trimester 2, through December 31, 2023. The White Hake Trimester TAC Area consists of statistical areas 513, 514, 515, 521, and 522. During the closure, common pool vessels fishing with trawl gear, sink gillnet gear, and longline/hook gear (except for Handgear A and Handgear B vessels), may not fish for, harvest, possess, or land regulated multispecies or ocean pout in or from this area. This closure of the White Hake Trimester TAC Area ends at the beginning of Trimester 3 of fishing year 2023 on January 1, 2024.

If a vessel declared its trip through the Vessel Monitoring System (VMS) or the interactive voice response system, and crossed the VMS demarcation line prior to November 13, 2023, it may complete its trip within the GOM Cod Trimester TAC Area. A vessel that has set gillnet gear prior to November 13, 2023, may complete its trip by hauling such gear.

If the common pool fishery exceeds its annual sub-Allowable Catch Limit (sub-ACL) for a stock in the 2023 fishing year, the overage must be deducted from the common pool's sub-ACL for that stock for fishing year 2024.

Weekly quota monitoring reports for the common pool fishery are on our website at: *https://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/h/nemultispecies.html.* We will continue to monitor common pool catch through vessel trip reports, dealer-reported landings, VMS catch reports, and other available information and, if necessary, will make additional adjustments to common pool management measures.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3) to waive prior notice and the opportunity for public comment and the 30-day delayed effectiveness period because it would be impracticable, unnecessary, and contrary to the public interest.

The regulations require the Regional Administrator to close a trimester TAC area to the common pool fishery when 90 percent of the Trimester TAC for a stock has been caught. Updated catch information through November 7, 2023, only recently became available indicating that the common pool fishery is projected to have caught 90 percent of its Trimester 2 TAC for white hake. The time necessary to provide for prior notice and comment, and a 30-day delay in effectiveness, would prevent the immediate closure of the White Hake Trimester TAC Area. This would be contrary to the regulatory requirement and would increase the likelihood that the common pool fishery would exceed its annual quota of white hake. Any overage of the Trimester 2 TAC is deducted from the Trimester 3 TAC, and any overage of the annual quota would be deducted from common pool's quota for the next fishing year, to the detriment of this stock. This could undermine conservation and management objectives of the Northeast Multispecies Fishery Management Plan. Prior notice and comment and a 30-day delay in effectiveness are unnecessary because fishermen were provided ample notice and opportunity to comment on the regulations that require this immediate closure. Fishermen expect these closures to occur in a timely way to prevent overages and their payback requirements. Overages of the trimester or annual common pool quota could cause negative economic impacts to the common pool fishery as a result of overage paybacks deducted from a future trimester or fishing year.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25365 Filed 11–13–23; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[RTID 0648–XC971]

Fisheries Off West Coast States; West Coast Groundfish Fisheries; Amendment 31 to the Pacific Coast Groundfish Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of agency decision.

SUMMARY: NMFS announces the approval of Amendment 31 to the Pacific Fishery Management Council's (Council) Pacific Coast Groundfish Fishery Management Plan (FMP). Amendment 31 defines stocks that are in need of conservation and management, consistent with the provisions and guidelines of the Magnuson-Stevens Fishery Conservation and Management Act. Amendment 31 defines stocks for 14 species within the fishery management unit. These species were prioritized because they had stock assessments in 2021 or 2023. Amendment 31 is necessary for NMFS to make stock status determinations, which in turn will help prevent overfishing, rebuild overfished stocks, and achieve optimum yield. Amendment 31 is administrative in nature and does not change harvest levels or timing and location of fishing, nor does it revise the goals and objectives or the management frameworks of the Pacific Coast Groundfish Fishery Management Plan.

DATES: The amendment was approved on November 8, 2023.

ADDRESSES: The amended FMP is available on the Council's website (*https://www.pcouncil.org*), as is the final supporting analysis.

FOR FURTHER INFORMATION CONTACT: Gretchen Hanshew (206) 526–6147, email at *gretchen.hanshew@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fisheries in the exclusive economic zone (EEZ) seaward of Washington, Oregon, and California under the Pacific Coast Groundfish fishery management plan (FMP). The Magnuson-Stevens Fishery Conservation and Management Act (MSA) requires that each regional fishery management council submit any FMP or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary). The MSA also requires that NMFS, upon receiving an FMP or amendment, immediately publish a notice that the FMP or amendment is available for public review and comment.

The Notice of Availability (NOA) for Amendment 31 was published in the **Federal Register** on August 23, 2023 (88 FR 57400), with a 60-day comment period that ended on October 22, 2023. NMFS received three comments during the public comment period on the NOA, all in support of Amendment 31. NMFS' authority for this action is limited by the MSA to approval, disapproval, or partial approval of the amendment submitted by the Council. NMFS summarized and responded to these comments under Comments and Responses, below.

NMFS determined that Amendment 31 is consistent with the MSA and other applicable laws, and the Secretary of Commerce approved Amendment 31 on November 8, 2023. The August 23, 2023 NOA (88 FR 57400) contains additional information on this action. Amendment 31 is administrative in nature and has no implementing regulations; no changes to existing Federal regulations are necessary and none were proposed.

The Council recommended stock definitions for 14 species of Pacific Coast groundfish after NMFS was unable to make stock status determinations in 2021. NMFS was unable to make stock status determinations because the ''stocks'' for which the Council was expecting status determinations did not exist in the FMP. Currently, the FMP has a list of 80+ species to which it pertains, and does not describe whether each species is a single stock within the fishery management unit or if it is multiple (*e.g.,* regional) stocks. The Council prioritized a sub-set of species for stock identification in Amendment 31. These species are black, canary, copper, quillback, squarespot, vermilion, and vermilion/sunset rockfishes; Dover, petrale, and rex soles; lingcod, Pacific spiny dogfish, sablefish, and shortspine thornyhead. These species were prioritized because they were subject to stock assessments in 2021 or were subject to stock assessments in 2023. The Council considered some of the biological, socioeconomic, and fishery management trade-offs that might be expected from implementation of future management actions based on the alternative stock definitions. The Council recommended Amendment 31 at its June 20–27, 2023 meeting. Amendment 31 was transmitted to NMFS by the Council on August 14, 2023. A detailed description of Amendment 31 is included in the NOA (88 FR 57400, August 23, 2023).

Comments and Responses

NMFS received two comment letters with three comments during the 60-day public comment period on the NOA. The comments were all in favor of NMFS' approval of the amendment and included some specific rationale. The comments and NMFS's responses are presented below.

Comment 1: One commenter endorses Amendment 31 because it aims to reduce overfishing and rebuild stocks back to sustainable levels, which will help prevent food chain and food web imbalances.

Response: NMFS agrees that defining stocks with Amendment 31will aid in preventing overfishing and rebuilding overfished stocks and that this may, in turn, also provide ecosystem benefits.

Comment 2: One commenter urges approval and effective implementation of Amendment 31 to prevent overfishing which would in turn increase marine ecosystems' resiliency to climate change stressors.

Response: NMFS agrees that Amendment 31 will lead to future management decisions that improve the long-term sustainability of the managed fisheries, which may improve resilience of marine ecosystems to non-fishing climate stressors. Effective implementation of stock definitions in Amendment 31 will come in future biennial harvest specifications and management measures actions, where the best scientific information will be used to inform management of the defined stocks within the context of the FMP and the mixed stock fishery.

Comment 3: One commenter expressed that Amendment 31 is warranted because the species that are the subject of Amendment 31 have already been verified as overfished stocks by governmental and nongovernmental organizations.

Response: NMFS agrees that the Amendment 31 stock definitions for the subject species are based on the best scientific information available, and that stocks are the unit at which NMFS may determine whether an overfished status is warranted. NMFS notes that the determination whether or not a stock is overfished is the sole responsibility of NMFS, based on best scientific

information available and the stocks' status determination criteria that are defined in the FMP.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2023–25268 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053]

RTID 0648–XD210

Fisheries of the Exclusive Economic Zone Off Alaska; ''Other Rockfish'' in the Western and Central Regulatory Areas of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of ''other'' rockfish in the Western and Central Regulatory Areas of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2023 total allowable catch of ''other'' rockfish in the Western and Central Regulatory Areas of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 13, 2023, through 2400 hours, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7241.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2023 total allowable catch (TAC) of ''other rockfish'' in the Western and Central Regulatory Areas of the GOA is 940 metric tons (mt) as established by the final 2023 and 2024 harvest specifications for groundfish of the GOA (88 FR 13238, March 2, 2023).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2023 ''other rockfish'' TAC in the Western and Central Regulatory Areas of the GOA will soon be reached. Therefore, NMFS is requiring that ''other rockfish'' in the Western and Central Regulatory Areas of the GOA be treated as prohibited species in accordance with § 679.21(a), except ''other rockfish'' species in the Western and Central Regulatory Areas of the GOA caught by catcher vessels using hook-and-line, pot, or jig gear as described in § 679.20(j).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay prohibiting retention of ''other rockfish'' in the Western and Central Regulatory Areas of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 9, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 et seq.

Dated: November 13, 2023.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25318 Filed 11–13–23; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 220
Thursday, November 16, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Doc. No. AMS–SC–23–0038]

Raisins Produced From Grapes Grown in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) proposes to implement a recommendation from the Raisin Administrative Committee (Committee) to increase the assessment rate established for the 2023–2024 and subsequent crop years. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by December 18, 2023.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rulemaking. Comments may be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237. Comments can also be submitted to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* Comments should reference the document number, and date and page number of this issue of the **Federal Register**. Comments submitted in response to this proposed rulemaking will be included in the record, will be made available to the public, and can be viewed at: *https://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Kathie Notoro, Marketing Specialist, or Gary Olson, Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901 or Email: *Kathie.Notoro@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rulemaking is issued under Marketing Agreement and Order No. 989, as amended (7 CFR part 989), regulating the handling of raisins produced from grapes grown in California. Part 989 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of raisins operating within the area of production, and a public member.

AMS is issuing this proposed rulemaking in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866, 13563, and 14094 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 *directs agencies to conduct proactive outreach to engage interested and affected parties through a variety of means, such as through field offices, and alternative platforms and media.* This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rulemaking has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this proposed rulemaking is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This proposed rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. Under the order now in effect, California raisin handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the proposed assessment rate would be applicable to all assessable raisins beginning on August 1, 2023, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

Section 989.79 provides authority for the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated

and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2018–2019 and subsequent crop years, an assessment rate of $22 per assessable ton of raisins handled (84 FR 2049) was in place. That rate continues in effect from crop year to crop year until modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS.

This proposed rulemaking would increase the assessment rate from $22 per ton to $24 per ton of assessable raisins for the 2023–2024 and subsequent crop years. Prior to arriving at this proposed assessment rate, the Committee considered information from its Audit Subcommittee (Subcommittee), which met on June 21, 2023. The Subcommittee discussed alternative spending levels before making a recommendation to the full Committee. On June 28, 2023, the full Committee discussed the recommendation of the Subcommittee and voted unanimously to recommend a budget of $5,241,000 and an assessment rate of $24 per ton as reasonable and necessary to properly administer the Order.

The Committee last amended the assessment rate in 2019 to $22 per ton, which continues to remain in effect; however, California raisin acreage and volume have steadily declined since 2019. The Committee determined the level of assessment revenue under the current rate as now insufficient to meet the rising costs of program operations given a production estimate of 192,000 tons of assessable raisins for the 2023–2024 crop year.

The proposed assessment rate of $24 is $2 higher than the rate currently in effect and is expected to generate assessment income of approximately $4,608,000 ($24 per ton multiplied by 192,000 assessable tons) for the 2023–2024 crop year. This assessment revenue, combined with other Committee income and monetary reserves is sufficient to cover the balance of $633,000 ($5,241,000 minus $4,608,000).

The major expenditures recommended by the Committee for the 2023–2024 crop year include $3,303,000 for marketing promotion; $1,205,000 for salaries and employee-related costs; $658,000 for administrative expenses; $55,000 for compliance activities; and $20,000 for research and studies. Budgeted expenditures for the 2022–2023 crop year were $3,592,000; $1,232,000; $703,900; $55,000; and $45,000, respectively. The proposed assessment rate increase would help cover the expenditures for the 2023–2024 crop year, while reducing the amount of money needing to be expended from reserves.

This proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's budget for subsequent crop years would be reviewed and, as appropriate, approved by AMS.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the AMS has considered the economic impact of this proposed rulemaking on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 1,700 producers of California raisins and approximately 17 handlers subject to regulation under the marketing order. Small agricultural producers of raisins are defined by the Small Business Administration (SBA) as those having annual receipts equal to or less than $4.0 million (NAICS code 111332, Grape Vineyards) and small agricultural service firms are defined as those whose annual receipts are equal to or less than $34.0 million (NAICS code 115114, Postharvest Crop Activities) (13 CFR 121.201).

Using USDA National Agricultural Statistics Service (NASS) data, the 2022 season average value of utilized production of California processed raisin-type grapes (most of which are dried into raisins) is $376.618 million. Dividing that figure by 1,700 producers yields an annual average revenue per producer of $221,540, well below the SBA large farm size threshold of $4.0 million. Therefore, in terms of average annual sales of processed raisin-type grapes, the majority of California raisin producers may be classified as small entities.

To make a similar computation for handlers, the first step is to estimate a representative handler price received per pound for packaged raisins. Recent USDA purchases under the Commodity Procurement Program provide such an estimate. For the most recent raisin crop year used by the RAC (August 2022–July 2023) the average price paid for packaged raisins purchased by the USDA for feeding programs was $1.56 per pound. For that time period, the RAC provided a list of quantities delivered by handlers. When multiplied by the $1.56 price per pound, the results showed that 5 handlers had annual raisin receipts greater than $34 million, the SBA threshold level for a large handler. The remaining 12 handlers out of 17 are small handlers, using the SBA criterion.

This proposed rulemaking would increase the assessment rate collected from handlers for the 2023–2024 and subsequent crop years from $22 to $24 per ton of assessable raisins acquired by handlers. The Committee reviewed its ongoing activities and determined the expenses that would be reasonable and necessary to continue program operations for the 2023–2024 crop year. Additionally, the Committee considered that California raisin acreage and volume have steadily declined. Consequently, the revenue collected from assessments also decreased, while program operating costs have continued to increase. Ultimately, the Committee recommended budget totals $5,241,000 for the 2023–2024 crop year. With the current assessment of $22 a ton, and an operating budget of $5,241,000, the Committee would face a deficit of over $1MM. At the recommended assessment rate of $24 per ton, the anticipated assessment income would be $4,608,000 and would help reduce the estimated deficit by approximately $384,000.

The major expenditures recommended by the Committee for the 2023–2024 crop year include $3,303,000 for marketing promotion; $1,205,000 for salaries and employee-related costs; $658,000 for administrative expenses;

$55,000 for compliance activities; and $20,000 for research and studies. Budgeted expenditures for the 2022–2023 crop year were $3,592,000; $1,232,000; $703,900; $55,000; and $45,000, respectively. The increased assessment rate is necessary to help cover the expenditures for the 2023–2024 crop year, while reducing the amount of money needing to be expended from reserves.

The Order provides authority for the Committee to formulate an annual budget of expenses and propose an assessment rate to cover such expenses authorized by AMS. Prior to arriving at this budget and assessment rate, the Committee considered alternative spending levels at its June 28, 2023, meeting but ultimately decided that the recommended budget and assessment rate were reasonable and necessary to properly administer the Order.

This proposed rulemaking would increase the assessment obligation imposed on handlers. While the increased assessment rate would impose some additional costs on handlers, the costs are minimal and applied uniformly on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived by the industry from the operation of the Order.

The Committee's meetings are widely publicized throughout the production area. The raisin industry and all interested persons are invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the June 28, 2023, meeting was public meeting and all entities, both large and small, were able to express views on this issue. In addition, interested persons are invited to submit comments on this proposed rulemaking, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rulemaking would not impose any additional reporting or recordkeeping requirements on either small or large California raisin handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rulemaking.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Committee and other available information, USDA has determined that this proposed rulemaking is consistent with and will effectuate the purposes of the Act.

A 30-day comment period is provided to allow interested persons to respond to this proposed rulemaking. All written comments timely received will be considered before a final determination is made on this proposed rule.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 989 as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 989.347 is revised to read as follows:

§ 989.347 Assessment rate.

On and after August 1, 2023, an assessment rate of $24 per ton is established for assessable raisins produced from grapes in California.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–25247 Filed 11–15–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

10 CFR Part 1021

[DOE–HQ–2023–0063]

RIN 1990–AA48

National Environmental Policy Act Implementing Procedures

AGENCY: Office of the General Counsel, Department of Energy.

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The U.S. Department of Energy (DOE or the Department) proposes to amend its implementing procedures (regulations) governing compliance with the National Environmental Policy Act (NEPA). The proposed changes would add a categorical exclusion for certain energy storage systems and revise categorical exclusions for upgrading and rebuilding transmission lines and for solar photovoltaic systems, as well as make conforming changes to related sections of DOE's NEPA regulations. The proposed changes are based on the experience of DOE and other Federal agencies, current technologies, regulatory requirements, and accepted industry practice. DOE invites public comments on the proposed changes.

DATES: DOE must receive comments by January 2, 2024 to ensure consideration.

ADDRESSES: Documents relevant to this proposed rulemaking are posted at *www.regulations.gov* (*Docket: DOE–HQ–2023–0063*). Documents posted to this docket include: this notice of proposed rulemaking and DOE's Technical Support Document, which provides additional information regarding certain proposed changes and a redline/strikeout version of affected sections of the DOE NEPA regulations indicating the changes in this proposed rule.

Submit comments, labeled ''DOE NEPA Implementing Procedures, RIN 1990–AA48,'' by one of the following methods:

1. *www.regulations.gov:* Enter ''Docket ID DOE–HQ–2023–0063'' in the search box. Click on ''Comment'' to submit comments, which you may enter directly on the web page or by uploading in a file.

2. *Postal Mail:* Mail comments to NEPA Rulemaking Comments, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Because security screening may delay mail sent through the U.S. Postal Service, DOE encourages electronic submittal of

comments through *www.regulations.gov.*

3. *Email:* send comments to *DOE-NEPA-Rulemaking@hq.doe.gov.*

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation—Submission of Comments'' (section IV) of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions concerning how to comment on this proposed rule, contact Ms. Carrie Abravanel, Office of NEPA Policy and Compliance, at *DOE-NEPA-Rulemaking@hq.doe.gov* or 202–586–4600.

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I. Introduction and Background

The National Environmental Policy Act, as amended, (42 U.S.C. 4321 *et seq.*) requires Federal agencies to provide a detailed statement regarding the environmental impacts of proposals for major Federal actions significantly affecting the quality of the human environment. The Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR parts 1500–1508) require agencies to develop their own NEPA implementing procedures to apply the CEQ regulations to their specific programs and decision-making processes (40 CFR 1507.3). DOE's NEPA procedures are contained in 10 CFR part 1021.

NEPA establishes three types of review for proposed actions—environmental impact statement, environmental assessment, and categorical exclusion—each involving different levels of information and analysis. An environmental impact statement is a detailed analysis of reasonably foreseeable environmental effects prepared for a major Federal action significantly affecting the quality of the human environment (42 U.S.C. 4332(2)(C) and 40 CFR part 1502 and section 1508.1(j)). An environmental assessment is a concise public document prepared by a Federal agency to set forth the basis for its finding of no significant impact or its determination that an environmental impact statement is necessary (42 U.S.C. 4336(b)(2) and 40 CFR 1501.5, 1501.6, and 1508.1(h)). A categorical exclusion is a category of actions that the agency has determined, in its agency NEPA procedures, normally does not have a significant effect on the human environment and therefore does not require preparation of an environmental assessment or environmental impact statement (40 CFR 1501.4, 1507.3(e)(2)(ii), and 1508.1(d)). DOE's procedures for applying categorical exclusions require the agency to consider whether extraordinary circumstances exist due to which a normally excluded action may have a significant environmental effect.

A. Establishment and Use of Categorical Exclusions

DOE establishes and revises categorical exclusions pursuant to a rulemaking, such as this one, for defined classes of actions that the Department determines are supported by a record showing that the actions normally do not have significant environmental impacts, individually or cumulatively. The rulemaking process provides the public with an opportunity to review and comment on DOE's proposed changes. DOE will consider the comments received during the public comment period.

Once established in DOE's NEPA procedures, use of a categorical exclusion requires evaluation of a proposed action against several conditions. DOE must determine, in accordance with 10 CFR 1021.410(b), that: (1) the proposed action fits within a categorical exclusion listed in appendix A or B to subpart D of part 1021; (2) there are no extraordinary circumstances [1] related to the proposal that may affect the significance of the environmental impacts of the proposed action and require preparation of an environmental assessment or environmental impact statement, consistent with 40 CFR 1501.4(b)(1) and (b)(2); and (3) the proposal has not been improperly segmented [2] to meet the definition of a categorical exclusion, there are no connected or related actions with cumulatively significant impacts, and the proposed action is not precluded by 40 CFR 1506.1 or 10 CFR 1021.211 as an impermissible interim action.

In addition, DOE evaluates whether the proposed action satisfies conditions included within the text of the individual categorical exclusion and the conditions known as ''integral elements'' that apply to all categorical exclusions listed in appendix B to subpart D of part 1021 (appendix B, paragraphs (1) through (5)). Together, these conditions limit the types of proposals that fit within a categorical exclusion and help ensure that adverse environmental impacts are avoided or reduced. These conditions are discussed generally in this section and also in section II of this document, which describes each of DOE's proposed changes.

The categorical exclusions discussed in this proposed rulemaking include conditions specific to the categorical exclusion. For example, the proposed action must follow applicable codes and best management practices. These codes and practices vary by technology and location (*e.g.,* fire protection codes that differ by state). Also, they change over time to reflect lessons learned and to address emerging technology and practices. The Technical Support Document provides links to and summarizes information on some of the relevant codes and best practices for the categorical exclusions that are included in this proposed rulemaking. As another example, the changes proposed in this rulemaking specify conditions regarding siting proposed actions on previously disturbed or developed land and on land contiguous to previously disturbed and developed land. DOE defines previously disturbed or developed as

[1] DOE defines extraordinary circumstances as ''unique situations presented by specific proposals, including, but not limited to, scientific controversy about the environmental effects of the proposal; uncertain effects or effects involving unique or unknown risks; and unresolved conflicts concerning alternative uses of available resources.'' (10 CFR 1021.410(b)(2))

[2] Segmentation can occur when a proposal is broken down into small parts in order to avoid the appearance of significance of the total action. (10 CFR 1021.410(b)(3))

''land that has been changed such that its functioning ecological processes have been and remain altered by human activity. The phrase encompasses areas that have been transformed from natural cover to non-native species or a managed state, including, but not limited to, utility and electric power transmission corridors and rights-of-way, and other areas where active utilities and currently used roads are readily available.'' (10 CFR 1021.410(g)(1)) As DOE explained in a 2011 notice of proposed rulemaking, ''In DOE's experience, the potential for certain types of actions to have significant impacts on the human environment is generally avoided when that action takes place within a previously disturbed or developed area, *i.e.,* land that has been changed such that the former state of the area and its functioning ecological processes have been altered.'' (76 FR 218; January 3, 2011) DOE's experience reviewing proposed projects across the United States since 2011 supports this same conclusion. DOE also has experience implementing categorical exclusions that allow construction on land that is contiguous to previously disturbed or developed areas and proposes to make certain siting on contiguous land part of one of the proposed categorical exclusions. The area of contiguous land affected would be small as discussed in 10 CFR 1021.410(g)(2). Any proposed use of contiguous land is subject to review against all the conditions relevant to the categorical exclusion, including the integral elements that require consideration of effects on threatened species, historic properties, and other environmentally sensitive resources. The Technical Support Document includes summaries of environmental assessments for projects proposed on previously disturbed or developed land and on contiguous land.

In addition to conditions within an individual categorical exclusion, the proposed action also must satisfy conditions known as ''integral elements.'' Integral elements are part of each categorical exclusion in appendix B. These conditions appear at the beginning of the appendix and are not repeated for each categorical exclusion. Integral elements require that, to fit within a categorical exclusion, the proposed action must not threaten a violation of applicable environment, safety, and health requirements; require siting and construction or major expansion of waste storage, disposal, recovery, or treatment facilities; disturb hazardous substances, pollutants, or contaminants that preexist in the environment such that there would be uncontrolled or unpermitted releases; have the potential to cause significant impacts on environmentally sensitive resources; or involve governmentally designated noxious weeds or invasive species, unless certain conditions are met.[3] In appendix B, DOE defines ''environmentally sensitive resource'' as a resource that has typically been identified as needing protection through Executive Order, statute, or regulation by Federal, state, or local government, or a federally recognized Indian tribe. Environmentally sensitive resources include historic properties, threatened and endangered species, floodplains, and wetlands, among others. (10 CFR part 1021, subpart D, appendix B)

Only if DOE determines that all the applicable conditions have been met may it issue a categorical exclusion determination. DOE posts its categorical exclusion determinations at *www.energy.gov/nepa/doe-categorical-exclusion-cx-determinations.*

B. Development of the Proposed Changes

In this proposed rulemaking, DOE proposes to add a categorical exclusion for certain energy storage systems and revise categorical exclusions for upgrading and rebuilding transmission lines and for solar photovoltaic (PV) systems, as well as make conforming changes to related sections of DOE's NEPA regulations. DOE last made changes to its categorical exclusions in these areas in 2011 (76 FR 63764; October 13, 2011). Since then, DOE has developed a better understanding of the potential environmental impacts of these types of actions through research, conducting environmental reviews, and engaging with industry, local communities, and other government agencies. The proposed changes are based on the experience of DOE and other Federal agencies, current technologies, regulatory requirements, and accepted industry practice. DOE consulted with CEQ during the development of these proposed changes.

DOE has documented the technical substantiation for the proposed changes in this preamble and in an accompanying Technical Support Document. The Technical Support Document summarizes environmental assessments for the types of projects addressed in this proposed rulemaking and other information. The environmental assessments demonstrate how DOE and other Federal agencies evaluated potential environmental impacts of these projects and determined that they would not result in a significant environmental effect. To be clear, not every environmental assessment discussed in the Technical Support Document reflects a project that would have qualified for a categorical exclusion proposed in this rulemaking. Such determinations would have to be made on a case-by-case basis.

DOE developed its support for this proposed rulemaking consistent with CEQ's 2010 guidance on establishing, applying, and revising categorical exclusions under NEPA (75 FR 75628; December 6, 2010). DOE also considered climate impacts and greenhouse gas (GHG) emissions in preparing these proposals consistent with CEQ's 2023 interim guidance on the consideration of GHG emissions and climate change (88 FR 1196; January 9, 2023). The description of the proposed changes in section II of this document includes a discussion of how the proposed changes may affect GHG emissions.

The public made suggestions for revising DOE's categorical exclusions in response to a Request for Information (RFI) published in the **Federal Register** on November 15, 2022. (87 FR 68385). Those suggestions, along with others made by DOE's NEPA Compliance Officers and other staff, led to the proposals included in this proposed rulemaking. DOE evaluated the proposals by reviewing environmental assessments prepared by DOE and by other Federal agencies, categorical exclusions established by other Federal agencies, technical reports, applicable requirements and industry practices, and other publicly available information.

Thirty-three individuals or entities responded to the Request for Information. The Request for Information and these comments are available at *www.regulations.gov/docket/DOE-HQ-2023-0002/comments.* Relevant to this proposed rulemaking, commenters asked DOE to add energy storage systems to its categorical exclusions, to expand the scope of its categorical exclusion for upgrading and rebuilding powerlines, and to expand its categorical exclusion for solar photovoltaic systems to at least 200 acres within previously disturbed or developed areas. DOE addresses these and related comments in its discussion of proposed changes in section II.B of this document. The identification number for individual commenter documents used on *www.regulations.gov* and the page(s) where a particular comment appears are

[3] This is a summary description of the integral elements. *See* 10 CFR part 1021, subpart D, appendix B for the full text.

included in section II.B of this document.

II. Description of Proposed Changes

A. Overview

DOE proposes to establish a new categorical exclusion for certain energy storage systems and to revise existing categorical exclusions for upgrading and rebuilding transmission lines and for solar photovoltaic systems. DOE's proposal also includes conforming changes to other categorical exclusions, to a class of actions normally requiring an environmental assessment, and to a class of actions normally requiring an environmental impact statement (10 CFR part 1021, subpart D, appendices B, C, and D). These proposed changes are discussed in sections II.B through II.D of this document.

These proposed changes, if finalized, would not require any changes to or otherwise affect categorical exclusion determinations completed prior to the effective date of any final rule.

B. Proposed Changes to Categorical Exclusion B4.13 for Upgrading and Rebuilding Existing Powerlines

Powerlines are a critical component of the electric grid that moves electricity from facilities that generate electricity to our communities, businesses, and factories. Upgrading and rebuilding [4] powerlines extends their useful life. Upgrades and rebuilds can also help reduce the need for new powerlines and can allow the replacement of components with newer, more efficient and resilient technology.

One example is reconductoring. Conductors are the wires that carry electricity. Most of the existing electric grid uses conductors with a steel core for strength surrounded by aluminum for the electrical current. More recently, conductor designs (called advanced conductors) with composite or carbon cores, in place of steel, have come into use. Advanced conductors provide a variety of benefits including increased capacity, which can be used to integrate renewable energy and other sources into the grid without the need to build new transmission lines. Use of advanced conductors reduces line losses (*i.e.,* power lost during transmission and distribution of electricity) relative to traditional conductors, thereby improving efficiency.[5] Improvements to capacity and efficiency can help to ensure reliability, reduce costs to consumers, and reduce GHG emissions associated with electricity generation, transmission, and distribution.

Upgrading and rebuilding powerlines also can avoid or reduce adverse environmental impacts, such as by relocating small [6] segments of the existing line to avoid a sensitive environmental resource. Upgrading and rebuilding powerlines also can enhance resilience. For example, an upgrade or rebuild project might convert segments of existing overhead powerlines to underground lines or replace old transmission poles to ensure continued safe operations.

Categorical exclusion B4.13 currently applies to upgrading or rebuilding ''approximately 20 miles in length or less'' of existing powerlines and allows for minor relocations of small segments of powerlines. DOE proposes to remove the mileage limitation, add options for relocating within an existing right of way or within otherwise previously disturbed or developed lands, and add new conditions.

The potential significance of environmental impacts from upgrading or rebuilding powerlines is more related to local environmental conditions than to the length of the powerlines. For example, the presence of environmentally sensitive resources along the existing right-of-way is more pertinent than the length of the existing powerlines to be upgraded or rebuilt. DOE reviewed environmental assessments for transmission line upgrades and rebuilds of various lengths. (*See* Technical Support Document, page 4.) The length of the projects is based on the endpoints, which are commonly substations (*e.g.,* rebuild the transmission line from substation A to substation B). Environmental assessments and other information summarized in the Technical Support Document, as well as DOE's experience with powerline upgrades and rebuilds do not indicate a particular mileage limit that would mark a threshold for significant impacts.

DOE also proposes to clarify options for relocating powerlines within the scope of categorical exclusion B4.13. Relocating segments of a powerline can improve resilience, avoid sensitive resources, or serve other purposes. (*See,* in the Technical Support Document, page 6, DOE/EA–1912 for an example of relocation to avoid cultural resources and DOE/EA–1967 to avoid a rock fall and landslide area.) Currently, B4.13 allows ''minor relocations of small segments of the powerlines.'' DOE proposes to delete ''minor'' because it is unnecessary to qualify ''relocations of small segments'' with ''minor.'' DOE also proposes to specify that, under the proposed revisions, small segments of powerlines may be relocated ''within an existing right of way or within otherwise previously disturbed or developed lands.'' This change would provide additional flexibility without increasing adverse environmental impacts. Any proposed relocation would be subject to all the conditions with the proposed categorical exclusion B4.13, including conformity to the integral elements that require consideration or potential impacts on environmentally sensitive resources and other potential impacts.

DOE's review of environmental assessments and other information in preparing this proposed rulemaking identified conditions that would be appropriate to add to categorical exclusion B4.13. Proposals to upgrade or rebuild powerlines normally incorporate practices that avoid or reduce potential land disturbance, erosion, disturbance of environmentally sensitive resources, and take other measures to protect the local environment. To account for this, DOE proposes to add a condition that the proposed project would be in accordance with applicable requirements and would incorporate appropriate design and construction standards, control technologies, and best management practices. This condition, together with the integral elements and consideration of extraordinary circumstances (described in section I.A of this document), would ensure that DOE considers whether a proposed upgrade or rebuild of an existing powerline would be sited and designed appropriately prior to determining whether categorical exclusion B4.13 applies.

DOE proposes a conforming change to its class of action, C4, that normally requires an environmental assessment for upgrading and rebuilding existing powerlines more than approximately 20 miles in length. That proposed change would remove the reference to powerline length and, instead, clarify that an environmental assessment

[4] A transmission line rebuild is typically a replacement of conductor and equipment without increasing capacity. Transmission line design and new materials and equipment would meet current standards and electrical clearance requirements. A transmission line upgrade is typically a replacement of conductor and equipment, or the addition of sensors or other advanced technology, to increase the line's capacity, such as by increasing the operating voltage or increasing the temperature rating.

[5] Grid Strategies, LLC, ''Advanced Conductors on Existing Transmission Corridors to Accelerate Low Cost Decarbonization,'' March 2022, available at: *https://acore.org/wp-content/uploads/2022/03/Advanced_Conductors_to_Accelerate_Grid_Decarbonization.pdf.*

[6] *See* 10 CFR 1021.410(g)(2) for a discussion of ''small'' in the context of determining the applicability of a DOE categorical exclusion.

normally would be prepared when the proposal does not qualify for categorical exclusion B4.13.

In response to DOE's November 2022 Request for Information,[7] Edison Electric Institute (EEI) suggested that DOE increase the length of powerlines in categorical exclusion B4.13 to ''at least 100 miles'' within previously disturbed or developed rights-of-way. (EEI (RFI 0010), pages 7–8) EEI stated that, ''Such [rights-of-way] are already managed from an environmental, safety, and reliability standpoint and thus, projects in these areas should not result in significant effects on the human environment.'' (EEI (RFI 0010), page 8) EEI further stated that this change would ''prioritize projects in existing [rights-of-way] over new greenfield projects'' and that utilizing existing rights-of-way would ''more efficiently build the transmission infrastructure necessary for the clean energy transformation.'' (EEI (RFI 0010), page 8) The Cross-Cutting Issues Group suggested that DOE omit the 20-mile limitation in B4.13 and stated that, ''Projects in previously disturbed or developed [rights-of-way] will not significantly impact the human environment regardless of the length of the powerlines.'' (Cross-Cutting Issues Group (RFI 0012), page 5) DOE's proposed changes to categorical exclusion B4.13 are consistent with these comments.

The Cross-Cutting Issues Group requested that DOE confirm that categorical exclusion B4.13 covers all types of powerlines, including ''gen-tie lines'' and ''powerlines that feed into a federal electric transmission system (*e.g.,* Tennessee Valley Authority)'' and related project elements such as access roads. (Cross-Cutting Issues Group (RFI 0012), pages 4–5) DOE interprets B4.13 to encompass all types of powerlines, including those identified by the commenter. In regard to access roads and other project elements, DOE's NEPA regulations explain, ''A class of actions [*e.g.,* a categorical exclusion] includes activities foreseeably necessary to proposals encompassed within the class of actions (such as award of implementing grants and contracts, site preparation, purchase and installation of equipment, and associated transportation activities).'' (10 CFR 1021.410(d))

[7] The Request for Information and these comments are available at *www.regulations.gov/docket/DOE-HQ-2023-0002/comments.*

C. Proposed New Categorical Exclusion B4.14 for Certain Energy Storage Systems

For purposes of this proposed rulemaking, an energy storage system is a device or group of devices assembled together, capable of storing energy in order to supply electrical energy at a later time. Energy storage can be used to integrate renewable energy (such as wind and solar energy) into the electric grid, help generation facilities operate at optimal levels to meet customer demand, and reduce the use of less efficient generating units that would otherwise run only at peak times. An energy storage system also provides protection from power interruptions and serves as reserve power in case of power outages or fluctuations. The most familiar type of energy storage system is a group of electrochemical batteries and associated equipment referred to as a battery energy storage system. Another form uses a flywheel, which converts excess electricity from the grid to kinetic energy in a fast-spinning rotor. As needed, the stored energy is converted back to electricity and returned to the grid or put to other use.

DOE and others have been developing large-scale energy storage systems for decades. Deployment of these systems has increased over the past decade. Today, energy storage systems support the operation of electric transmission facilities, microgrids, energy generation facilities, and commercial and industrial facilities.[8]

DOE proposes to establish new categorical exclusion B4.14 for the construction, operation, upgrade, or decommissioning of an electrochemical-battery or flywheel energy storage system within a previously disturbed or developed area or within a small area contiguous to a previously disturbed or developed area. Section I.A of this document includes discussion of DOE's definition of previously disturbed or developed area and DOE's experience referring to contiguous areas in its categorical exclusions. The total acreage used for an energy storage system will be defined by the needs of the proposed project. Based on past experience, DOE anticipates that energy storage systems typically require 15 acres or less and would be sited close to energy, transmission, or industrial facilities. (*See* Technical Support Document, page 24.) Consistent with this expectation and because contiguous land might be undisturbed and undeveloped, DOE proposes that siting outside a previously disturbed or developed be limited to a ''small'' contiguous area. DOE would consider whether a contiguous area is small ''in the context of the particular proposal, including its proposed location. In assessing whether a proposed action is small, in addition to the actual magnitude of the proposal, DOE considers factors such as industry norms, the relationship of the proposed action to similar types of development in the vicinity of the proposed action, and expected outputs of emissions or waste. When considering the physical size of a proposed facility, for example, DOE would review the surrounding land uses, the scale of the proposed facility relative to existing development, and the capacity of existing roads and other infrastructure to support the proposed action.'' (10 CFR 1021.410(g)(2)) In addition, the proposed categorical exclusion includes conditions that the proposed project be in accordance with applicable requirements (such as land use [9] and zoning requirements) and would incorporate appropriate design and construction standards, control technologies, and best management practices. In addition, DOE would review the proposed project against the criteria, including integral elements and extraordinary circumstances, described in section I.A of this document. This review would ensure that DOE considers the potential environmental effects of a proposed energy storage system prior to determining whether categorical exclusion B4.14 applies. In proposing this categorical exclusion, DOE has evaluated environmental assessments and findings of no significant impact prepared by DOE and other Federal agencies, categorical exclusion determinations made by DOE, and other information. (*See* Technical Support Document, page 24.)

DOE also proposes conforming changes to three related categorical exclusions. Based on its past experience with energy storage systems, in 2011, DOE added ''power storage (such as flywheels and batteries, generally less than 10 MW)'' as an example of conservation actions to categorical

[8] The U.S. Energy Information Administration published information about large-scale energy storage for electricity generation (*www.eia.gov/energyexplained/electricity/energy-storage-for-electricity-generation.php*) and market trends for battery storage (*www.eia.gov/analysis/studies/electricity/batterystorage/*). Also, DOE published an energy storage market report in 2020 (*www.energy.gov/sites/prod/files/2020/12/f81/Energy%20Storage%20Market%20Report%202020_0.pdf*).

[9] On DOE sites and in other locations, land use planning may be documented in a site land use plan, or be subject to siting processes or other comparable systems. Use of land use and zoning requirements is inclusive of these processes.

exclusion B5.1, Actions to conserve energy or water. DOE also added ''load shaping projects (such as the installation and use of flywheels and battery arrays)'' to the list of example actions in categorical exclusion B4.6, Additions and modifications to transmission facilities. DOE now proposes to delete ''power storage'' from the examples in B5.1. DOE would not include the 10 MW (megawatt) limit in new categorical exclusion B4.14 because capacity, whether denominated in megawatts as a measure of instantaneous output or megawatt-hours as a measure of the total amount of energy capable of being stored, is not a reliable indicator of potential environmental impacts. Including a capacity limit within the categorical exclusion could mean that technology improvements resulting in more power storage within the same physical footprint may not qualify for the categorical exclusion even though the potential environmental impacts have not changed. DOE also proposes to delete the example of flywheels and battery arrays from B4.6 but retain the reference to ''load shaping projects'' and add ''reducing energy use during periods of peak demand'' as a new example. DOE would add a note to B4.6 that energy storage systems are addressed in B4.14. DOE also would add this note to categorical exclusion B4.4, Power marketing services and activities, which was established in 1992 and lists storage and load shaping as examples. These conforming changes would avoid confusion over which categorical exclusion and associated conditions apply to energy storage systems.

In response to DOE's November 2022 Request for Information,[10] three commenters (Cross-Cutting Issues Group, Duke Energy, and EEI) requested that DOE include energy storage systems, and the installation and operation of such systems, in categorical exclusions B4.4 and B4.6. Cross-Cutting Issues Group explained that including energy storage systems explicitly in B4.4 and B4.6 would ''provide more certainty'' as project proponents explore different types of energy storage system technologies (such as compressed air energy storage and molten salt storage), ''particularly the timing and costs associated with deploying such projects.'' (Cross-Cutting Issues Group (RFI 0012), page 6) EEI and Cross-Cutting Issues Group asked DOE to explicitly include the addition or modification of a ''battery array or other energy storage device(s)'' as part of these categorical exclusions. (EEI (RFI 0010), pages 9–10; Cross-Cutting Issues Group (RFI 0012), page 6)

DOE's proposed changes address these comments. DOE believes that the best way to ensure consistency is to have a single categorical exclusion for energy storage systems. DOE is proposing that new categorical exclusion B4.14 be limited to electrochemical-battery and flywheel energy storage systems. At this time, DOE has not identified sufficient information to conclude that compressed air energy storage, thermal energy storage (*e.g.,* molten salt storage), or other technologies normally do not present the potential for significant environmental impacts. DOE welcomes comments that provide analytic support for whether these other energy storage technologies meet the requirements for a categorical exclusion. If DOE identifies sufficient support, DOE may revise the categorical exclusion in the final rule to include additional energy storage technologies.

D. Proposed Changes to Categorical Exclusion B5.16 for Solar Photovoltaic Systems

Solar photovoltaic (PV) technology converts sunlight into electrical energy. Individual PV cells, which may produce only 1 or 2 watts of electricity, are connected together to form modules (otherwise known as panels). The modules are combined with other components (*e.g.,* to convert electricity from direct current (DC) to alternating current (AC)) to create a solar PV system. These systems can be located in a wide variety of locations and sized for an individual home or business up to utility-scale, generating hundreds of megawatts.[11]

Solar PV systems do not release GHGs while operating, though, as with any industrial activity, manufacturing and installing solar PV systems can release GHGs. The U.S. Energy Information Administration reports that, ''Studies conducted by a number of organizations and researchers have concluded that PV systems can produce the equivalent amount of energy that was used to manufacture the systems within 1 to 4 years. Most PV systems have operating lives of up to 30 years or more.'' [12] Thus, on a life-cycle basis, solar PV systems provide many years of electricity generation without GHG emissions.

DOE's current categorical exclusion B5.16, Solar photovoltaic systems, includes the installation, modification, operation, and removal of solar PV systems located on a building or other structure or, if located on land, within a previously disturbed or developed area generally comprising less than 10 acres. DOE proposes to change ''removal'' of a solar PV system to ''decommissioning.'' Decommissioning encompasses recycling and other types of actions that occur when a facility is taken out of service. DOE also proposes to remove the acreage limitation for proposed projects. Based on DOE's experience, acreage is not a reliable indicator of potential environmental impacts. As discussed in section I.B of this document, the potential significance of environmental impacts is more related to local environmental conditions than to acreage. DOE's review of various environmental assessments indicate that an acreage limit would not serve as an appropriate indicator of significant impacts. This conclusion is illustrated, for example, by environmental assessments for solar PV projects larger than 1,000 acres on previously disturbed or developed land that would not result in significant environmental impacts. (*See* Technical Support Document, page 42.)

The nature and significance of environmental impacts is determined by a proposed project's proximity to and potential effects on environmentally sensitive resources and other conditions accounted for in categorical exclusion B5.16 and in the integral elements, extraordinary circumstances, and other factors described in section I.A of this document. If the proposed changes are finalized, DOE would consider the integral elements and the presence of any extraordinary circumstances when reviewing proposed solar PV projects' eligibility for this categorical exclusion. This review would ensure that DOE considers potential environmental impacts of a proposed solar PV system prior to determining whether categorical exclusion B5.16 applies. For example, in preparing the Technical Support Document, DOE observed that some large solar PV systems have been proposed for agricultural land. While integrating solar PV systems with farms may provide a variety of economic and environmental benefits to farmers,[13]

[10] The Request for Information and these comments are available at *www.regulations.gov/docket/DOE-HQ-2023-0002/comments.*

[11] DOE's Solar Energy Technologies Office has a website that describes solar PV technologies (*www.energy.gov/eere/solar/solar-photovoltaic-technology-basics*).

[12] U.S. Energy Information Administration ''Solar explained'' available at *www.eia.gov/energyexplained/solar/solar-energy-and-the-environment.php;* retrieved August 27, 2023.

[13] U.S. Energy Information Administration ''Solar explained'' available at *www.eia.gov/energyexplained/solar/solar-energy-and-the-environment.php;* retrieved August 27, 2023.

doing so also raises questions about land use and the protection of important farmlands. One of the integral elements ensures that DOE considers the potential impacts on prime or unique farmland, or other farmland of statewide or local importance. (10 CFR part 1021, appendix B, paragraph (4)(v).)

DOE also proposes to make conforming changes in appendix C, Classes of Actions that Normally Require EAs but not Necessarily EISs, and in appendix D, Classes of Actions that Normally Require EISs. These appendices each include a class of actions, C7 and D7, that associates the level of NEPA review for interconnection requests and power acquisition with the power output of the electric generation resource. In 2011, DOE proposed for C7 that an environmental assessment normally would be required for the interconnection of, or acquisition of power from, new generation resources that are equal to or less than 50 average megawatts ''and that would not be eligible for categorical exclusion under 10 CFR part 1021.'' (76 FR 233; January 3, 2011) DOE did not receive public comment on the proposed addition regarding categorical exclusion eligibility. In the 2011 final rule, DOE did not include the condition regarding eligibility for a categorical exclusion. DOE explained this decision by stating ''to improve clarity, DOE is removing the previously proposed condition that the new generation resource 'would not be eligible for categorical exclusion under this part.' DOE normally would not prepare an environmental assessment when a categorical exclusion would apply. Therefore, the condition is unnecessary and potentially confusing.'' (76 FR 63784; October 13, 2011) DOE's practice continues to be that it ''normally would not prepare an environmental assessment when a categorical exclusion would apply.'' DOE is again proposing to add a condition regarding the applicability of a categorical exclusion to C7, however. In light of the proposed change to B5.16—which would remove the acreage restriction for solar PV systems, thereby allowing the categorical exclusion to apply to systems generating up to hundreds of megawatts—DOE believes that including a condition in C7 is appropriate and helpful. It will clarify DOE's practice that an environmental assessment is normally required ''unless the generation resource is eligible for a categorical exclusion.'' DOE did not propose a similar condition in 2011 for D7, which applies to new generation resources greater than 50 average megawatts. DOE is now proposing to add the same condition to both C7 and D7 for the reasons previously described. For D7, DOE also is proposing to specify that an environmental impact statement is not required when an environmental assessment was prepared that resulted in a finding of no significant impact. This is standard practice, and DOE proposes to add this text only to avoid any potential confusion.

In response to DOE's November 2022 Request for Information,[14] EEI suggested that DOE revise categorical exclusion B5.16 to apply to ''solar photovoltaic systems, both large- and small-scale, and increase the acreage to at least 200 acres within previously disturbed or developed areas to fully capture the extent of large-scale solar installation that utilize more than 10 areas and may not be contiguous.'' (EEI (RFI 0010), page 10) DOE's proposal in this rulemaking is consistent with this comment.

III. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866, 13563, and 14094

Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011) and amended by E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. Many benefits and costs associated with this proposed rule are not quantifiable. The direct benefits include reduced cost and time for environmental analysis incurred by DOE, project proponents, and the public. Indirect benefits are expected to include deployment of technologies that improve the reliability and resilience of the nation's electric grid and that expand electricity generation capacity while reducing emissions of GHGs. For the reasons stated in this preamble, this proposed regulatory action is consistent with these principles.

This regulatory action has been determined not to be ''a significant regulatory action'' under E.O. 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this action is not subject to review under that Executive order by OIRA of OMB.

B. Review Under Executive Orders 12898 and 14096

E.O. 12898, ''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations,'' as supplemented and amended by E.O. 14096, ''Revitalizing Our Nation's Commitment to Environmental Justice for All,'' requires each Federal agency, consistent with its statutory authority, to make achieving environmental justice part of its mission. E.O. 14096 directs Federal agencies to carry out environmental reviews under NEPA in a manner that ''(A) analyzes direct, indirect, and cumulative effects of Federal actions on communities with environmental justice concerns; (B) considers best available science and information on any disparate health effects (including risks) arising from exposure to pollution and other environmental hazards, such as information related to the race, national origin, socioeconomic status, age, disability, and sex of the individuals exposed; and (C) provides opportunities for early and meaningful involvement in the environmental review process by

[14] The Request for Information and these comments are available at *www.regulations.gov/docket/DOE-HQ-2023-0002/comments.*

communities with environmental justice concerns potentially affected by a proposed action, including when establishing or revising agency procedures under NEPA.'' DOE is providing opportunities for public engagement in this proposed rulemaking, including opportunities for communities with environmental justice concerns. Also, in determining whether the proposed categorical exclusions apply to a future proposed action, DOE will consider whether the proposed action threatens a violation of these Executive Orders, consistent with the first integral element listed in appendix B of DOE's NEPA procedures.

C. Review Under National Environmental Policy Act

The Department's NEPA procedures assist the Department in fulfilling its responsibilities under NEPA and the CEQ regulations but are not themselves final determinations of the level of environmental review required for any proposed action. The CEQ regulations do not direct agencies to prepare an environmental assessment or environmental impact statement before establishing agency procedures that supplement the CEQ regulations to implement NEPA (40 CFR 1507.3). In establishing a new categorical exclusion and making other changes as described in this notice, DOE is following the requirements of CEQ's procedural regulations, which include publishing the Notice of Proposed Rulemaking in the **Federal Register** for public review and comment, considering public comments, and consulting with CEQ regarding conformity with NEPA and the CEQ regulations. (*See* 40 CFR 1507.3(b)).

In this proposed rule, DOE proposes amendments that establish, modify, and clarify procedures for considering the environmental effects of DOE actions within DOE's decisionmaking process, thereby enhancing compliance with the letter and spirit of NEPA. DOE has preliminarily determined that this proposed rule would qualify for categorical exclusion under 10 CFR part 1021, subpart D, appendix A6, because it is a strictly procedural rulemaking, and no extraordinary circumstances exist that require further environmental analysis. Therefore, DOE has preliminarily determined that promulgation of these amendments is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an environmental assessment or an environmental impact statement.

D. Review Under Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of the General Counsel's website: *https://energy.gov/gc under Resources.*

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The proposed revisions to 10 CFR part 1021 streamline the environmental review for proposed actions, resulting in a decrease in burdens associated with carrying out such reviews. For example, the proposed revisions to DOE's categorical exclusions are expected to reduce the number of environmental assessments that applicants would need to pay to have prepared for DOE's consideration. Applicants may sometimes incur costs in providing environmental information that DOE requires when making a categorical exclusion determination. The Government Accountability Office found in 2014 that there is little data available on the costs for preparing NEPA reviews and that agencies ''generally do not reports costs that are 'paid by the applicant' because these costs reflect business transactions between applicants and their contractors and are not available to agency officials.'' [15] In 2011, DOE estimated the cost of preparing environmental assessments over the prior decade at an average of $100,000 and a median of $65,000.[16] DOE does not have more current cost data. The costs of making a categorical exclusion determination are less than those to prepare an EA. Although DOE does not have data on what percentage of EAs were funded by applicants that qualified as small entities, a beneficial cost impact is expected to accrue to entities of all sizes.

Based on the foregoing, DOE certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this proposed rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

E. Review Under Paperwork Reduction Act

This proposed rulemaking will impose no new information or record-keeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.*

F. Review Under Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4) requires each Federal agency to assess the effects of Federal regulatory actions on state, local, and tribal governments, in the aggregate, or to the private sector, other than to the extent such actions merely incorporate requirements specifically set forth in a statute. Section 202 of UMRA requires a Federal agency to perform a detailed assessment of the anticipated costs and benefits of any rule that includes a Federal mandate which may result in costs to State, local, or Tribal governments, or to the private sector, of $100 million or more in any one year (adjusted annually for inflation) (2 U.S.C. 1532(a) and (b)). Section 204 of UMRA requires each agency that proposes a rule containing a significant Federal intergovernmental mandate to develop an effective process for obtaining meaningful and timely input from elected officers of State, local, and Tribal governments (2 U.S.C. 1534).

The proposed rule would amend DOE's existing regulations governing compliance with NEPA to better align DOE's regulations, including its categorical exclusions, with its current activities and recent experiences. The proposed rule would not result in the expenditure by State, local, and Tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year. Accordingly, no assessment or analysis is required under the UMRA.

[15] GAO–14–369, NATIONAL ENVIRONMENTAL POLICY ACT: Little Information Exists on NEPA Analyses, April 2014, available at *www.gao.gov/assets/gao-14-369.pdf.*

[16] 76 FR 237, January 3, 2011.

G. Review Under Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. The proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

H. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt state law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt state law and would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. No further action is required by E.O. 13132.

I. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met, or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of E.O. 12988.

J. Review Under Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1)(i) is a significant regulatory action under E.O. 12866, or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy, and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Executive Order 12630

DOE has determined pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 18, 1988), that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the United States Constitution.

IV. Public Participation—Submission of Comments

DOE will accept comments, data, and information regarding this notice of proposed rulemaking no later than the date provided in the **DATES** section at the beginning of this document. Interested individuals are invited to submit data, views, or arguments with respect to the specific sections addressed in this proposed rule using the methods described in the **ADDRESSES** section at the beginning of this document.

1. *Submitting comments via www.regulations.gov.* Your contact information will be viewable by DOE's Office of the General Counsel staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment. However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through *www.regulations.gov* will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

2. *Submitting comments via email or mail.* Comments and documents submitted via email or mail will also be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

3. *Confidential Business Information.* Pursuant to the provisions of 10 CFR 1004.11, any person submitting information or data he or she believes to be confidential and exempt by law from public disclosure should submit two well-marked copies: One copy of the document marked ''CONFIDENTIAL'' including all the information believed to be confidential, and one copy of the document marked ''NON-CONFIDENTIAL'' with the information believed to be confidential deleted. Submit these documents via email to *DOE-NEPA-Rulemaking@hq.doe.gov.* DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

4. *Campaign form letters.* Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and request for comment.

List of Subjects in 10 CFR Part 1021

Environmental impact statements.

Signing Authority

This document of the Department of Energy was signed on November 8, 2023, by Samuel T. Walsh, General Counsel, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 9, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE proposes to amend part 1021 of chapter X of title 10, Code of Federal Regulations, as set forth below:

PART 1021—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

■ 1. The authority citation for part 1021 continues to read as follows:

Authority: 42 U.S.C. 7101 *et seq.;* 42 U.S.C. 4321 *et seq.;* 50 U.S.C. *et seq.*

■ 2. Appendix B of subpart D of part 1021 is amended by:

■ a. Revising B4.4, B4.6, and B4.13;

■ b. Adding B4.14; and

■ c. Revising B5.1 and B5.16.

The revisions and addition read as follows:

Appendix B to Subpart D of Part 1021—Categorical Exclusions Applicable to Specific Agency Actions

* * * * *

B4. * * *

* * * * *

B4.4 Power marketing services and activities

Power marketing services and power management activities (including, but not limited to, storage, load shaping and balancing, seasonal exchanges, and other similar activities), provided that the operations of generating projects would remain within normal operating limits. (*See* B4.14 of this appendix for energy storage systems.)

* * * * *

.6 Additions and modifications to transmission facilities

Additions or modifications to electric power transmission facilities within a previously disturbed or developed facility area. Covered activities include, but are not limited to, switchyard rock grounding upgrades, secondary containment projects, paving projects, seismic upgrading, tower modifications, load shaping projects (such as reducing energy use during periods of peak demand), changing insulators, and replacement of poles, circuit breakers, conductors, transformers, and crossarms. (*See* B4.14 of this appendix for energy storage systems.)

* * * * *

B4.13 Upgrading and rebuilding existing powerlines

Upgrading or rebuilding existing electric powerlines, which may involve relocations of small (as discussed at 10 CFR 1021.410(g)(2)) segments of the powerlines within an existing right of way or within otherwise previously disturbed or developed lands (as discussed at 10 CFR 1021.410(g)(1)). Covered actions would be in accordance with applicable requirements, including the integral elements listed at the start of appendix B of this part; and would incorporate appropriate design and construction standards, control technologies, and best management practices.

B4.14 Construction and operation of electrochemical-battery or flywheel energy storage systems

Construction, operation, upgrade, or decommissioning of an electrochemical-battery or flywheel energy storage system within a previously disturbed or developed area or within a small (as discussed at 10 CFR 1021.410(g)(2)) area contiguous to a previously disturbed or developed area. Covered actions would be in accordance with applicable requirements (such as land use and zoning requirements) in the proposed project area and the integral elements listed at the start of appendix B of this part, and would incorporate appropriate design and construction standards, control technologies, and best management practices.

* * * * *

B5. * * *

B5.1 Actions to conserve energy or water

(a) Actions to conserve energy or water, demonstrate potential energy or water conservation, and promote energy efficiency that would not have the potential to cause significant changes in the indoor or outdoor

concentrations of potentially harmful substances. These actions may involve financial and technical assistance to individuals (such as builders, owners, consultants, manufacturers, and designers), organizations (such as utilities), and governments (such as state, local, and tribal). Covered actions include, but are not limited to weatherization (such as insulation and replacing windows and doors); programmed lowering of thermostat settings; placement of timers on hot water heaters; installation or replacement of energy efficient lighting, low-flow plumbing fixtures (such as faucets, toilets, and showerheads), heating, ventilation, and air conditioning systems, and appliances; installation of drip-irrigation systems; improvements in generator efficiency and appliance efficiency ratings; efficiency improvements for vehicles and transportation (such as fleet changeout); transportation management systems (such as traffic signal control systems, car navigation, speed cameras, and automatic plate number recognition); development of energy-efficient manufacturing, industrial, or building practices; and small-scale energy efficiency and conservation research and development and small-scale pilot projects. Covered actions include building renovations or new structures, provided that they occur in a previously disturbed or developed area. Covered actions could involve commercial, residential, agricultural, academic, institutional, or industrial sectors. Covered actions do not include rulemakings, standard-settings, or proposed DOE legislation, except for those actions listed in B5.1(b) and (c) of this appendix.

(b) Covered actions include rulemakings that establish energy conservation standards for consumer products and industrial equipment, provided that the actions would not:

(1) Have the potential to cause a significant change in manufacturing infrastructure (such as construction of new manufacturing plants with considerable associated ground disturbance);

(2) Involve significant unresolved conflicts concerning alternative uses of available resources (such as rare or limited raw materials);

(3) Have the potential to result in a significant increase in the disposal of materials posing significant risks to human health and the environment (such as RCRA hazardous wastes); or

(4) Have the potential to cause a significant increase in energy consumption in a state or region.

(c) Covered actions also include rulemakings that establish energy conservation standards for new Federal buildings and Federal buildings undergoing major renovation, provided that the actions would not have the potential to:

(1) Result in a significant decrease in indoor air quality; or

(2) Result in a significant increase in emissions of air pollutants.

* * * * *

B5.16 Solar photovoltaic systems

(a) The installation, modification, operation, or decommissioning of commercially available solar photovoltaic systems:

(1) Located on a building or other structure (such as rooftop, parking lot or facility, or mounted to signage, lighting, gates, or fences); or

(2) Located within a previously disturbed or developed area.

(b) Covered actions would be in accordance with applicable requirements (such as land use and zoning requirements) in the proposed project area and the integral elements listed at the start of appendix B of this part, and would incorporate appropriate control technologies and best management practices.

■ 3. Amend Appendix C of subpart D of part 1021 by revising C4 and C7 to read as follows:

C to Subpart D of Part 1021—Classes of Actions That Normally Require EAs But Not Necessarily EISs

* * * * *

C4 Upgrading, Rebuilding, or Construction of Powerlines

(a) Upgrading or rebuilding existing powerlines when the action does not qualify for categorical exclusion B4.13; or construction of powerlines:

(1) More than approximately 10 miles in length outside previously disturbed or developed powerline or pipeline rights-of-way; or

(2) More than approximately 20 miles in length within previously disturbed or developed powerline or pipeline rights-of-way.

* * * * *

C7 Contracts, Policies, and Marketing and Allocation Plans for Electric Power

(a) Establishment and implementation of contracts, policies, and marketing and allocation plans related to electric power acquisition that involve:

(1) The interconnection of, or acquisition of power from, new generation resources that are equal to or less than 50 average megawatts, unless the generation resource is eligible for a categorical exclusion;

(2) Changes in the normal operating limits of generation resources equal to or less than 50 average megawatts; or

(3) Service to discrete new loads of less than 10 average megawatts over a 12-month period.

* * * * *

■ 4. Amend Appendix D to subpart D of part 1021 by revising D7 to read as follows:

Appendix D to Subpart D of Part 1021—Classes of Actions That Normally Require EISs

* * * * *

D7 Contracts, Policies, and Marketing and Allocation Plans for Electric Power

(a) Establishment and implementation of contracts, policies, and marketing and allocation plans related to electric power acquisition that involve:

(1) The interconnection of, or acquisition of power from, new generation resources greater than 50 average megawatts, unless the generation resource is eligible for a categorical exclusion or was evaluated in an environmental assessment resulting in a finding of no significant impact;

(2) Changes in the normal operating limits of generation resources greater than 50 average megawatts; or

(3) Service to discrete new loads of 10 average megawatts or more over a 12-month period.

* * * * *

[FR Doc. 2023–25174 Filed 11–15–23; 8:45 am]

BILLING CODE 6450–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 210

[Docket No. 2022–5]

Termination Rights, Royalty Distributions, Ownership Transfers, Disputes, and the Music Modernization Act

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Supplemental notice of proposed rulemaking; extension of comment period.

SUMMARY: The U.S. Copyright Office is extending the deadline to submit reply comments in connection with a supplemental notice of proposed rulemaking regarding the applicability of the derivative works exception to termination rights under the Copyright Act to the new statutory mechanical blanket license established by the Music Modernization Act and other matters relevant to identifying the proper payee to whom the mechanical licensing collective must distribute royalties.

DATES: The comment period for the proposed rule published September 26, 2023, at 88 FR 65908, is extended. Written reply comments are due no later than 11:59 p.m. Eastern Time on Tuesday, December 5, 2023.

ADDRESSES: For reasons of governmental efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://copyright.gov/rulemaking/mma-termination.* If electronic submission of comments is not feasible due to lack of access to a computer or the internet,

please contact the Copyright Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION: On September 26, 2023, the U.S. Copyright Office issued a supplemental notice of proposed rulemaking seeking comments from the public on questions regarding the applicability of the derivative works exception to termination rights under the Copyright Act to the new statutory mechanical blanket license established by the Music Modernization Act and other matters relevant to identifying the proper payee to whom the mechanical licensing collective must distribute royalties.[1] The supplemental notice set an October 26, 2023 deadline for submitting initial comments and a November 13, 2023 deadline for reply comments. On October 11, 2023, the Office extended these deadlines to November 8, 2023 and November 28, 2023, respectively.[2]

To ensure that members of the public have sufficient time to prepare responses to the Office, and to ensure that the Office can proceed on a timely basis with its inquiry of the issues identified in its supplemental notice with the benefit of a complete record, the Office is further extending the reply comment period deadlines as set forth here. Reply comments will now be due by 11:59 p.m. Eastern Time on Tuesday, December 5, 2023.

Dated: November 13, 2023.

Suzanne V. Wilson,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2023–25341 Filed 11–15–23; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0392; FRL–5949.1–01–OAR]

RIN 2060–AT07

National Emission Standards for Hazardous Air Pollutants: Rubber Tire Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants for Rubber Tire Manufacturing, as required by the Clean Air Act (CAA). To ensure that all emissions of hazardous air pollutants (HAP) from sources in the source category are regulated, the EPA is proposing emissions standards for the rubber processing subcategory of the rubber tire manufacturing industry, which is the only unregulated subcategory within the Rubber Tire Manufacturing source category.

DATES: Comments must be received on or before January 2, 2024. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before December 18, 2023.

Public hearing: If anyone contacts us requesting a public hearing on or before November 21, 2023, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2019–0392, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2019–0392 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2019–0392.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2019–0392, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact U.S. EPA, Attn: Mr. Korbin Smith, Sector Policies and Programs Division, Mail Drop: D243–04, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–2416; and email address: *smith.korbin@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the hearing will be held via virtual platform on December 1, 2023. The hearing will convene at 11:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.*

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing no later than 1 business day after a request has been received. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be November 28, 2023. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers at: *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 4 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *smith.korbin@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting

[1] 88 FR 65908 (Sept. 26, 2023).

[2] 88 FR 70412 (Oct. 11, 2023).

information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by November 24, 2023. The EPA may not be able to arrange accommodations without advance notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2019–0392. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov.*

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2019–0392. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to *https://www.regulations.gov/* any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed in the *Submitting CBI* section of this document.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/.* Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in the *Instructions* section of this document. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services (*e.g.,* Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the Office of Air Quality Planning and Standards (OAQPS) CBI Office at the email address *oaqpscbi@epa.gov,* and as described earlier in this preamble, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: U.S. Environmental Protection Agency, Attention Docket ID No. EPA–HQ–OAR–2019–0392, OAQPS Document Control Officer (C404–02), OAQPS, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this preamble the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

acfm actual cubic feet per minute
BDL below detection limit
BLDS baghouse leak detection system
CAA Clean Air Act
CBI Confidential Business Information
CEDRI compliance and emissions data reporting interface
CEMS continuous emission monitoring system
CFR Code of Federal Regulations
DLL detection level limited
DRE destruction and removal efficiency
dscfm dry standard cubic feet per meter
EPA Environmental Protection Agency
ERT electronic reporting tool
fPM filterable particulate matter
g gram
g/Mg grams per megagram
HAP hazardous air pollutant(s)
ICR information collection request
km kilometer
lb pound

lb/hr pounds per hour
lb/Mton pounds per million tons
lb/ton pounds per ton
MACT maximum achievable control technology
Mg megagram
mg/dscm milligrams per dry standard cubic meter
NESHAP national emission standards for hazardous air pollutants
ng/dscm nanograms per dry standard cubic meter
NTTAA National Technology Transfer and Advancement Act
O&M operations and maintenance
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PAH polycyclic aromatic hydrocarbon
PM particulate matter
ppm parts per million
ppmv parts per million by volume
ppmvd parts per million by volume dry
PRA Paperwork Reduction Act
RDL representative detection level
RFA Regulatory Flexibility Act
RTO regenerative thermal oxidizer
RTR risk and technology review
scfm standard cubic feet per minute
SSM startup, shutdown, and malfunction
THC total hydrocarbons
ton/hr tons per hour
TOSHI target organ-specific hazard index
tpy tons per year
µg microgram
UMRA Unfunded Mandates Reform Act
UPL upper predictive limit
VCS voluntary consensus standards
VOC volatile organic compound

Organization of this document. The information in this preamble is organized as follows:

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E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing our Nation's Commitment to Environmental Justice for All

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the National Emission Standards for Hazardous Air Pollutants (NESHAP) and associated regulated industrial source categories that are the subject of this proposal. Table 1 is not intended to be exhaustive but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, State, local, and Tribal government entities would not be affected by this proposed action. As defined in the ''Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990'' (see 57 FR 31576; July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA–450/3–91–030; July 1992), the ''Tire Production'' source category ''is any facility engaged in producing passenger car and light duty truck tires, aircraft tires, and miscellaneous other tires.'' This source category has been referred to as the ''Rubber Tire Manufacturing'' source category since the EPA first proposed NESHAP requirements for this source category in 2000. (See 65 FR 62414; October 18, 2000.)

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS code [1]
Rubber Tire Manufacturing	40 CFR part 63, subpart XXXX	326211, 326212, 314992

[1] North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

A memorandum showing the rule edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart XXXX, proposed in this action is available in the docket (Docket ID No. EPA–HQ–OAR–2019–0392). Following signature by the EPA Administrator, the EPA also will post a copy of this document to *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.*

II. Background

A. What is the statutory authority for this action?

This action proposes to amend the NESHAP for the Rubber Tire Manufacturing source category.

The statutory authority for this action is provided by section 112 of the CAA, as amended (42 U.S.C. 7401, *et seq.*). In the first stage of the CAA section 112 standard-setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as ''beyond-the-floor'' standards.

CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years. While conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floors that were established during earlier rulemakings. *Nat. Resources Def. Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008); *Ass'n of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

CAA section 112(f) requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. This review is known as the ''residual risk review,'' and it must occur within 8 years after promulgation of the standards. When the EPA conducts the ''technology review'' together with the ''residual risk review,'' the combined review is known as a ''risk and technology review'' (RTR).

The EPA initially promulgated the Rubber Tire Manufacturing NESHAP on July 9, 2002 (67 FR 45588). These standards are codified at 40 CFR part 63, subpart XXXX.

In 2016, a coalition of environmental advocacy groups filed a lawsuit to compel the EPA to fulfill its statutory duty to conduct the CAA sections 112(d) and 112(f)(2) reviews of 13 NESHAPs, including the NESHAP for the Rubber Tire Manufacturing source category. *Blue Ridge Environmental Defense League* v. *McCarthy,* No. 1:16–cv–00364. As a result of that litigation, the EPA was required to complete its review of the Rubber Tire Manufacturing source category. The resulting residual RTR conducted for the Rubber Tire Manufacturing NESHAP was published in the **Federal Register** on July 24, 2020 (85 FR 44752) (2020 RTR).

In an April 2020 decision by the U.S. Court of Appeals for the District of Columbia Circuit, the court held that the EPA has an obligation to address unregulated HAP emissions from a source category when the Agency conducts the 8-year technology review required by CAA section 112(d)(6). *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d, at 1098–99 (D.C. Cir. 2020) (''*LEAN* decision or *LEAN*''). The parties in the *Blue Ridge Environmental Defense League* case filed a joint motion for an extension of the deadline to allow the EPA to revise the 2020 final rule to comply with the *LEAN* opinion. The court granted the motion, setting a new deadline for this rule of October 27, 2022. *Blue Ridge Environmental Defense League,* Order (Apr. 15, 2021). This deadline was subsequently extended to November 13, 2024. *Id.,* Order (Mar. 14, 2022).

In light of this litigation history, this proposed rule includes proposed new emission standards to address currently unregulated emissions of HAP from the rubber processing subcategory of Rubber Tire Manufacturing, pursuant to the *LEAN* decision and CAA sections 112(d)(2) and (d)(3).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

The Rubber Tire Manufacturing source category consists of facilities that produce rubber tire components including but not limited to rubber compounds, sidewalls, tread, tire beads, tire cord, and liners. The source category covered by the NESHAP currently includes 15 facilities. The Rubber Tire Manufacturing source category is split into 4 subcategories for different phases of rubber tire manufacturing. These subcategories include rubber processing, tire production, tire cord production, and puncture sealant application.

The 2002 NESHAP for the Rubber Tire Manufacturing source category established emission limits on a subcategory basis as follows.

1. Rubber Processing

There are currently no emission limits for the rubber processing subcategory.

2. Tire Production

There are 2 equivalent standards for the tire production subcategory, and sources can choose to comply with either standard. The first standard, which is based on HAP materials purchased and used in the process, is an emission limit that requires that emissions of each HAP in table 16 to 40 CFR part 63, subpart XXXX, that is used in the tire production process not exceed 1,000 grams (g) HAP per megagram (Mg) (2 pounds per ton (lb/ton)) of total cements and solvents used at the tire production affected source, and requires that the amount of each HAP not in table 16 to 40 CFR part 63, subpart XXXX, that is used in the tire production process not exceed 10,000 g HAP per Mg (20 lb/ton) of total cements and solvents used at the tire production affected source.

The second standard is a production-based emission-limit option. For this option, emissions of HAP must not exceed 0.024 g/Mg (0.00005 lb/ton) of rubber used at the tire production affected source.

3. Tire Cord Production

There are 3 equivalent standards for the tire cord production subcategory, and sources can choose which standard to comply with within this subcategory, depending, in part, on whether the source is an existing or new source. The first standard is a production-based emission-limit option for existing tire cord production affected sources. As part of this standard, emissions must not exceed 280 g HAP per Mg (0.56 lb/ton) of fabric processed at the tire cord production affected source.

The second standard is a production-based emission-limit option for new or reconstructed tire cord production affected sources. As part of this standard, emissions must not exceed 220 g HAP per Mg (0.43 lb/ton) of fabric processed at the tire cord production affected source.

The third standard is a HAP constituent emission-limit option available to both existing and new or reconstructed tire cord production affected sources. To comply with this standard, emissions of each HAP in table 16 to 40 CFR part 63, subpart XXXX, that is used in the tire cord production process must not exceed 1,000 g HAP per Mg (2 lb/ton) of total coatings used at the tire cord production affected source, and emissions of each HAP not in table 16 to 40 CFR part 63, subpart XXXX, that is used in the tire cord production process must not exceed 10,000 g HAP per Mg (20 lb/ton) of total coatings used at the tire cord production affected source.

4. Puncture Sealant Application

There are 3 equivalent standards for the puncture sealant application subcategory, and sources can choose which standard to comply with within this subcategory depending, in part, on whether the source is an existing or new source. The first standard is a percent reduction emission-limit option for existing puncture sealant application spray booths. As part of this standard, facilities are required to reduce spray booth HAP (measured as volatile organic compounds (VOCs)) emissions by at least 86 percent by weight.

The second standard is a percent reduction emission-limit option for new or reconstructed puncture sealant application spray booths. As part of this standard, facilities are required to reduce spray booth HAP (measured as VOCs) emissions by at least 95 percent by weight.

The third standard is a HAP constituent emission-limit option for both existing and new or reconstructed puncture sealant application spray booths. As part of this standard, emissions of each HAP in table 16 to 40 CFR part 63, subpart XXXX, must not exceed 1,000 g HAP per Mg (2 lb/ton) of total puncture sealants used at the puncture sealant affected source, and emissions of each HAP not in table 16 to 40 CFR part 63, subpart XXXX, must not exceed 10,000 g HAP per Mg (20 lb/ton) of total puncture sealants used at the puncture sealant affected source.

5. Alternatives for Meeting Emission Limits

Compliance alternatives are available for the 3 subcategories currently subject to emission limits (tire production, tire cord production, and puncture sealant application) to meet the emission limits mentioned earlier in section II.B of this preamble. For more information on these compliance alternatives, a detailed breakdown of the compliance alternatives for these subcategories may be found at 40 CFR 63.5985, 40 CFR 63.5987, and 40 CFR 63.5989, for tire production, tire cord production, and puncture sealant application, respectively.

6. Recent Actions Relating to the NESHAP for the Rubber Tire Manufacturing Source Category

In the 2020 RTR, the EPA found that the risk associated with air emissions from rubber tire manufacturing was acceptable and that the current NESHAP provides an ample margin of safety to protect public health. The EPA determined that there were no developments in practices, processes, or control technologies that warranted revisions to the standards. Based on the analysis conducted as part of the RTR, no revisions to the numerical emission limits were made for any of the Rubber Tire Manufacturing subcategories. The 2020 RTR addressed periods of startup, shutdown, and malfunction (SSM) by clarifying that emissions during SSM operations are subject to the NESHAP. In addition, the 2020 amendments included provisions requiring electronic reporting of performance test results and reports, compliance reports, and Notification of Compliance Status reports.

C. What data collection activities were conducted to support this action?

To inform this current action, the EPA sent an information request pursuant to CAA section 114 (hereinafter ''CAA section 114 information request'') to all 5 parent companies that operate major source rubber tire facilities (15 major source facilities) within the United States. The CAA section 114 information request was conducted in 2 phases.

The first phase was sent to the parent companies in June 2022. It consisted of a questionnaire relating to rubber tire manufacturing processes. The questionnaire requested the following information from rubber tire facilities: facility information, including facility location and production background; process and control information from each mixer at the facility, including ingredients added and associated tire component for each combination of ingredients; available mixer emissions data for filterable particulate matter (fPM) HAP and VOC HAP; mixing schematics; and emission controls in use at the facility.

The second phase of the CAA section 114 information request sought emissions data on mixers through stack testing and required each company that received the request to submit the data and associated documentation via an EPA-developed response template. Draft emission factors developed by the U.S. Rubber Tire Manufacturers Association (USTMA) in 2008, and available in the Mixing 30800111 tab in the Emission Factors Tables excel file at *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-fifth-edition-volume-i-chapter-4-evaporation-loss-0,* were reviewed and those compounds whose unit risks were assessed to provide risks near or above 1-in-1 million were selected for emissions testing. Those compounds included polycyclic aromatic hydrocarbons (PAHs)—aniline, dibenzofuran, hydroquinone, naphthalene, and *o*-toluidine. In addition, HAP metals, fPM, and total hydrocarbons (THC) were required to be collected using EPA test methods. The second phase of the CAA section 114 information request specified the emission testing procedures and methods to be followed, the process information to be collected during emission testing, how to report and submit the data to the EPA, and required contact information for the facility.

The measured HAP were reported in units of nanograms per dry standard cubic meter (ng/dscm) and rates in pounds per hour (lb/hr). The amount of rubber processed in units of tons per hour (ton/hr) was recorded, and the HAP data were also reported in units of lb/ton rubber processed. For HAP testing, one 3-run test was conducted for each mixer when organic HAP emissions were expected to be highest. THC measured in parts per million by volume dry (ppmvd) as propane were also collected during the second phase. For THC, data were also collected over a minimum 30-day period. Emissions of fPM and metal HAP were measured in units of milligrams per dry standard cubic meter (mg/dscm) and lb/hr, and data were collected per parent company for a minimum of six runs. The amount of rubber processed was recorded and the fPM and metal HAP data were reported in the units of lb/ton rubber processed. For units and facilities, the testing runs were split between mixing silica-containing compounds and non-silica-containing compounds, due to an expected difference in emission profiles.

Other parameters measured during testing included: gas flow rate, measured in actual cubic feet per minute (acfm); oxygen (O_2) and carbon dioxide (CO_2), measured in dry percent volume; and moisture, measured in percent volume. The measured flow rates were converted to standard cubic feet per minute (scfm) and dry standard cubic feet per minute (dscfm). The THC

measurements were converted to ppmvd.

D. What other relevant background information and data are available?

In November of 2022, the USTMA voluntarily provided to the EPA test reports containing metals and particulate matter (PM) data. Of the test reports provided, only 1 report (pertaining to Mixer #5 and #7 of the Goodyear Danville, Virginia facility) contained the fPM and corresponding rubber production data needed to calculate a production-based emission limit (pounds of fPM per ton of rubber produced). As a result, we considered fPM data from Mixer #5 and #7 from the Goodyear Danville facility when setting the MACT standard for fPM.

III. Analytical Procedures and Decision Making

The current Rubber Tire Manufacturing NESHAP does not contain any emission limits for the rubber processing subcategory. For the HAP emitted from this subcategory, we are proposing to establish MACT emission limits pursuant to CAA section 112(d)(2) and 112(d)(3). The results and proposed decisions based on the analyses performed pursuant to CAA section 112(d)(2) and 112(d)(3) are presented in section IV of this preamble. We discuss these emissions in the following 3 groupings: THC, PAH, and PM & metal HAP.

A. Total Hydrocarbons

In response to the CAA section 114 information request, we received THC emissions data from the rubber processing subcategory that we did not have in 2002 when subpart XXXX was first promulgated nor when we conducted the 2020 RTR. The emissions data received indicate that THC is emitted from the rubber processing subcategory. Measured THC includes organic HAP, including but not limited to 2-butanone, acetophenone, cumene, hexane, isooctane, methylene chloride, phenol, toluene, and xylene, which are the compounds identified by the rubber manufacturing association (now USTMA) as being emitted during rubber processing in original testing to determine emission factors for the Rubber Tire Manufacturing NESHAP. Draft emission factors developed by the U.S. Rubber Tire Manufacturers Association (USTMA) in 2008 are available in the Mixing 30800111 tab in the Emission Factors Tables excel file at *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-fifth-edition-volume-i-chapter-4-evaporation-loss-0.*

The THC emissions data also includes PAHs and other VOCs that are not HAP, such as ethanol. Because the THC measurements, by definition, include all relevant organic HAP (as well as non-HAP), and considering the significant difficulty of measuring numerous individual, speciated organic HAP compounds, we are proposing a MACT standard in accordance with CAA section 112(d)(2) and (d)(3) to limit THC emissions as a surrogate for organic HAP emissions, as described further in section IV.A.2 of this preamble. We solicit comment on the use of THC as a surrogate for organic HAP, as well as on the EPA's approach to testing for THC, as opposed to testing for individual speciated organic HAP. As explained below, we consider the use of THC as a surrogate to be an appropriate alternative to testing mixers to identify all individual, speciated, organic HAP emitted during rubber processing, and subsequently setting separate standards and monitoring requirements for each specific identified HAP.

B. Polycyclic Aromatic Hydrocarbons

PAHs are a group of over 100 different chemicals that are formed during the incomplete burning of coal, oil and gas, garbage, or other organic substances. PAHs are usually found as a mixture containing 2 or more of these compounds, such as soot. Additives to rubber provide characteristics important for tire performance; included in those additives is carbon black, which, depending on its origin, includes many PAHs. In response to the CAA section 114 information request, the EPA received PAH emissions data from the rubber processing subcategory that we did not have in 2002 when subpart XXXX was first promulgated nor in 2020 when we conducted the RTR. We used this new emissions data to develop the proposed MACT standards in accordance with CAA section 112(d)(2) and (d)(3). Specifically, we are proposing to use THC emissions as a surrogate for PAH and all organic HAP emissions, as discussed further in section IV.A.1 of this preamble.

C. Particulate Matter and Metal HAP

PM, specifically fPM, is a criteria pollutant created and emitted by many activities, including addition of carbon black to rubber while mixing. Filterable particulate matter contains a number of compounds including filterable metals, which are HAP. Baghouses, or fabric filters, employed at tire manufacturing facilities control and collect fPM and its inherent filterable metals, and, in some instances, the collected fPM is reintroduced into the mixers. In response to the CAA section 114 information request, the EPA received fPM and metal HAP emissions data from rubber processing that we did not have in 2002 when subpart XXXX was first promulgated nor in 2020 when we conducted the 2020 RTR. The emissions data received indicate that fPM and metal HAP are emitted from rubber processing. Pursuant to this data and information, we are proposing a MACT standard in accordance with CAA section 112(d)(2) and (d)(3) to limit fPM emissions as a surrogate for metal HAP emissions, as described further in section IV.A.3 of this preamble.

IV. Analytical Results and Proposed Decisions

When developing MACT standards, the MACT ''floor'' for existing sources is calculated based on the average performance of the best performing sources in each category or subcategory. The MACT floor for new sources is based on the single best performing source. The MACT floor for new sources cannot be less stringent than the emissions performance that is achieved in practice by the best controlled similar source. To account for variability in the rubber processing operations and resulting emissions, we calculated the MACT floors using the 99 percent Upper Predictive Limit (UPL) approach with available stack test data.[1]

The UPL approach addresses emissions data from the best performing source or sources in setting MACT standards. The UPL also accounts for uncertainty associated with emission values in a dataset, which can be influenced by factors such as the number of samples available for developing MACT standards and the number of samples that will be collected to assess compliance with the emission limit. The UPL approach has been used in many environmental science applications. As explained in more detail in the memorandum, *Use of Upper Prediction Limit for Calculating MACT Floors,* available in the docket for this action, the EPA uses the UPL approach to reasonably estimate the emissions performance of the best performing source or sources to establish MACT floor standards.

In addition, under CAA section 112(d)(2), the EPA must examine more stringent ''beyond-the-floor'' regulatory options to determine the appropriate level for the MACT standards. Unlike the MACT floor minimum stringency

[1] For more information regarding the general use of the UPL and why it is appropriate for calculating MACT floors, see the memorandum *Use of Upper Prediction Limit for Calculating MACT Floors,* which is available in the docket for this action.

requirements, the EPA must consider various impacts of the more stringent regulatory options in determining whether MACT standards are to reflect beyond-the-floor requirements. These impacts include the cost of achieving emission reductions beyond those achieved by the MACT floor, and any non-air quality health and environmental impacts and energy requirements that would result from imposing controls beyond the MACT floor. If the EPA concludes that the more stringent regulatory options are not reasonable, the EPA sets the standards at the MACT floor level. However, if the EPA concludes that impacts associated with beyond-the-floor levels of control are reasonable in light of the additional considerations, the EPA selects those levels as MACT.

Data submitted to the EPA in response to the CAA section 114 information request included air emissions test results from 12 rubber processing mixers at 6 facilities in the source category. The responses also included the types of materials being processed and the types of controls in use at mixers within the source category. The types of tires produced included passenger and light truck tires, off road tires, truck tires, earth moving tires, and aircraft tires, which are representative of the major types of tires produced by facilities in the Rubber Tire Manufacturing source category. Similarly, all of the tire component types of rubber compounds (inner liner, ply coat, belt coat, base/sidewall, apex, tread) were represented. The types of air emission controls included fPM controls (*e.g.,* fabric filter baghouses, cartridge dust collectors, and scrubbers) on all mixers and regenerative thermal oxidizers (RTOs) on 3 mixers at 3 facilities (in addition to the fPM controls).

Due to issues with availability of testing equipment and due to unforeseen issues with some of the emissions testing, not all data for the second phase of the CAA section 114 information request was timely submitted. The EPA received some data after the requested deadline, and some of the late-submitted data was not submitted in time for us to consider it for the proposal. The EPA anticipates incorporating these additional data, which includes data from 6 additional mixers (Continental Mt Vernon Mixer 19 and 21, Cooper Texarkana Mixer 1, 5, and 8, and Titan Tire Mixer 6 (just 30-day THC data)) when we develop the final rule. Three of these mixers (Continental Mt Vernon Mixer 19 and 21, Cooper Texarkana Mixer 8) operate RTOs, with the two mixers from Continental (Mixer 19 and 21) operating RTOs continuously for all batch types and Cooper (mixer 8) operating only when utilizing silica containing compounds. Although we have not had adequate time to evaluate the data from these mixers it is possible that the mixers (especially those that operate RTOs) may be among the top performing mixers tested, and thus be the new basis of the MACT floor calculations. Additionally, we anticipate that the addition of data for these 6 mixers will change the number of mixers used to calculate the MACT floors both for mixers using silica-containing compounds and for mixers using non-silica-containing compounds, thus resulting in a change of the proposed calculated MACT floor emission limits. All the CAA section 114 data, including the late-submitted data are available at *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.* We are specifically requesting comment on the late-submitted data, which was not received in time for us to consider for proposal.

The CAA provides that MACT standards for existing sources may be no less stringent, but may be more stringent, than the average emission limitation achieved by the best performing 12 percent of the existing sources (or best performing 5 sources in the category or subcategory where there are fewer than 30 sources) for which the Administrator has information. Since there are over 29 mixers for each of the silica-containing and non-silica-containing compounds, the MACT floors are calculated using the top 12 percent of data available. For this proposal, the EPA was able to use THC data for 11 mixers, and 12 percent of 11 mixers is 1.32 mixers. When determining the best performing 12 percent of existing sources for the MACT floor pool, we round fractional amounts to the next whole number to ensure that the MACT floor calculations are based on no fewer than the best performing 12 percent of existing sources. In this instance, we rounded up to 2 mixers for purposes of determining the existing source MACT floor. As previously mentioned, we received late-submitted data for an additional 6 mixers that were not provided in time to consider for this proposal, but which we intend to consider for the final rule; when the data from the additional 6 mixers are included, the number of mixers identified as the best performers is expected to change from 2 to 3 (*i.e.,* 17 mixers, and 12 percent of 17 mixers is 2.04, which rounds up to 3 mixers). It is possible that the fPM and metal HAP MACT floor may change when including the new data. For additional information on the data collected in the CAA section 114 information request, please see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

A. What are the results of our analyses of unregulated pollutants and how did we set MACT standards?

1. Polycyclic Aromatic Hydrocarbons

The EPA received data from five facilities for PAH emissions. The PAH compounds measured were aniline, dibenzofuran, hydroquinone, naphthalene, and *o*-toluidine. The PAH emissions were collected using U.S. EPA SW–846 Method 0010, extracted using Method 3542, and analyzed using Method 8270E.[2]

Many of the measured emissions were below the detection limit of the approved testing method, and others were detection level limited (DLL). Results are considered below detection limit (BDL) when every measured result for a compound in a test run is less than the laboratory's reported detection level. Data are considered DLL when the results in a given test run are a mixture of values less than and greater than the laboratory's reported detection level for that compound. All of the test results for hydroquinone and dibenzofuran were BDL. The test results for aniline, naphthalene, and *o*-toluidine included values that were above the detection level.

Reported levels of two PAH compounds—dibenzofuran and hydroquinone—are below current detection levels at each facility; therefore, the EPA is not proposing emission limits for dibenzofuran or hydroquinone. Moreover, because the World Health Organization recognizes 17 dioxin-like congeners[3] (7 polychlorinated dioxins and 10 polychlorinated dibenzofurans), the USTMA emission factor data contain no polychlorinated dioxins or polychlorinated dibenzofurans, and measured unpolychlorinated dibenzofuran values are BDL, the EPA is proposing that no emission limits for dioxin-like compounds are needed.

[2] *https://www.epa.gov/hw-sw846/sw-846-compendium.*

[3] The International Union of Pure and Applied Chemistry defines congeners as chemical substances ''related to each other by origin, structure, or function.''

The remaining PAH species—aniline, naphthalene, and *o*-toluidine—are also organic HAP and hydrocarbons and so will be accounted for in THC measurements. Therefore, the EPA is not proposing a separate emission limit for PAHs and is instead proposing a limit for THC emissions. Total THC results include the effect of PAH, organic HAP, and VOC contained in exhaust streams and are well suited to serve as surrogates for these compounds. We are soliciting comment on the use of THC as a surrogate in place of setting emission limits for PAHs, specifically.

A detailed description of the analysis of the PAH data is included in the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* located in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0392).

2. Total Hydrocarbon Emissions

We received long-term (30 days or longer) THC emissions test results from 5 facilities and a total of 11 mixers in response to the second phase of the CAA section 114 information request. From 5 mixers, we also received short-term THC data (*e.g.,* 3 to 11 runs lasting from 20 minutes to 3 hours per run). The following were monitored continuously for each mixer over a period of at least 30 days: uncorrected THC as propane measured in parts per million by volume (ppmv) using EPA Method 25A, oxygen volume (percent), moisture volume (percent), the quantity of rubber processed, and the start and stop timestamps for each batch of rubber processed. Additional data collected during these tests included the tire component processed and whether the processed tire component contained silica. Although all rubber mixing operations produce THC emissions, the addition of silica, which is used to create longer wearing and more fuel-efficient tread rubber compounds, reacts with other compounds during the mixing operation, leading to increased THC emissions during the mixing operation. Some facilities vent mixer exhaust to an RTO to reduce emissions when mixing silica-containing compounds, and 1 tested facility exhausts the mixing of all rubber compounds to an RTO.

Flow rate was measured during short-term testing (3 to 11 runs with 20- to 360-minute run duration) over several runs for five mixers. For the remaining six mixers for which 30-day THC monitoring was performed, flow rate data were not available. However, the six mixers without flow-rate data are located at facilities that included at least one other mixer with available flow-rate data, and the flow rates were comparable among mixers at different facilities. The flow rate data were used to estimate the hourly mass emissions of THC from the THC concentration data. The THC concentration (ppmv) was corrected for each measurement to a dry basis (ppmvd) if a simultaneous moisture content measurement was available. If a moisture content measurement was not available, then the as-measured concentration (ppmv) was used. Moisture in the air was typically less than 2 percent, so adjusting the THC measurements using a default moisture content for those concentrations without moisture would not have a significant effect on emissions. The oxygen concentrations were always close to ambient levels, so the THC concentrations were not corrected to a standard oxygen concentration. The ppmvd (or ppmv) values were combined with the exhaust flow (dscfm) to calculate the lb/hr THC emission rates. If the THC measurements were made upstream from an RTO (*i.e.,* THC levels were measured before reaching the control device), then the emission rates were corrected to account for the measured destruction and removal efficiency (DRE) of the RTO. We are soliciting comment on this approach regarding the 30-day THC data.

The CAA section 114 information request required that, during the THC monitoring, facilities record the amount of rubber produced for silica-containing and non-silica-containing rubber, including the start and end times of each batch and whether the batch was silica-containing or non-silica containing. The information request sought data that was separated into silica-containing and non-silica-containing batches, due to differences in raw ingredients, resulting in different expected emission profiles when silica is added. The EPA expected different emission profiles between the two processes that use different raw materials, because the addition of silica leads to chemical reactions producing additional organics. The expected increase in organics, is represented by higher levels of THC emissions, compared to non-silica batches. The data received in the CAA section 114 information request confirmed that THC emissions from silica batches are higher, resulting in the EPA determination that it is appropriate to set two separate standards for silica-containing and non-silica-containing batches. EPA seeks comment on its approach to propose two separate standards, based on those material-based processes exhibiting markedly different emission profiles.

The time data were used to match the THC and production data to calculate daily THC emissions and production in pounds per hour of THC and rubber for silica-containing and non-silica-containing rubber. The THC lb/hr emissions data were combined with the hourly production data to calculate the daily THC emission rate in terms of grams of THC emitted per megagram (g/Mg) of rubber produced for each mixer. The EPA calculated separate values for silica-containing and non-silica-containing rubber compounds.

For several mixers, responses to the CAA section 114 information request showed negative THC concentration values for significant periods of time. Individual THC values (*i.e.,* those recorded every minute) that were more negative than −5 ppmv were excluded from the dataset on the assumption that they represented faulty THC monitoring measurements and were not replaced. Individual THC measurements between 0 and −5 ppmv were kept in the data but were treated as a 0 ppmv value when calculating the daily average THC concentration in ppmv. We are soliciting comment on the proposed approach to addressing negative THC values.

From these THC values and production data for silica-containing and non-silica-containing rubber compounds, we calculated UPL values for each mixer for 7-day and 15-day rolling averages in terms of grams of THC emitted per megagram (g/Mg) of silica-containing or non-silica-containing rubber produced. Separate UPL values were calculated for silica-containing and non-silica-containing compound production. Consistent with the approach we have developed to set MACT standards, we also determined the representative detection level (RDL) for THC values, as well as 3 times the RDL (3xRDL) for THC values and compared the 3xRDL values to the UPL values. When the 99-percent UPL values exceed 3xRDL values, the EPA uses the 99-percent UPL values for emission limit setting purposes, but when 3xRDL values exceed the 99-percent UPL values, the EPA uses 3xRDL values for emission limit setting purposes because the standard needs to be established at a level that sources can demonstrate with reasonable confidence.

The RDL process for THC values is determined at 6 percent of the high end of the measurement range appropriate for the best performing sources. This means that once the EPA determines the

THC parts per million (ppm) values from the best performers, the EPA selects an appropriate instrument range, which may not necessarily be the range used in a particular instance by a particular source. For instance, if the best performers had THC ppm values from 1 to 67 ppm, then an appropriate instrument range would be 0 to 100 ppm, even though one or more of the best performers may have used an instrument with a range of 0 to 1,000 ppm. Note that common instrument ranges include 0 to 10 and 0 to 100 ppm; furthermore, many instruments allow custom ranges, so ranges from 0 to 50 ppm and 0 to 500 ppm are available. Also note that dual range instruments are available in the commerce stream such that a primary (low) range and secondary (high) range can be used as needed for THC measurements.

The EPA considered 7- and 15-day rolling averages for both silica-containing and non-silica-containing compounds because they are more representative of emissions over time due to the variability across the mixing operation compared to a 1-day emission limit, considering that mixers may not mix both silica-containing and non-silica-containing materials in a single day.

The EPA is proposing a 15-day rolling average THC emission limit for mixers of both silica-containing and non-silica-containing compounds, rather than a 7-day rolling average THC emission limit, because emissions begin to normalize after 15 days with fewer significant deviations in the rolling-average THC values compared to a 7-day rolling average. We believe a 15-day rolling average THC emission limit better represents actual emissions from mixers and better encompasses variability due to batch type. In addition, separate 15-day rolling average THC emission limits are being proposed for mixers of silica-containing and non-silica-containing compounds due to differences in emissions profiles of the mixtures, which results in distinct THC ranges for these 2 types of compounds.

The EPA is proposing an emission limit for THC as a surrogate for organic HAP emitted from rubber mixers for silica-containing and non-silica-containing compounds. Total quantities of THC emitted from rubber processing invariably contain organic HAP. Because EPA Method 25A measures the carbon content of compounds, as opposed to mass of individual compounds, THC values are not speciated into specific compounds; rather, total THC results include the effect of, and therefore encompass the emissions of PAH, organic HAP, and VOC contained in exhaust streams. As such, THC serves as a form of categorical ''umbrella,'' capturing various pollutants, and is therefore well suited to serve as a surrogate for these compounds. The destruction of THC, will indiscriminately result in the destruction of organic HAP. Therefore, and based on our understanding of the processes at these facilities, we believe that there is an expected relationship between controlling THC emissions and controlling organic HAP emissions.

Data gathered from responses to the CAA section 114 information request identified that the primary control device utilized for organic compound emissions control on rubber tire mixers is an RTO, and destruction of THC will reliably indicate destruction of organic HAP. Because multiple organic HAP may be emitted from the mixers, it is more practical to monitor and measure THC emissions than to monitor and measure individual organic HAP. Furthermore, EPA is not aware of any evidence that there is any emission control device (other than an RTO), that would directly regulate organic HAP and be as, or more, effective at reducing organic HAP than simply regulating THC emissions themselves. As discussed above, it is expected that lower aggregate THC emissions are associated with lower total organic HAP emissions. It is also more practical to establish an emission limit for THC than for individual organic HAP because a THC emission limit accounts for variability in individual organic emission rates among different batches of rubber compound being mixed.

Based on responses to the CAA section 114 information request, the EPA determined that 97 mixers are located at major sources of rubber tire manufacturing. The EPA has THC data for 11 mixers, and 3 of these mixers are equipped with RTOs. For one mixer controlled by an RTO (Continental, Mount Vernon, Illinois, Mixer #22), the emissions are continuously routed to the RTO, and the THC emissions were measured at the outlet of the RTO for silica and non-silica emissions. For the other two mixers equipped with RTOs (Goodyear, Fayetteville, North Carolina, Mixer #8; and Goodyear, Danville, Virginia, Mixer #110), THC emissions are only routed to the RTOs when the mixers are running batches that contain silica, such as tread rubber. For these two mixers, the THC emissions were required to be measured at the outlet of the mixer, but before the RTO. This sampling location was selected because several mixers share the tested RTO; therefore, to get data representative of a single mixer, it was necessary to test at the outlet of the mixer prior to the combined stream at the RTO. The most recent measured DREs provided by the facilities for these mixers were applied to determine the controlled THC emission rate in g/Mg rubber produced.

a. THC Existing Source Standard for Silica-Containing Compounds

The EPA determined the existing source MACT floor THC emission limit for silica-containing compounds based on the top two performing mixers. As discussed in section IV of this preamble, for a source category of this size, the CAA requires the EPA to use the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has information) when establishing the MACT floor level of control. Based on responses to the CAA section 114 information request, there are an estimated 56 mixers that use silica, and the MACT floor is calculated using the available data for the top performing 12 percent of mixers. The EPA has THC data for 11 mixers, and 12 percent of 11 mixers is 1.32 mixers. When determining the best performing 12 percent of existing sources for the MACT floor pool, we round fractional amounts to the next whole number to ensure that the MACT floor calculations are based on no fewer than the best performing 12 percent of existing sources. In this instance, we rounded up to 2 mixers for purposes of determining the existing source MACT floor. The existing source MACT floor THC emission limit for silica-containing compounds is based on the average 15-day emission rate achieved by the two lowest emitting mixers. For these 2 mixers, the EPA included each mixer's daily average THC emission rate in a list, and then calculated 15-day rolling averages from the daily averages.

The proposed THC emission limits for existing mixers are based on the calculated 99 percent UPL or 3xRDL, whichever is higher, calculated from the 15-day rolling averages of the data combined from the 2 mixers controlled by RTOs, and represents the average performance of the 2 mixers.

Based on these data, we are proposing an existing source MACT floor THC limit for mixing silica-containing compounds of 9.4 g/Mg rubber produced (18,840 pounds per million tons (lb/Mton)), based on a 15-day rolling average. The maximum THC ppm value from the best performers is 385 ppm, so an appropriate instrument range would be 0 to 500 ppm, which leads to an RDL value of 30 ppm and a 3xRDL value of 90 ppm. When this

3xRDL value is combined with the average flow rate, percent removal, and production of the best performers, the result is 7.7 g/Mg rubber processed (15,430 lb/Mton). Since the 3xRDL value is less than the UPL value of 9.4 g/Mg rubber processed (18,840 lb/Mton), the UPL value is the basis for the proposed existing source MACT floor for mixing silica-containing compounds. We request comment on the proposed MACT floor THC emission limit for mixing silica-containing compounds.

b. THC Beyond-the-Floor Analysis for Existing Source Standard for Silica-Containing Compounds

In addition to determining the MACT floor level of control, the EPA must examine more stringent ''beyond-the-floor'' regulatory options to determine MACT. Unlike the MACT floor minimum stringency requirements, when considering beyond-the-floor options, the CAA provides that the EPA must consider various impacts of the more stringent regulatory options in determining whether MACT standards are to reflect beyond-the-floor requirements. If the EPA concludes that the more stringent regulatory options are not reasonable, then the EPA selects the MACT floor as MACT. However, if the EPA concludes that the beyond-the-floor levels of control are reasonable in light of additional emissions reductions achieved, then the EPA selects those levels as MACT.

As part of our beyond-the-floor analysis, we identify control options or techniques that have the ability to achieve emission reductions beyond the MACT floor level of control. The EPA did not identify any new control options or techniques other than those which are currently used by existing facilities. However, the EPA performed an illustrative analysis, estimating costs associated with requiring mixers to meet the current emission limit achieved by the single best performing mixer, as a potential beyond-the-floor option. The existing source MACT floor limit for mixing silica-containing compounds is based on the combined UPL for the 2 lowest emitting mixers controlled by an RTO. We evaluated the cost effectiveness of going beyond the floor to adopt the single lowest emitting mixer controlled by an RTO. The UPL for the single lowest emitting mixer controlled by an RTO and mixing silica-containing compounds is 9.4 g/Mg rubber produced (18,840 lb/Mton), based on a 15-day rolling average.

To comply with such a standard, we estimate that existing mixers that use silica-containing compounds would be required to use an RTO or similar control device. In order to achieve this standard, RTOs would likely need to have a higher DRE than that required for the existing source emission limit to achieve the level of emission reduction of the best performing source. To increase the DRE, we estimate that RTOs would need to increase their operating temperature. To represent this increase, we calculated the estimated cost of increasing the operating temperature of an RTO from 1400 degrees Fahrenheit (°F) to 1600 °F. The beyond-the-floor standard would achieve an additional 8.7 Mg per year (9.6 tpy) of THC reductions. The incremental cost-effectiveness, compared to the MACT floor level of control, would be about $35,000 per additional Mg ($32,000/ton) of THC reduced beyond the MACT floor level of control, due to the increased fuel consumption to operate the RTO at a higher temperature and achieve a higher DRE.

The EPA proposes to conclude that the cost of setting THC emission limits beyond the MACT floor for silica-containing compounds existing sources is not reasonable when considering cost. Therefore, the EPA is proposing to set THC emission limits for silica-containing compounds existing sources at the MACT floor level of control. We request comment on our approach to considering beyond-the-floor controls.

For additional information see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

c. THC Existing Source Standard for Non-Silica-Containing Compounds

For the existing source THC MACT floor emission limit for non-silica-containing compounds, the EPA has THC data from 1 mixer that is controlled by an RTO for non-silica-containing compounds and from 10 other mixers that use non-silica-containing compounds and are not equipped with an RTO. As discussed in the beginning of section IV of this preamble, for a source category of this size, the CAA requires the EPA to use the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has information) when establishing the MACT floor level of control. There are an estimated 41 mixers that do not use silica, and the MACT floor is calculated using data from the top performing 12 percent of mixers for which we have data. The EPA has THC data for 11 mixers, and 12 percent of 11 mixers is 1.32 mixers. When determining the best performing 12 percent of existing sources for the MACT floor pool, we round fractional amounts to the next whole number to ensure that the MACT floor calculations are based on no fewer than the best performing 12 percent of existing sources. In this instance, we rounded up to 2 mixers for purposes of determining the existing source MACT floor.

To determine the MACT floor emission limit for non-silica-containing compounds, the EPA combined the THC emissions data from the one mixer with an RTO controlling the mixing of non-silica-containing compounds (Continental, Mount Vernon, Illinois, Mixer #22) and the emissions data from the next best performing mixer (Goodyear, Lawton, Texas, Mixer #1). The UPL was then calculated from the 15-day averages for the combined Goodyear and Continental mixers for non-silica-containing compounds and determined to be 16.4 g/Mg rubber produced (32,870 lb/Mton).

The maximum THC value from the best performers is 37 ppm, so an appropriate instrument range would be 0 to 50 ppm, which leads to an RDL value of 3 ppm and a 3xRDL value of 9 ppm. When this 3xRDL value is combined with the average flow rate and production of the best performers, the result is 45.4 g/Mg rubber processed (91,000 lb/Mton). Since the 3xRDL value is greater than the UPL value of 16.4 g/Mg rubber processed (32,870 lb/Mton), the 3xRDL value is the basis for the proposed existing source MACT floor for mixing non-silica-containing compounds. The proposed existing source MACT floor THC emission limit for mixing non-silica-containing compounds is 45.4 g/Mg rubber produced (91,000 lb/Mton), based on a 15-day rolling average. For additional information see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

We request comment on our proposed approach to setting the existing source MACT floor THC emission limit for non-silica-containing compounds from mixers and the proposed MACT floor emission limit.

d. THC Beyond-the-Floor Analysis for Existing Source Standard for Non-Silica-Containing Compounds

As discussed earlier in this document, as part of our beyond-the-floor analysis, we identify control options or techniques that have the ability to achieve emission reductions beyond the MACT floor level of control. The EPA

did not identify any new control options or techniques other than what is currently used. However, the EPA evaluated the beyond-the-floor option of requiring mixers to meet the current emission limit of the single best performing mixer. The EPA has THC data from one facility that operates an RTO at all times (Continental, Mt. Vernon, Illinois, Mixer #22). As explained below, the 15-day UPL for mixing non-silica-containing compounds from that mixer, measured at the outlet of the RTO, is 13.4 g/Mg (26,860 lb/Mton), while its 3xRDL value is 17.2 g/Mg (34,470 lb/Mton), based on a 15-day rolling average.

Based on data collected in response to the CAA section 114 information request, of the mixers for which we have data, we expect that three mixers (25 percent) of the 12 mixers for which we have data, would be able to comply with the existing source UPL for non-silica-containing compounds without requiring an RTO or similar control device. We expect all mixers would need to operate an RTO or similar control device to achieve the level of emission reduction of the best performing source. We assume that if an additional 25 percent of mixers needed to install RTOs, as many as four additional RTOs would be needed (25 percent of 41 = 10.25, which would round up to 11 mixers; an average of 3 mixers per RTO would require at least 4 new RTOs for those 11 mixers) to meet a beyond-the-floor emission limit. The total annual cost of those four additional RTOs would be $2.2 million per year.

Additionally, in order to establish MACT standards that achieve emissions reductions beyond the MACT floor level of control, RTOs would likely need to have a higher DRE compared to the existing source emission limit to meet the lower new source emission limit. To increase the DRE, we estimate that RTOs would have to increase their operating temperature. To represent this increase, we calculated the estimated cost of increasing the operating temperature of an RTO from 1400 °F to 1600 °F. The annual cost difference to operate one RTO at 1600 degrees F compared to 1400 degrees F is estimated to be $16,000 per year, due to higher gas and electricity costs. The total annual cost for 14 RTOs would be $226,000 per year. The total combined cost for new RTOs and increased RTO operating temperature would be $2.4 million per year.

The beyond-the-floor emission limit would achieve an additional 57.5 Mg (63.2 tpy) of THC reductions at an added cost of approximately $42,000/Mg of THC reduced ($38,000/ton), based on the installation of four additional RTOs and the increased fuel consumption to operate the RTOs at a higher temperature to achieve a higher DRE. For additional information see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

We propose to conclude that setting THC emission limits beyond the MACT floor for non-silica-containing compounds existing sources is not reasonable when considering cost. Therefore, we are proposing to set THC emission limits for non-silica-containing compounds existing sources at the MACT floor level of control. We request comment on our approach to considering beyond-the-floor control.

e. THC New Source Standard

The THC MACT emission limits for new sources are based on the emission limitation achieved by the best controlled similar source. For both silica-containing and non-silica-containing compounds, the best controlled source were mixers that operate an RTO. One mixer (Continental, Mount Vernon, Illinois, Mixer #22), routes all emissions (silica and non-silica) to an RTO. This mixer serves as the best performing source for non-silica-containing compounds.

There are 3 mixers that operate silica-containing compounds that are controlled by RTOs for which the EPA has data (Goodyear, Fayetteville, North Carolina, Mixer #8, Continental, Mount Vernon, Illinois, Mixer #22, and Goodyear, Danville, Virginia, Mixer #110).

We calculated the 15-day UPL rolling average emission rate for the mixers controlled by RTOs that control the mixing of silica-containing compounds and the one mixer controlled by an RTO that also controls the mixing of non-silica-containing compounds.

f. THC New Source Standard for Silica-Containing Compounds

For mixing silica-containing compounds, the proposed new source UPL is 2.1 grams of THC per megagram (g/Mg) of rubber produced (4,210 lb/Mton). The maximum THC value from the best performers is 37 ppm, so an appropriate instrument range would be 0 to 100 ppm, which leads to an RDL value of 6 ppm and a 3xRDL value of 18 ppm. When this 3xRDL value is combined with the average flow rate, percent removal, and production of the best performers, the result is 1.8 g/Mg rubber processed (3,610 lb/Mton). Since the 3xRDL value is less than the UPL value of 2.1 g/Mg rubber processed (4,210 lb/Mton), the UPL value is the basis for the proposed new source MACT floor for mixing silica-containing compounds. For additional information see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

g. THC New Source Standard for Non-Silica-Containing Compounds

For mixing non-silica-containing compounds, the proposed new source UPL is 13.4 grams of THC per megagram (g/Mg) of rubber produced (26,860 lb/Mton). The maximum THC value from the best performers is 2 ppm, so an appropriate instrument range would be 0 to 10 ppm, which leads to an RDL value of 0.6 ppm and a 3xRDL value of 1.8 ppm. When this 3xRDL value is combined with the average flow rate and production of the best performers, the result is 17.2 g/Mg rubber processed (34,470 lb/Mton). Since the 3xRDL value is greater than the UPL value of 13.4 g/Mg rubber processed (26,860 lb/Mton), the 3xRDL value is the basis for the proposed new source MACT floor for mixing silica-containing compounds. For additional information see the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

The proposed new and existing source THC MACT floor limits are summarized in table 3.

TABLE 3—PROPOSED THC MACT FLOOR LIMITS FOR NEW AND EXISTING RUBBER PROCESSING SOURCES

Rubber compound type	New source MACT floor limit THC per rubber produced [primary THC instrument range, ppm]	Existing source MACT floor limit THC per rubber produced [primary THC instrument range, ppm]
Silica-Containing	2.1 g/Mg (4,200 lb/Mton) [0–100]	9.4 g/Mg (18,800 lb/Mton) [0–500].

TABLE 3—PROPOSED THC MACT FLOOR LIMITS FOR NEW AND EXISTING RUBBER PROCESSING SOURCES—Continued

Rubber compound type	New source MACT floor limit THC per rubber produced [primary THC instrument range, ppm]	Existing source MACT floor limit THC per rubber produced [primary THC instrument range, ppm]
Non-Silica-Containing	17.2 g/Mg (34,400 lb/Mton) [0–10]	45.4 g/Mg (90,800 lb/Mton) [0–50].

A detailed description of the analysis of THC data, and the controls necessary to reduce THC emissions, is included in the document, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,* available in the docket for this action.

3. Particulate Matter and Metal HAP

Based on responses to the CAA section 114 information request, the EPA has fPM data from seven mixers and metal HAP data from five mixers. The EPA had no reason to assume a difference in fPM and metal HAP emissions based on the mixing of silica-containing or non-silica-containing compounds, as silica is known to cause an increase in organic emissions, which does not impact PM; thus, a single emission standard was calculated for both classes of compounds. For each mixer, the EPA calculated the 99 percent UPL for both fPM and the sum of the metal HAP that were measured (antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, mercury, nickel, phosphorus, and selenium). As discussed in the beginning of section IV of this preamble, for a source category of this size, the CAA requires the EPA to determine the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has information) when establishing the MACT floor level of control. There are an estimated 97 mixers in the source category, and the MACT floor is calculated using data from the top performing 12 percent of mixers for which we have data. The EPA has fPM data from 7 mixers and metal HAP data for 5 mixers. The EPA calculated 12 percent of 7 mixers (fPM) and 12 percent of 5 mixers (metal HAP) which results in 0.84 and 0.6, respectively. When determining the best performing 12 percent of existing sources for the MACT floor pool, we round fractional amounts to the next whole number to ensure that the MACT floor calculations are based on no fewer than the best performing 12 percent of existing sources. In this instance, we rounded up to one mixer for purposes of determining the existing source MACT floor for fPM and metal HAP.

When setting new source MACT floors, the emission limit is achieved in practice by the best controlled similar source. As a result, the MACT floors for both new and existing sources are based on the best performing existing source. Based on responses to the CAA section 114 information request, all mixers in this subcategory are controlled by a fabric filter baghouse or similar control devices that control PM emissions.

The EPA calculated the MACT floor for fPM as 3,410 lb/Mton rubber produced (1.7 grams of fPM per megagram (g/Mg) of rubber produced) and a total metal HAP emission rate of 74.1 lb/Mton rubber produced (0.037 g/Mg). The lowest fPM emission rate and the lowest metal HAP emission rate were measured at the same mixer, and the fPM and metal HAP emissions were measured simultaneously. Because the metal HAP are emitted as fPM, the EPA is proposing to use fPM as a surrogate for metal HAP and also an alternative emission limit for total metal HAP. Data gathered from the CAA section 114 information request identified that the primary control devices utilized for metal HAP emissions on rubber tire mixers are fabric filter baghouses, and capture of fPM will reliably indicate capture of metal HAP. It is also practical to use fPM as a surrogate for metal HAP because the fPM emission limit accounts for variability in individual metal HAP emission rates among different batches of rubber compound being mixed.

The EPA is proposing to require facilities to measure fPM using EPA Method 5 and the metal HAP will be measured using EPA Method 29. Facilities may choose either the emission limit for fPM or the alternative emission limit for total metal HAP to comply. We request comment on our proposal to use fPM as a surrogate for metal HAP emission limits at the MACT floor level and on our MACT floor calculations.

All existing mixers in the subcategory are already controlled by fabric filter baghouses to recover raw materials in the form of fPM and recycle them back to the process and to minimize nuisance emissions. The proposed emission limits for new and existing sources are based on the use of a fabric filter baghouse. As part of our beyond-the-floor analysis, we identify control options and techniques that have the ability to achieve an emission limit more stringent than the MACT floor. No control options or techniques were identified that would achieve HAP reductions greater than the best performing mixer. Because the proposed standards for new and existing sources are based on the best performing mixer, which is already controlled by a fabric filter baghouse, and no more effective controls than a fabric filter baghouse for fPM or metal HAP are in use or were identified, we did not identify any beyond-the-floor options to evaluate for either existing or new mixers. We request comment on whether there are any beyond-the-floor control options that the EPA should consider for controlling fPM emissions from the rubber processing subcategory.

The rubber processing operations and resulting emissions, the stack test data were used to calculate the fPM MACT floor limits based on the 99 percent UPL. Because the UPL value exceeds the 3xRDL value, the UPL value was used to establish the MACT floor. The fPM MACT floor limits were calculated based on concentration of fPM, in units of g/Mg (lb/Mton) of rubber produced. The new and existing source fPM and metal HAP MACT floor limits are summarized in table 4.

TABLE 4—PROPOSED FPM MACT FLOOR LIMITS AND TOTAL METAL HAP ALTERNATIVE FOR NEW AND EXISTING RUBBER PROCESSING SOURCES

Pollutant	New source MACT floor limit (g/Mg rubber produced)	Existing source MACT floor limit (g/Mg rubber produced)
fPM	1.70 (3,400 lb/Mton rubber produced)	1.70 (3,400 lb/Mton rubber produced).

TABLE 4—PROPOSED FPM MACT FLOOR LIMITS AND TOTAL METAL HAP ALTERNATIVE FOR NEW AND EXISTING RUBBER PROCESSING SOURCES—Continued

Pollutant	New source MACT floor limit (g/Mg rubber produced)	Existing source MACT floor limit (g/Mg rubber produced)
Alternative: Total Metal HAP	0.037 (74 lb/Mton rubber produced)	0.037 (74 lb/Mton rubber produced).

A detailed description of the analysis of fPM and metal HAP, and the control devices to reduce fPM and metal HAP emissions, is included in the memorandum, *Maximum Achievable Control Technology (MACT) Analysis for the Rubber Processing Subcategory in the Rubber Tire Manufacturing Industry,*'' available in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0392).

B. What performance testing, monitoring, and recordkeeping and reporting are we proposing?

1. Performance Testing

We are proposing, based on the new and existing source limits for rubber processing, that new sources demonstrate initial compliance within 180 days after startup, and existing sources demonstrate initial compliance within 3 years after the promulgation of the final rule. We are proposing that the initial performance tests to demonstrate compliance with the MACT standards of tables 3 and 4 of this preamble are conducted using the methods identified in table 5. Subsequent performance testing will be required every 5 years, using the methods identified in table 5.

TABLE 5—SUMMARY OF PROPOSED TEST METHODS

Pollutant or parameter	EPA method
Velocity/Volumetric Flow Rate	1 and 2
Oxygen and Carbon Dioxide	3B
Moisture	4
PM	5
Metal HAP	29

Additionally, consistent with the existing performance testing requirements of the Rubber Tire Manufacturing NESHAP (40 CFR 63.5992), owners or operators must operate and maintain their dual range THC continuous emission monitoring system (CEMS) in accordance with Performance Specification (PS) 8A and 40 CFR part 60, appendix F, procedure 2. Note that as an alternative to using a dual range THC CEMS, owners or operators may choose to use more than one THC CEMS.

2. Parameter Monitoring

Under this proposal, sources would be required to maintain continuous compliance with the emission limits, which, for fPM or metals, would be demonstrated through control device parameter monitoring coupled with periodic emissions testing described earlier in this preamble, and, for THC, via use of THC CEMS.

We are proposing to amend the parametric monitoring currently specified in the rule to add table 16 to the NESHAP to include parameter monitoring requirements for fPM control devices that we expect would be used to comply with the standards for fPM from rubber processing, as surrogates for metal HAP. Proposed additional requirements include the following:

For fPM controls, continuously operate a baghouse leak detection system (BLDS). We propose that owners or operators would install, operate, and maintain BLDS such that, among other things: concentrations of 1.0 milligram per dry standard cubic meter can be detected; sensors can provide output of relative fPM loadings; the BLDS has alarm systems that indicate when an increase in relative loading occurs; and the BLDS is installed an operated consistent with the guidance provided in ''*Office of Air Quality Planning and Standards (OAQPS) Fabric Filter Bag Leak Detection Guidance*'' (see EPA–454/R–98–015). These requirements are consistent with those for a BLDS in our Mineral Wool Production and Ferroalloys Production MACT standards.

3. Recordkeeping and Reporting

Under this proposal, and consistent with existing requirements in the Rubber Tire Manufacturing NESHAP, a source owner or operator will be required to submit semiannual compliance summary reports electronically; these reports document both compliance with the requirements of the Rubber Tire Manufacturing NESHAP and any deviations from compliance with any of those requirements.

Owners and operators would be required to maintain the records specified by 40 CFR 63.10 and, in addition, would be required to maintain records of all inspection and monitoring data, in accordance with the Rubber Tire Manufacturing NESHAP (40 CFR 63.6011).

C. What other actions are we proposing?

We are proposing to update the electronic reporting requirements found in 40 CFR 63.6009(k) and in 40 CFR 63.6010(g) and (h) to reflect new procedures for reporting CBI. The update provides an email address to which source owners and operators can electronically mail CBI to the OAQPS CBI Office when submitting compliance reports.

D. What compliance dates are we proposing, and what is the rationale for the proposed compliance dates?

Amendments to the Rubber Tire Manufacturing NESHAP proposed in this rulemaking for adoption under CAA section 112(d)(2) and (3) are subject to the compliance deadlines outlined in the CAA under section 112(i). For existing sources, CAA section 112(i)(3) provides that there shall be compliance ''as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard'' subject to certain exemptions further detailed in the statute.[4] In determining what compliance period is as ''expeditious as practicable,'' we consider the amount of time needed to plan and construct projects and change operating procedures. As provided in CAA section 112(i), all new affected sources would comply with these provisions by the effective date of the final amendments to the Rubber Tire Manufacturing NESHAP or upon startup, whichever is later.

The EPA projects that many existing sources would need to install add-on controls to comply with the proposed emission limits, including new RTOs and new or upgraded fabric filter baghouses. These sources would require time to construct, conduct performance testing, and implement monitoring to comply with the revised provisions.

[4] *Association of Battery Recyclers* v. *EPA,* 716 F.3d 667, 672 (D.C. Cir. 2013) (''Section 112(i)(3)'s 3-year maximum compliance period applies generally to any emission standard . . . promulgated under [section 112]'' (brackets in original)).

Sources would also be required to install THC CEMS and conduct performance testing. Therefore, we are proposing to allow 3 years for existing sources to comply with the new emission standards.

All affected facilities would have to continue to meet the current provisions of 40 CFR part 63, subpart XXXX, until the applicable compliance date of the amended rule. The final action is not a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10).

For all affected sources that commence construction or reconstruction on or before November 16, 2023, we are proposing that it is necessary to provide 3 years after the effective date of the final rule (or upon startup, whichever is later) for owners and operators to comply with the provisions of this action. For all affected sources that commence construction or reconstruction after November 16, 2023, we are proposing that owners and operators comply with the provisions by the effective date of the final rule (or upon startup, whichever is later).

We solicit comment on these proposed compliance periods, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended provisions and the time needed to make the adjustments for compliance with any of the revised provisions. We note that information provided may result in changes to the proposed compliance dates.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

As listed in CFR 63.5982 (b)(4), the rubber processing affected source is the collection of all rubber mixing processes (*e.g.,* banburys and associated drop mills) that either mix compounds or warm a rubber compound before the compound is processed into components of rubber tires. The mixed rubber compound itself is also included in the rubber processing affected source. Among the 15 major sources that are subject to the NESHAP, 12 facilities perform rubber processing, while 3 facilities do not perform rubber processing and use rubber that is processed at other facilities. One rubber tire major source is now closed but has a currently active title V permit.

B. What are the air quality impacts?

This action proposes first-time MACT floor emission standards for THC (as a surrogate for organic HAP), metal HAP, and fPM from rubber processing. These first-time MACT floor emission standards will limit HAP emissions and require, in some cases, the installation of additional controls at rubber tire manufacturing plants that are major sources of HAP. We estimate that the rubber tire manufacturing industry will comply with the proposed standards for THC, metal HAP, and fPM through the installation and operation of control devices.

For THC, we estimate that the installation of RTOs or similar control devices will achieve annual reductions of THC of 909.6 Mg (996 tons) across the source category.

For fPM and metal HAP, we estimate that the replacement or upgrade of fabric filter baghouses will achieve annual reductions of fPM of 7.92 Mg (8.72 tons) or 0.14 Mg (318 pounds) of metal HAP across the source category.

Indirect or secondary air emissions impacts are impacts that would result from the increased energy usage associated with the operation of control devices (*e.g.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts are due to use of natural gas needed to operate control devices and other equipment. We propose to conclude that the secondary impacts of this action are minimal, resulting from the operation of the control device, and would comprise CO_2 and fugitive methane (CH_4) emissions from the combustion of the natural gas required to maintain an RTO.

C. What are the cost impacts?

This action proposes MACT floor emission limits for new and existing sources in the Rubber Tire Manufacturing source category, specifically the rubber processing subcategory. Although the action contains proposed requirements for new sources, we are not aware of any new sources being constructed now or planned in the next 3 years, and, consequently, we did not estimate any cost impacts for new sources. We estimate the total annualized cost of the proposed rule to existing sources in the Rubber Tire Manufacturing source category to be $20.8 million per year. The costs are a combination of the annualized capital and annual operating costs for installing and operating RTOs or similar control devices to control THC and organic HAP; baghouses and associated BLDSs to control PM and metal HAP; and THC CEMS to monitor THC emissions. The capital and annual costs are summarized in table 6.

TABLE 6—SUMMARY OF CAPITAL AND ANNUAL COSTS

Cost element	Total capital investments (million)	Annualized equipment and operation and maintenance costs (million)
RTOs (23 new)	$71.9	$12.7
Baghouses (39 new and 29 upgraded)	13.7	1.8
THC CEMS (97 new)	14.0	4.2
BLDS and PM Testing	2.2	1.4
Recordkeeping and Reporting Costs	.....	0.7
Totals	101.8	20.8

The estimated annual costs are based on operation and maintenance of the added control systems. A memorandum titled *Rubber Processing Control Costs, Emission Reductions, And Cost Effectiveness,* includes details of our cost assessment and is included in the docket for this action (Docket ID EPA–HQ–OAR–2019–0392).

D. What are the economic impacts?

The EPA conducted economic impact analyses for the proposed rule, as detailed in the memorandum, *Economic Impact and Small Business Analysis for the National Emission Standards for Hazardous Air Pollutants: Rubber Tire Manufacturing Amendments, Proposal,* which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0392). The economic impacts of the proposed rule are calculated as the percentage of total annualized costs incurred by affected ultimate parent owners to their revenues. This ratio provides a measure of the direct economic impact to ultimate parent owners of facilities while presuming no impact on consumers. We estimate that none of the ultimate parent owners affected by this proposed rule will incur total annualized costs of 1 percent or greater of their revenues. Thus, these economic impacts are low for affected companies and the industry impacted by the proposed rule, and there will not be substantial impacts on the markets for affected products. The costs of the proposed rule are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms.

E. What are the benefits?

The benefits of this rule include any benefits relating to the reduction of emissions of HAP or surrogates of HAP. Reduction of emissions of $PM_{2.5}$ will result in associated reduction in $PM_{2.5}$-related mortality and morbidity. Ecosystem effects related to deposition of sulfur will also be avoided.

F. What analysis of environmental justice did we conduct?

The EPA defines environmental justice as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' [5] The EPA further defines fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.'' In recognizing that communities with environmental justice concerns often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,*[6] which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The technical guidance states that a regulatory action may involve potential environmental justice concerns if it could: (1) Create new disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; (2) exacerbate existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; or (3) present opportunity to address existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples through this action under development.

The demographic analysis was conducted for the 2020 RTR. There are no known changes that would increase demographic risk, thus the EPA relied on the 2020 demographic analysis for this rulemaking. The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Rubber Tire Manufacturing Source Category Operations,* made available in the 2020 action; see Docket ID No. EPA–HQ–OAR–2019–0392.

In the 2020 RTR, the EPA examined the potential for the 21 source category facilities to pose concerns to communities living in proximity to facilities. Specifically, the EPA analyzed how demographics and risk are distributed pre-control, enabling us to address the core questions that are posed in the EPA's 2016 *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis.*

To examine the potential for environmental justice concerns, the EPA conducted a baseline proximity analysis and baseline risk-based analysis (*i.e.,* before implementation of any controls proposed by this action). The baseline proximity demographic analysis is an assessment of individual demographic groups in the total population living within 5 kilometers (km) (approximately 3.1 miles) and 50 km (approximately 31 miles) of the facilities. The baseline risk-based demographic analysis is an assessment of risks to individual demographic groups in the population living within 5 km and 50 km of the facilities prior to the implementation of any controls proposed by this action. The results of the proximity analysis for populations living within 50 km are included in the document titled *Analysis of Demographic Factors for Populations Living Near Rubber Tire Manufacturing Source Category Operations,* which is available in the docket for this action.

Under the risk-based demographic analysis, the total population, population percentages, and population count for each demographic group for the entire U.S. population are shown in the column titled ''Nationwide Average for Reference'' in table 7 of this document. These national data are provided as a frame of reference to compare the results of the proximity analysis and the baseline risk-based analysis.

The results of the proximity analysis indicate that a total of approximately 516,000 people live within 5 km of the 21 Rubber Tire Manufacturing facilities. The percent of the population that is African American (24 percent) is double the national average (12 percent). The percent of people living below the poverty level and the percent of people over the age of 25 without a high school diploma are higher than the national averages. The results of the baseline proximity analysis indicate that the proportion of other demographic groups living within 5 km of Rubber Tire Manufacturing facilities is similar to or below the national average. The baseline risk-based demographic analysis, which focuses on populations that have higher cancer risks, suggests that African Americans and people living below the poverty level are overrepresented at all cancer risk levels greater than 1-in-1 million. At all risk levels, in most cases, populations living around facilities where the percentage of the population below the poverty level is 1.5 to 2 times the national average also are above the national average for African American, Native American, Hispanic/Latino, or Other/Multiracial.

a. Baseline Proximity Analysis

The column titled ''Baseline Proximity Analysis for Pop. Living within 5 km of Rubber Tire Manufacturing Facilities'' in table 7 of this preamble shows the share and count of people for each of the demographic categories for the total population living within 5 km (approximately 3.1 miles) of Rubber Tire Manufacturing facilities. These are the

[5] *https://www.epa.gov/environmentaljustice.*

[6] See *https://www.epa.gov/environmentaljustice/technical-guidance-assessing-environmental-justice-regulatory-analysis.*

results of the baseline proximity analysis.

Approximately 516,000 people live within 5 km of the 21 Rubber Tire Manufacturing facilities assessed. The results of the proximity demographic analysis indicate that the percent of the population that is African American (24 percent, 124,000 people) is double the national average (12 percent). The percent of the people living below the poverty level (21 percent, 108,000 people) and percent of people over the age of 25 without a high school diploma (16 percent, 83,000 people) are higher than the national averages (14 percent and 14 percent, respectively). The baseline proximity analysis indicates that the proportion of other demographic groups living within 10 km of Rubber Tire Manufacturing facilities is similar to or below the national average.

b. Baseline Risk-Based Demographics

The baseline risk-based demographic analysis results are shown in the furthest right column of table 7 of this preamble. This analysis focused on the populations living within 5 km (approximately 3.1 miles) of the Rubber Tire Manufacturing facilities with estimated cancer risks greater than or equal to 1-in-1 million resulting from source category emissions (table 7 of this preamble). The risk analysis indicated that emissions from the source category, prior to the controls we are proposing, expose approximately 4,500 people living near 21 facilities to a cancer risk at or above 1-in-1 million and expose no people to a chronic noncancer target organ-specific hazard index (TOSHI) greater than 1.

In baseline, there are 4,500 people living around 21 Rubber Tire Manufacturing facilities with a cancer risk greater than or equal to 1-in-1-million resulting from Rubber Tire Manufacturing source category emissions. The percent of the baseline population with estimated cancer risks great than or equal to 1-in-1 million who are African American (25 percent, 1,000 people) is more than 2 times the average percentage of the national population that is African American (12 percent). The percent of the population with cancer risks greater than or equal to 1-in-1 million resulting from Rubber Tire Manufacturing source category emissions prior to the proposed controls that is Below the Poverty Level (21 percent, 1,000 people) is similar to that in the baseline proximity analysis (21 percent, 108,000 people).

TABLE 7—SOURCE CATEGORY: COMPARISON OF BASELINE DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION RESULTING FROM RUBBER TIRE MANUFACTURING SOURCE CATEGORY EMISSIONS LIVING WITHIN 5 km OF FACILITIES TO THE NATIONAL AVERAGE AND PROXIMITY DEMOGRAPHICS

Demographic group	Nationwide average for reference (million or "M")	Baseline proximity analysis for pop. living within 5 km of rubber tire manufacturing facilities (thousand or "K")	Cancer risk ≥1-in-1 million within 5 km of rubber tire manufacturing facilities ("baseline")
Total Population	328 M	515,800	4,524.
Race and Ethnicity by Percent:			
White	60 percent [197M]	63 percent [325K]	66 percent [3K].
Minority	40 percent [131M]	37 percent [191K]	34 percent [2K].
Race and Ethnicity by Percent:			
African American	12 percent [40M]	24 percent [124K]	25 percent [1K].
Native American	0.7 percent [2M]	0.7 percent [4K]	0 percent [0].
Hispanic or Latino (includes white and nonwhite).	19 percent [62M]	5 percent [26K]	3 percent [100].
Other and Multiracial	8 percent [27M]	8 percent [41K]	6 percent [300].
Income by Percent:			
Below Poverty Level	13 percent [44M]	21 percent [108K]	21 percent [1K].
Above Poverty Level	87 percent [284M]	79 percent [407K]	79 percent [4K].
Education by Percent:			
Over 25 and without a High School Diploma.	12 percent [40M]	16 percent [83K]	12 percent [500].
Over 25 and with a High School Diploma.	88 percent [288M]	84 percent [433K]	88 percent [4K].
Linguistically Isolated by Percent:			
Linguistically Isolated	5 percent [18M]	2 percent [10K]	1 percent [50].

Notes: Nationwide population and demographic percentages are based on Census's 2015–2019 American Community Survey (ACS) 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

G. What analysis of children's environmental health did we conduct?

In the July 24, 2020, final Rubber Tire Manufacturing RTR rule (85 FR 44752), the EPA conducted a residual risk assessment and determined that risk from the Rubber Tire Manufacturing source category was acceptable, and the standards provided an ample margin of safety to protect public health (see Docket Item No. EPA–HQ–OAR–2019–0392–0013). There are no known changes that would increase risk, thus the EPA relied on the 2020 demographic analysis for this rulemaking. In addition, this action proposes first-time emissions standards for THC and filterable PM & metal HAP) for the rubber processing subcategory, which will further reduce emissions. Specifically, we estimate that the new emission limits will reduce THC and filterable PM emissions by 996 tpy and 8.72 tpy, respectively.

This action's health and risk assessments are protective of the most vulnerable populations, including children, due to how we determine exposure and through the health benchmarks that we use. Specifically, the risk assessments we perform assume a lifetime of exposure, in which populations are conservatively presumed to be exposed to airborne concentrations at their residence continuously, 24 hours per day for a 70-year lifetime, including childhood. With regards to children's potentially greater susceptibility to noncancer toxicants, the assessments rely on the EPA's (or comparable) hazard identification and dose-response values that have been

developed to be protective for all subgroups of the general population, including children.

VI. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are interested in additional data that may improve the analyses. We are specifically interested in receiving any information regarding developments in practices, processes, and control technologies that reduce HAP emissions for the rubber processing sub-category within the Rubber Tire Manufacturing source category.

VII. Submitting Data Corrections

The site-specific emissions data used in setting MACT standards for THC and fPM/Metal HAP as emitted from the Rubber Tire Manufacturing source category are available at *https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous.*

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any ''improved'' data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. Your data should be prepared using our Electronic Reporting Tool (ERT), whose instructions are available at the internet address *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert,* and your ERT files should be submitted to our Compliance and Emissions Data Reporting Interface (CEDRI). Be sure to include a complete copy of the relevant test reports as a portable document format (PDF) file as an attachment to your ERT file.

For information on how to submit comments, including the submittal of data corrections, refer to the instructions provided in the introduction of this preamble.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1982.06. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

We are proposing changes to the reporting and recordkeeping requirements for the Rubber Tire Manufacturing NESHAP by incorporating the reporting and recordkeeping requirements associated with the new and existing source MACT standards proposed for the rubber processing subcategory source.

Respondents: Rubber tire manufacturing facilities conducting rubber processing operations.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart XXXX).

Estimated number of respondents: 12.

Frequency of response: Initially, semiannually, annually.

Estimated Annual burden: The average annual burden to industry over the next 3 years from the proposed recordkeeping and reporting requirements is estimated to be 2,121 hours per year. Burden is defined at 5 CFR 1320.3(b).

Estimated Annual cost: The annual recordkeeping and reporting costs for all facilities to comply with all of the requirements in the NESHAP is estimated to be $2.13 million per year. This includes labor costs of $258,000 per year and non-labor capital and O&M costs of $1.87 million per year for monitoring systems for the proposed rubber processing amendments when they are fully implemented.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. The EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. OMB must receive comments no later than December 18, 2023.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The Agency has determined that none of the four ultimate parent companies owning the potentially affected facilities are small entities, as defined by the U.S. Small Business Administration. Details of this analysis are presented in ''*Economic Impact and Small Business Analysis for the National Emission Standards for Hazardous Air Pollutants: Rubber Tire Manufacturing Amendments, Proposal,*'' which is located in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0392).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in the Unfunded Mandates Reform Act, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. The EPA does not know of any rubber tire manufacturing facilities owned or operated by Indian Tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why

the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action proposes emission standards for a currently unregulated emission source; therefore, the rule should result in health benefits to children by reducing the level of HAP emissions emitted from the rubber tire manufacturing process.

However, EPA's Policy on Children's Health applies to this action. Information on how the Policy was applied is available under ''Children's Environmental Health'' in the **SUPPLEMENTARY INFORMATION** section of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. Therefore, the EPA conducted searches for the Rubber Tire Manufacturing NESHAP through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute. We also conducted a review of voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 5, 25A, 29, SW–846, M0010, SW–846 M3542, SW–846, M8270E, M204, PS 8A, and QA Procedure 2. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to that of the EPA's referenced method, the EPA ordered a copy of the standard and reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering, and policy equivalence to procedures in the EPA referenced methods. The EPA may reconsider determinations of impracticality when additional information is available for any particular VCS.

Two voluntary consensus standards were identified as acceptable alternatives to EPA test methods for the purposes of this rule. The voluntary consensus standard ANSI/ASME PTC 19–10–1981—Part 10 (2010), ''Flue and Exhaust Gas Analyses,'' is an acceptable alternative to EPA Method 3B (the manual portion only and not the instrumental portion).

The voluntary consensus standard ASTM D6784–16—Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method) D6784–16 was reapproved in 2016 to include better quality control than earlier 2008 version. It is an acceptable alternative to EPA Methods 101A and Method 29 (portion for particulate mercury only) as a method for measuring mercury. [Note: this acceptability applies to concentrations between approximately 0.5 and 100 µg/Nm^3].

The EPA proposes to incorporate by reference the VCS ANSI/ASME PTC 19.10–1981- Part 10 (2010), ''Flue and Exhaust Gas Analyses.'' The manual procedures (but not instrumental procedures) of VCS ANSI/ASME PTC 19.10–1981—Part 10 may be used as an alternative to EPA Method 3B for measuring the oxygen or carbon dioxide content of the exhaust gas. This standard is acceptable as an alternative to EPA Method 3B and is available from ASME at *http://www.asme.org;* by mail at Three Park Avenue, New York, NY 10016–5990; or by telephone at (800) 843–2763. This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. The gases covered in ANSI/ASME PTC 19.10–1981 are oxygen, carbon dioxide, carbon monoxide, nitrogen, sulfur dioxide, sulfur trioxide, nitric oxide, nitrogen dioxide, hydrogen sulfide, and hydrocarbons; however, the use in this rule is only applicable to oxygen and carbon dioxide.

The EPA proposes to incorporate by reference the VCS ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)'' as an acceptable alternative to EPA Method 29 (particulate portion for mercury only) as a method for measuring mercury concentrations ranging from approximately 0.5 to 100 micrograms per normal cubic meter. This test method describes equipment and procedures for obtaining samples from effluent ducts and stacks, equipment and procedures for laboratory analysis, and procedures for calculating results. VCS ASTM D6784–16 allows for additional flexibility in the sampling and analytical procedures for the earlier version of the same standard VCS ASTM D6784–02 (Reapproved 2008).

Detailed information on the VCS search and determination can be found in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Rubber Tire Manufacturing Amendments,* which is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2017–0329). The 2 VCS may be obtained from *https://www.astm.org* or from the ASTM Headquarters at 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania 19428–2959.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action do not result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns.

The EPA additionally identified and addressed environmental justice concerns in the demographic analysis conducted for the 2020 RTR. There are no known changes that would increase demographic risk, thus the EPA relied on the 2020 demographic analysis for this rulemaking. The methodology and the results of the demographic analysis are presented in section V.F. of this preamble, as well as in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Rubber Tire Manufacturing Source Category Operations,* made available in the 2020 action; see Docket ID No. EPA–HQ–OAR–2019–0392.

The EPA believes that this action is likely to reduce existing adverse effects on communities with environmental justice concerns. The EPA is proposing MACT standards for THC as a surrogate for organic HAP and PM as a surrogate for metal HAP. EPA expects that facilities may have to implement control measures to reduce emissions to comply with the MACT standards and that HAP exposures for the communities with environmental justice concerns living near these facilities would decrease.

The EPA will additionally identify and address environmental justice concerns by conducting outreach after signature of this proposed rule. The EPA will reach out to tribes through a monthly policy call and with consultation letters. The EPA will address this rule during the monthly Environmental Justice call for communities burdened by disproportionate environmental impacts. The information supporting this Executive Order review is contained in section V.F of this preamble.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

[FR Doc. 2023–25276 Filed 11–15–23; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 501, 502, 538, and 552

[GSAR Case 2020–G510; Docket No. GSA–GSAR–2023–0025; Sequence No. 1]

RIN 3090–AK20

General Services Administration Acquisition Regulation; Federal Supply Schedule Economic Price Adjustment

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Services Administration is proposing to amend the General Services Administration Acquisition Regulations to standardize and simplify the Multiple Award Schedule (Schedule) clauses for economic price adjustments. This rule removes certain economic price adjustment requirements within these clauses to better align with commercial standards and practices.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before January 16, 2024 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to GSAR Case 2020–G510 to: *https://www.regulations.gov* via the Federal eRulemaking portal by searching for ''GSAR Case 2020–G510''. Select the link ''Comment Now'' that corresponds with GSAR Case 2020–G510. Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''GSAR Case 2020–G510'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite GSAR Case 2020–G510, in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. Thomas O'Linn, Procurement Analyst at *gsarpolicy@gsa.gov* or 202–445–0390. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at *GSARegSec@gsa.gov* or 202–501–4755. Please cite GSAR Case 2020–G510.

SUPPLEMENTARY INFORMATION:

I. Background

The General Services Administration (GSA) conducts routine reviews of its acquisition regulations and acquisition policies and procedures. The review indicated a need to standardize and simplify the Schedule clause for economic price adjustments.

The Schedule program, also known as the Federal Supply Schedule (FSS) program, establishes long-term governmentwide contracts with commercial companies. Schedule contracts routinely last up to 20 years and are issued as fixed price with economic price adjustment (EPA) Indefinite Delivery Indefinite Quantity (IDIQ) contracts. Schedule contracts provide access to commercial products, services, and solutions at fair and reasonable pricing to the Federal Government and other authorized customers (*e.g.,* state and local governments).

The use of EPA provides for upward and downward revision of contract pricing upon the occurrence of specified conditions over the anticipated 20 year contract period of performance. The Schedule program has a long history of providing the ability for Schedule contractors to submit EPA requests (*e.g.,* see 47 FR 50242 dated November 5, 1982).

Currently, Schedule contracts contain at least one of the following EPA clauses (*i.e.,* a Schedule contract may include more than one EPA clause based on their offering and participation in Transactional Data Reporting (TDR)): (1) Alternate I of GSAR clause 552.216–70, Economic Price Adjustment-FSS Multiple Award Schedule Contracts; (2) an authorized deviation of GSAR clause 552.216–70; (3) clause I–FSS–969, Economic Price Adjustment-FSS Multiple Award Schedule; or (4) an Alternate to clause I–FSS–969. The primary focus of these EPA clauses is the establishment of the procedures, including, but not limited to specific procedural limits (*e.g.,* timing and frequency) around the submission of EPA price increase requests. In terms of price decrease requests, all four clauses require such requests to be handled in accordance with GSAR clause 552.238–81, Price Reductions. Altogether, for the most part these four Schedule EPA clauses are very similar, with only minor differences, most of which are related to the EPA mechanism(s) proposed by the contractor (*e.g.,* annual fixed increases or increases based on their published or publicly available commercial price list) and the applicability of TDR.

In March 2022, in response to the highest level of inflation in over 40 years as well as other factors (*e.g.,* supply chain disruptions), GSA issued Acquisition Letter MV–22–02 to provide a temporary moratorium on the enforcement of certain procedural limits contained in the Schedule EPA clauses. The moratorium relaxes the limits on the frequency, timing, and number of EPA price increase requests.

Since the issuance of Acquisition Letter MV–22–02, the Schedule program has seen benefits. The relaxing of these procedural limits has provided industry Schedule partners with greater flexibility and agility in response to market changes and economic conditions that impact their Schedule pricing. This flexibility has increased their ability to support federal customers in acquiring critically needed products, services, and solutions through a single contracting action. In the absence of this flexibility, they would likely have chosen not to respond to order-level solicitations and/or requested the removal of the items from their Schedule contract to avoid selling them at a loss. The loss of such items under such conditions, increases the administrative costs and time for federal agencies and other customers in meeting their needs.

The positive results of Acquisition Letter MV–22–02 underscore the need for the Schedule program to continually evolve and provide a viable and

competitive vendor base for needed products, services, and solutions at competitive prices. The absence of items from the competitive marketplace increases the administrative cost for the Government, customers, and Schedule contractors; reduces the efficacy of the Schedule program; and undercuts objectives to support small business especially in underserved communities.

GSA is seeking to standardize and simplify the Schedule clauses for EPA. The revisions will result in the consolidation of the four existing Schedule EPA clauses into a single Schedule EPA clause. The revisions will also remove several procedural limits contained in these clauses to better align with commercial standards and practices. GSA anticipates these changes will increase the number and extent of offerings available through the Schedule program, improve customer satisfaction by ensuring needed products, services, and solutions are initially offered and are not removed from the Schedule program, and reduce administrative costs on Schedule contractors, particularly small businesses and new entrants.

II. Discussion and Analysis

This proposed rule amends the GSAR to standardize and simplify the Schedule clauses related to economic price adjustments. A summary of the revisions is as follows:

A. GSAR clause 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts, is being revised, renumbered, and renamed 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts. The clause is being renumbered to be consistent with the numbering used for Schedule provisions and clauses. The current clause number reflects the clause being located in GSAR part 516. This is inconsistent with the current practice of locating Schedule provisions and clauses within GSAR part 538, specifically section 538.273. The clause is being renamed to remove the words ''Multiple Award Schedule'' since it is duplicative of the acronym ''FSS'' that is already included in the clause title. The clause title is also being renamed in order to spell out the acronym ''FSS''. Spelling out of the acronym ''FSS'' is consistent with the current practice of using the words ''Federal Supply Schedule'' in GSAR provision and clause titles where appropriate.

The revisions to the clause itself provide for the: (1) standardization and simplification of existing Schedule EPA requirements; (2) retention of the Schedule Contracting Officer's authority to reject, accept, or partially accept an EPA request; (3) creation of a definition for ''economic price adjustment method'' for the purpose of formalizing within resultant contracts offerors' proposed EPA mechanism(s), the applicable pricing subject to EPA, and any other agreed upon requirements; (4) clarification on what is not covered by an EPA request; (5) ability for the EPA method to be revised via mutual agreement during contract performance; and (6) establishment of a single consolidated Schedule EPA clause.

Currently, the Schedule solicitation contains the following provision: SCP–FSS–001, Instructions Applicable to All Offerors. Paragraph (i)(3)(v) of this provision requests offerors propose an EPA mechanism. The EPA mechanisms available within the Schedule solicitation for offerors to choose from are: a published or publicly-available commercial price list; a fixed annual escalation rate; and relevant market indicator (*e.g.,* the Bureau of Labor Statistics Employment Cost Index (ECI)). Paragraph (c) of the clause I–FSS–969 also includes the ability to determine an appropriate mechanism in response to unforeseeable major changes in market conditions.

Schedule contracts currently contain at least one of the following clauses: (1) Alternate I of GSAR clause 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts; (2) an authorized deviation of GSAR clause 552.216–70; (3) clause I–FSS–969, Economic Price Adjustment—FSS Multiple Award Schedule; or (4) an Alternate to clause I–FSS–969. The incorporation of one or more of these clauses into a Schedule contract is dependent on the EPA mechanism(s) proposed by the offeror and whether the offeror elected to participate in TDR. For example, the authorized deviation to GSAR clause 552.216–70 applies to Schedule contracts subject to TDR that use published or publicly-available commercial price lists as the EPA mechanism. These four Schedule EPA clauses include essentially the same requirements (*e.g.,* timing, number, and frequency of EPA price increase requests), with only minor differences, most of which are related to the clause prescription (*i.e.,* type of EPA mechanism selected by the contractor and applicability of TDR).

In consideration of the above existing requirements, the revised clause seeks to consolidate the four existing EPA clauses into a single clause. The new clause maintains GSA's responsibility to: ensure schedules operate at the lowest overall cost alternative and feature fair and reasonable pricing at the Schedule level throughout contract performance; review, process, and, if necessary, negotiate EPA requests. This could mean accepting, rejecting, or partially accepting EPA requests. For example, paragraph (f) of the revised clause maintains the Schedule contracting officer's options in response to an EPA request. Currently, this requirement is found within each of the four EPA clauses (*e.g.,* see paragraph (f) of clause I–FSS–969).

The revised clause moves GSA closer to the commercial marketplace and provides greater flexibility and agility in terms of responding to market changes, economic conditions, and Government/customer requirements. For example, due to the inflexibility of the existing Schedule EPA clauses some Schedule contractors have removed items from their Schedule contract to avoid selling those items at a loss. The absence of such items has an unnecessary negative impact on the Schedule program. The lack of items on the Schedule program directly impacts competition and the availability of needed items; increases administrative costs to the Government, customers, and Schedule contractors; reduces the efficacy of the Schedule program; and undercuts the objectives to support small businesses and new entrants.

B. Alternate I of GSAR clause 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts, is being deleted in its entirety. The Alternate is being deleted because it is no longer necessary as a result of the aforementioned revisions. The newly created GSAR clause 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts, addresses Schedule EPA requirements.

C. Section 538.273, FSS solicitation provisions and contract clauses, is being revised to provide for the prescription of the newly created GSAR clause 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts. Section 538.273 is the appropriate location for the prescription of this new clause because this is the section that provides the prescription for Schedule provisions and clauses.

D. GSAR clause 552.238–115, Special Ordering Procedures for the Acquisition of Order-Level Materials, is being revised to update paragraph (d)(10)(i) from ''552.216–70 Economic Price Adjustment—FSS Multiple Award Schedule Contracts'' to ''552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts.'' This revision is appropriate because 552.238–118 is the GSAR clause that is

replacing the GSAR clause 552.216–70 under the proposed revisions.

E. Section 502.101 Definitions, is being revised to add the definition for EPA method.

F. The table in section 501.106 OMB Approval under the Paperwork Reduction Act, is being revised to reflect the proposed revisions and existing requirements not currently shown in the table.

III. Expected Impact of the Rule

GSA believes that these changes benefit the Schedule program as a whole. For example, GSA anticipates that these changes will increase the number and extent of offerings available through the Schedule program, improve customer satisfaction/reduce customer cost by ensuring needed products, services, and solutions are not removed from the Schedule program due to market volatility, and reduce administrative costs on Schedule contractors, particularly small businesses and new entrants.

GSA receives hundreds of modification requests each month from contractors to remove items from their Schedule contracts or declined orders due to price variability in the commercial market. By statute, the procedures for the Schedule program are competitive so long as they are open to all and contracts and orders results in the lowest overall cost alternative. GSA anticipates this rule will help it ensure customers experience the lowest overall cost alternative on their orders by maximizing the chance that full solutions are available on the Schedule contract, thus minimizing the need to conduct multiple separate acquisitions to fulfill a requirement.

Currently, Schedule contracts include at least one of the following four clauses related to the submission and processing of EPA requests during contract performance: (1) an authorized deviation to GSAR clause 552.216–70; (2) Alternate I of GSAR clause 552.216–70; (3) clause I–FSS–969; or (4) an Alternate of clause I–FSS–969. These changes standardize and simplify the EPA requirements contained in these four clauses. These changes will result in the consolidation of these clauses into a single Schedule EPA clause. These changes do not alter the way Schedule contractors conduct business, or their ability to submit an EPA request.

The qualitative anticipated benefits include, but are not limited to, the creation of a single standardized Schedule EPA clause; greater flexibility around EPA requests; providing clarity around EPA within the Schedule program; providing a connection between the Schedule solicitation and resultant contracts; and greater flexibility and agility for purposes of responding to changing conditions.

GSA anticipates the quantitative benefits to be related to improved regulatory familiarization. GSA calculates the estimated total cost for Schedule contractors to familiarize themselves with existing EPA requirements as $3,251,640 (*i.e.,* 3 hours * $77.42 [1] (GS–12 Step 5 base pay plus ''Rest of US Locality Pay'' plus ''Fringe'') * 14,000 approximate number of current Schedule contractors)). After these revisions: GSA estimates the total cost as $2,709,700 (*i.e.,* 2.5 hours * $77.42 (GS–12 Step 5 base pay plus ''Rest of US Locality Pay'' plus ''Fringe'') * 14,000 approximate number of current Schedule contractors)). Resulting in a reduction in estimated total cost of $541,940.

IV. Executive Orders 12866, 13563, and 14094

Executive Order (E.O.) 12866 (Regulatory Planning and Review) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. E.O. 14094 (Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in E.O. 12866 and E.O. 13563. OIRA has determined that this rule is not a significant regulatory action, and, therefore, is not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

V. Regulatory Flexibility Act

GSA does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule is to standardize and simplify existing EPA requirements related to Schedules (*e.g.,* revise GSAR clause 552.216–70, Economic Price Adjustment-FSS Multiple Award Schedule Contracts). The underlying purpose of the changed text remains the same (*i.e.,* supporting the submission and processing of EPA requests), and therefore any burden would have been identified previously. However, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared consistent with 5 U.S.C. 603.

The Regulatory Secretariat Division will be submitting a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. GSA invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

GSA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (GSAR Case 2020–G510), in correspondence.

The analysis is summarized as follows:

The objective of the rule is to standardize and simplify the clauses for Schedule related to EPA. These revisions will result in the consolidation of the four existing Schedule clauses into a single Schedule EPA clause. These revisions also remove certain procedural limits contained in these clauses to better align with commercial standards and practices. GSA anticipates that these changes will increase the number and extent of offerings available through the Schedule program, improve customer satisfaction/reduce customer costs by ensuring needed products, services, and solutions are not removed from the Schedule, and reduce administrative costs on Schedule contractors, particularly small businesses and new entrants.

Title 40 of the United States Code (U.S.C.) Section 121 authorizes GSA to issue regulations, including the GSAR, to control the relationship between GSA and contractors. In addition, 41 U.S.C. 152 provides GSA authority over the Schedule program.

The rule applies to both large and small businesses, which are awarded Schedule contracts. Information obtained from FAS as well as the recent renewal of Information Collections 3090–0235 and 3090–0306 were used as the basis for estimating the number of Schedule contractors that this rule may impact. For Fiscal Year 2022 there were approximately 14,000 Schedule contractors, of which over 12,000 (85 percent) were small business entities. In addition, according to the recent renewal of Information Collections 3090–0235 and 3090–0306, GSA processes approximately 2,561 EPA requests annually. GSA anticipates this rule will not significantly impact this number.

The rule does not implement new or changed reporting, recordkeeping, or other

[1] 2023 Rest of US, 12 Step 5 × 2.0 fringe = $77.42; the rate is adjusted upward by 100% to adjust for overhead and benefits.

compliance requirements for Schedule contracts. The rule merely updates and clarifies existing EPA requirements currently used in Schedule contracts.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives to this rule which would accomplish the stated objectives. This rule does not initiate or impose any new administrative or performance requirements on small business contractors because the requirements prescribed in existing Schedule EPA clauses are already being followed. The rule merely updates and clarifies these existing requirements so as to reduce burden for both the government and contractors as it relates to EPA within Schedule contracts.

VI. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 3501) does apply; however, these changes do not impose additional information collection requirements to the burden previously approved under the Office of Management and Budget (OMB) Control Number 3090–0235, titled: Federal Supply Schedule Pricing Disclosures and Sales Reporting and OMB Control Number 3090–0306, titled: Transactional Data Reporting. Both OMB information collections, however, will be updated to reflect the change in the clause title and number from 552.216–70, Economic Price Adjustment—FSS Multiple Award Schedule Contracts, to 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts.

List of Subjects in 48 CFR Parts 501, 502, 538, and 552

Government procurement.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA proposes to amend 48 CFR parts 501, 502, 538, and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 501, 502, 538, and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 501—GENERAL SERVICES ADMINISTRATION ACQUISITION REGULATION SYSTEM

■ 2. In section 501.106 amend Table 1 by—

■ a. Revising the entry for ''516.506'';

■ b. Removing the entry for ''552.216–70 and its corresponding OMB Control No.; and

■ c. Adding in numerical order, entries for ''552.238–83'' and ''552.238–118''.

The revision and additions read as follows:

GSAR reference	OMB control No.
* *	* *
516.506	3090–0248, 3090–0306.
* *	* *
552.238–83	3090–0235, 3090–0306.
* *	* *
552.238–118	3090–0235.
* *	* *

PART 502—DEFINITIONS OF WORDS AND TERMS

■ 3. Amend section 502.101 by adding in alphabetical order, the definition of ''Economic Price Adjustment (EPA) Method'' to read as follows:

502.101 Definitions.

* * * * *

Economic Price Adjustment (EPA) method means the agreed upon procedure by which pricing may be adjusted throughout the contract period to include, but not limited to, the mechanism(s) to be used to adjust pricing (*e.g.,* adjustments based on established pricing), the pricing subject to adjustment, and any other requirements (*e.g.,* timing, frequency, limits on increases.

* * * * *

PART 538—FEDERAL SUPPLY SCHEDULE CONTRACTING

■ 4. Amend section 538.273 by adding paragraph (d)(38) to read as follows:

538.273 FSS solicitation provisions and contract clauses.

* * * * *

(d) * * *

(38) 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts. Use in Federal Supply Schedule solicitations and contracts.

* * * * *

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

552.216–70 [Removed]

■ 5. Remove section 552.216–70.

■ 6. Amend section 552.238–115 by revising the date of the clause and paragraph (d)(10)(i) to read as follows:

552.238–115 Special Ordering Procedures for the Acquisition of Order-Level Materials.

* * * * *

Special Ordering Procedures for the Acquisition of Order-Level Materials (DATE)

* * * * *

(d) * * *

(10) * * *

(i) 552.238–118, Economic Price Adjustment—Federal Supply Schedule Contracts.

* * * * *

■ 7. Add section 552.238–118 to read as follows:

552.238–118 Economic Price Adjustment—Federal Supply Schedule Contracts.

As prescribed in 538.273(d), insert the following clause:

552.238–118 Economic Price Adjustment—Federal Supply Schedule Contracts (DATE)

(a) *Definition.*

Economic price adjustment method, as used in this clause, means the agreed upon procedures by which pricing may be adjusted throughout the contract period to include, but not limited to, the mechanism(s) to be used to adjust pricing (*e.g.,* adjustments based on established pricing), the pricing subject to adjustment, and any other requirements (*e.g.,* timing, frequency, limits on increases).

(b) *General.* This contract provides for economic price adjustment (EPA) to contract pricing based on the established EPA method. EPA provides for the increase and decrease to stated contract pricing upon the occurrence of specified conditions described in the EPA method, such as market index changes or unforeseeable significant changes in market conditions.

(c) *Exceptions.* This clause does not cover—

(1) Adjustments based on statute, Executive Order, or regulation (*e.g.,* Service Contract Labor Standards (41 U.S.C. chapter 67) and AbilityOne procurements (FAR subpart 8.7));

(2) Adjustments based on a change clause (*e.g.,* paragraph (c) of GSAR clause 552.212–4, Contract Terms and Conditions—Commercial Products and Commercial Services (FAR DEVIATION 52.212–4));

(3) Price reductions made under GSAR clause 552.238–81, Price Reductions;

(4) Adjustments based on GSAR clause 552.238–117, Price Adjustment-Failure to Provide Accurate Information; and

(5) Adjustments based on a contract clause that authorizes an adjustment based on specified actions or conditions.

(d) *Economic price adjustment method.* The EPA method may be revised through mutual agreement of the parties. In the event of a conflict between the EPA method and this contract, the contract shall control.

(e) *Submission requirements.* The Contractor shall submit EPA requests to the Federal Supply Schedule (FSS) Contracting Officer pursuant to the EPA method. EPA requests shall fully conform to the requirements of the EPA method and include sufficient information to support the request.

The FSS Contracting Officer may request additional information from the Contractor.

(f) *Contracting Officer responsibilities.* The FSS Contracting Officer will—

(1) Review the EPA request to ensure conformance with the EPA method,

(2) Make a determination. The FSS Contracting Officer may use any information (*e.g.,* market research) deemed necessary to support their determination. The FSS Contracting Officer may determine to—

(i) Accept the EPA request either in whole or in part,

(ii) Reject the EPA request either in whole or in part, or

(iii) Take any other action deemed to be in the best interest of the Government (*e.g.,* negotiate a more favorable EPA).

(3) Notify the Contractor of their determination, and

(4) Modify the contract, as applicable, to reflect the determination. Contract items that need to be removed from the contract as a result of rejection or an inability to reach agreement are to be removed in accordance with 552.238–79, Cancellation.

(g) *Effective date.* EPA requests approved by the FSS Contracting Officer under this clause shall apply to orders issued on or after the effective date of the contract modification. Blanket Purchase Agreements (BPAs) may be modified by the ordering agency in accordance with the terms and conditions of the BPA.

(h) *Update of contract pricing and catalog data.* The Contractor shall update its FSS pricing and any other FSS catalog data in accordance with the terms and conditions of this contract.

(End of clause)

[FR Doc. 2023–25221 Filed 11–15–23; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

RIN 0648–BK85

Magnuson-Stevens Fishery Conservation and Management Act; Seafood Import Monitoring Program

AGENCY: International Affairs, Trade, and Commerce, National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; withdrawal.

SUMMARY: The National Marine Fisheries Service (NMFS) withdraws the Seafood Import Monitoring Program (SIMP) proposed rule, which was published in the **Federal Register** on December 28, 2022. The SIMP proposed rule intended to add species to SIMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act. In addition, the proposed rule would have amended SIMP regulations to clarify the responsibilities and definitions, and make other necessary administrative modernizations. In light of the extensive public comments received regarding the December 2022 proposed rule, NMFS has decided to conduct a comprehensive program review in order to strengthen the impact and effectiveness of SIMP. Critical aspects of that review will include better defining the problem that we are working to address and establishing clear, achievable goals through constructive engagement with our stakeholders. Comments received on the December 2022 proposed rule will also be taken into consideration as part of the review. While NMFS conducts this comprehensive review, SIMP will continue to operate in its current form, all existing requirements remain in force, and the list of priority species currently subject to SIMP requirements remains unchanged. In addition, NMFS will continue to support industry and other stakeholders in SIMP compliance during the review.

DATES: The proposed rule published on December 28, 2022 (87 FR 79836) is withdrawn on November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Rachael Confair, Office of International Affairs, Trade, and Commerce, NMFS, 301–427–8361, *rachael.confair@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 28, 2022, NMFS issued its SIMP proposed rule (85 FR 58321). The proposed rule was initially open for 90 days of public comment, and this period was extended for an additional 30 days. It included a proposal to incorporate additional priority species in SIMP, as well as to make other administrative changes.

SIMP has been in effect for more than 1,100 unique species, representing 13 species groups, for approximately 4 years. SIMP was established as a screening tool to identify and deter products derived from Illegal, Unreported, and Unregulated (IUU) fishing, as well as misrepresented seafood from entering the U.S. market. The information required under SIMP can lead to the interdiction of IUU fish and fish products as they enter the United States, but it was not designed to achieve that outcome, nor has that been typically how it functions. It is primarily a permitting, reporting and recordkeeping program that conducts post-entry audits, and in some cases, enforcement inspections and, when potentially illegal imports are identified, follow-up investigations.

Program Review

It is clear, based on the comments received, combined with feedback received over the past few years, that this is the right time to review SIMP. There are a diverse array of viewpoints, and sometimes unrealistic expectations, on what SIMP should or could be doing. In order to strengthen our impact and effectiveness, it is important to better define our goals, and then identify clear mechanisms to achieve them.

As an integral part of this undertaking, NMFS will actively seek engagement and input from all relevant stakeholder groups, including industry, non-governmental organizations, other Federal agencies, congressional representatives, and foreign governments. NMFS intends to bring together an informal interagency working group to review our approach and identify possible strategies for increasing the effectiveness and impact of SIMP on countering IUU fishing and seafood fraud. This collaborative effort will also explore alternative or complementary approaches available to address seafood traceability for NMFS and its interagency partners. Some questions that NMFS will consider during the review are:

1. *Determine the goals:* What is the problem or problems that SIMP was designed to address? Are there changes that should be made to the goals? What do we want to achieve and what is the best way to do it?

2. *Determine whether the goals are achievable:* Are the goals feasible? What does success look like? Are there limitations of resources, technology, or other elements that must be considered in determining whether the goals are achievable?

3. *Determine what is needed to achieve the goals:* Are there additional authorities needed for NOAA or other agencies to achieve these goals? What new tools are needed to accomplish this goal? Are there existing tools that could be used more effectively? How can we use a whole-of-government approach to achieve these goals?

NMFS will review and consider all aspects of the Program, including the initial constraints that shaped SIMP's original framework. NMFS will use both the public comments received and internal and external program assessments to refine the areas of focus. NMFS also plans to conduct public listening sessions to solicit written and oral feedback from public stakeholders, as well as participating in other

engagement opportunities with stakeholders or groups of stakeholders.

The withdrawal of this proposed rule does not preclude NMFS from reinitiating rulemaking concerning the issues addressed in the proposed rule. Should that occur, NMFS will re-propose the action and provide new opportunities for comment. More information on SIMP and the NMFS review are available online at the Agency's website (*https://www.fisheries.noaa.gov/action/noaa-fisheries-withdrawal-its-simp-proposed-rule-and-announcement-comprehensive-review*).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Alexa Cole,

Director; Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service.

[FR Doc. 2023–25309 Filed 11–14–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 231106–0262; RTID 0648–XD357]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; 2024 and Projected 2025 Bluefish Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes Atlantic bluefish specifications for the 2024 fishing year and projects specifications for fishing year 2025, as recommended by the Mid-Atlantic Fishery Management Council. This action is necessary to establish allowable harvest levels for the stock to prevent overfishing and promote rebuilding, using the best scientific information available. This rule also informs the public of the proposed fishery specifications and provides an opportunity for comment on the proposed action.

DATES: Comments must be received by December 1, 2023.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2023–0126, by the following method:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *https://www.regulations.gov,* and enter ''NOAA–NMFS–2023–0126'' in the Search box;

2. Click the ''Comment'' icon, complete the required fields; and

3. Enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). If you are unable to submit your comment through *https://www.regulations.gov,* contact Cynthia Ferrio, Fishery Policy Analyst, *Cynthia.Ferrio@noaa.gov.*

The Mid-Atlantic Fishery Management Council prepared a draft environmental assessment (EA) for this action that describes the proposed measures and other considered alternatives. The EA also provides an economic analysis, as well as an analysis of the biological, economic, and social impacts of the proposed measures and other considered alternatives. Copies of the specifications document, including the EA, are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org/supporting-documents.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission jointly manage the Atlantic Bluefish Fishery Management Plan (FMP). The FMP requires the specification of annual regulatory limits for up to 3 years at a time, including: an acceptable biological catch (ABC), commercial and recreational annual catch limits (ACL), commercial and recreational annual catch targets (ACT), a commercial quota, a recreational harvest limit (RHL), and other management measures. This action proposes bluefish specifications for the 2024 fishing year, and projects specifications for 2025, based on Council and Commission recommendations.

Recent research track and management track assessments for bluefish (December 2022 and June 2023, respectively) determined that the stock is no longer overfished and overfishing is not occurring. However, the spawning stock biomass has not yet reached its target, so the fishery remains under its rebuilding plan. These proposed specifications would decrease the 2024 acceptable biological catch by 43 percent from 2023, based on recommendations from the Council's Scientific and Statistical Committee (SSC), results from these assessments, and the rebuilding plan for the stock.

The Council's Bluefish Monitoring Committee recommended that no uncertainty buffers be applied to either the commercial or recreational sector in 2024 or 2025, but did recommend that commercial discards be accounted for in the specifications process beginning in fishing year 2024. In prior years, commercial discards have been considered negligible, but with updated assessment information, it is recommended that discards from both sectors be included. Although the stock is no longer overfished and therefore transferring quota between recreational and commercial sectors is no longer prohibited by governing regulations, no sector quota transfer is recommended because the fishery is still under a rebuilding plan. The resulting 2024 specifications would decrease the commercial quota by 43 percent, and the RHL by 15 percent from 2023. At their joint meeting in August 2023, the Council and the Commission's Bluefish Board reviewed and approved these specifications as recommended by the SSC and Monitoring Committee. No changes were recommended to recreational management measures (*i.e.,* bag limits), as the average recreational harvest since 2021 (11.54 million pounds (lb); 5,234 metric tons (mt)) remains below the proposed RHL for 2024 (11.96 million lb; 5,425 mt). Status quo recreational measures are also intended to promote continued stability and consistency in the fishery while minimizing the risk of an overage in the recreational sector.

Although catch limits are decreasing, neither sector of the fishery is expected to be substantially impacted by this action. Harvest in both sectors has been decreasing in recent years; coastwide commercial landings have not exceeded 2.2 million lb (998 mt) in the last 3

years, and recreational harvest averaged 11.54 million lb (5,234 mt), both lower than the proposed future limits.

Proposed Specifications

This action proposes the Council's recommendations for 2024 and projected 2025 bluefish catch specifications, which are consistent with the SSC and Monitoring Committee recommendations (Table 1). These proposed specifications would decrease catch limits in 2024 based on best available information from the recent assessments and the rebuilding plan, but increases to limits are projected in 2025. A comparison of the current 2023, proposed 2024, and projected 2025 specifications is summarized below in Table 1. As previously mentioned, the Council did not recommend any changes to recreational management measures in these specifications, as the expected recreational landings under the existing measures are likely to achieve the proposed RHL without exceeding it. Therefore, all other Federal management measures, including commercial management measures, recreational season (open all year) and recreational fish size (none), would also remain unchanged under this action.

TABLE 1—COMPARISON OF 2023, PROPOSED 2024, AND PROJECTED 2025 BLUEFISH SPECIFICATIONS *

	2023 (Current)		2024 (Proposed)		2025 (Projected)	
	Million lb	Metric tons	Million lb	Metric tons	Million lb	Metric tons
Overfishing Limit	45.17	20,490	25.87	11,734	27.49	12,467
ABC = Fishery ACL	30.62	13,890	17.48	7,929	21.83	9,903
Commercial ACL = Commercial ACT	4.29	1,945	2.45	1,110	3.06	1,386
Recreational ACL = Recreational ACT	26.34	11,945	15.03	6,819	18.78	8,517
Commercial Discards	0	0	0.02	11	0.02	11
Recreational Accountability Measures	5.59	2,536	0	0	0	0
Recreational Discards	6.64	3,012	3.08	1,396	3.08	1,396
Commercial Total Allowable Landings (TAL)	4.29	1,945	2.42	1,099	3.03	1,375
Recreational TAL	14.11	6,400	11.96	5,423	15.70	7,121
Sector Transfer	0	0	0	0	0	0
Commercial Quota	4.29	1,945	2.42	1,099	3.03	1,375
RHL	14.11	6,400	11.96	5,423	15.70	7,121

*Specifications are derived from the ABC in metric tons (mt). When values are converted to millions of pounds the numbers may shift due to rounding. The conversion factor used is 1 mt = 2204.6226 lb.

The coastwide commercial quota is allocated to coastal states from Maine to Florida based on percent shares specified in the FMP. Table 2 provides the proposed commercial state allocations based on the Council-recommended coastwide commercial quotas for 2024 and 2025, and the phased-in changes to the percent share allocations to the states specified in Amendment 7. No states exceeded their allocated quota in 2022, or are projected to do so in 2023; therefore, no accountability measures for the commercial fishery are required for the 2024 fishing year based on the data available at this time.

TABLE 2—PROPOSED 2024 AND PROJECTED 2025 BLUEFISH STATE COMMERCIAL QUOTA ALLOCATIONS

State	2024 (Proposed)			2025 (Projected)		
	Percent share	Quota (lb)	Quota (kg)	Percent share	Quota (lb)	Quota (kg)
Maine	0.43	10,398	4,716	0.35	10,582	4,800
New Hampshire	0.33	7,983	3,621	0.30	9,123	4,138
Massachusetts	8.17	198,205	89,904	8.66	262,663	119,142
Rhode Island	8.01	194,201	88,088	8.41	255,061	115,694
Connecticut	1.19	28,847	13,085	1.16	35,309	16,016
New York	14.40	349,264	158,424	15.74	477,518	216,598
New Jersey	14.40	349,216	158,402	14.26	432,630	196,238
Delaware	1.29	31,167	14,137	1.09	32,990	14,964
Maryland	2.54	61,527	27,908	2.38	72,265	32,779
Virginia	9.30	225,585	102,324	8.44	256,125	116,176
North Carolina	32.05	777,159	352,513	32.04	972,012	440,897
South Carolina	0.06	1,562	709	0.07	2,250	1,021
Georgia	0.05	1,195	542	0.06	1,897	860
Florida	7.80	189,071	85,761	7.04	213,625	96,899
Total	100	2,425,085	1,100,000	100	3,033,561	1,376,000

The catch limits for 2025 were projected based on the new assessment data and the fourth year of the rebuilding plan model. The Council will review the projected 2025 specifications in light of any new information to determine if changes need to be made prior to their implementation. We will publish a notice prior to the 2025 fishing year to confirm these limits as projected or announce any necessary changes.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson Stevens Fishery Conservation

and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Bluefish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

NMFS finds that a 15-day comment period for this action provides a reasonable opportunity for public participation in this action pursuant to Administrative Procedure Act section 553(c) (5 U.S.C 553(c)), while also ensuring that the final specifications are in place for the start of the bluefish fishing year on January 1, 2024. Stakeholder and industry groups have been involved with the development of this action and have participated in public meetings throughout the past year. A prolonged comment period and subsequent potential delay in implementation past the start of the 2024 fishing year would be contrary to the public interest, as it could create confusion both in the bluefish industry around current quotas and with state agencies as they prepare their annual management measures.

This action is exempt from review under Executive Order 12866 because it contains no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

The Councils conducted an evaluation of the potential socioeconomic impacts of the proposed specifications in conjunction with an EA. There are no proposed regulatory changes in this bluefish action, so none are considered in the evaluation. The proposed action would decrease the 2024 ABC by 43 percent, the commercial quota by 43 percent, and the recreational harvest limit by 15 percent from 2023, consistent with the Mid-Atlantic Council SSC's recommendations, the results of the 2023 management track assessment, and the rebuilding plan for the stock. This action proposes no changes to recreational management measures beyond annual catch limits, such as bag limits.

This action would affect entities that participate in commercial bluefish fishing (those that hold commercial bluefish permits), and those with Federal for-hire (party/charter) recreational fishing permits for bluefish. Vessels may hold multiple fishing permits and some entities own multiple vessels and/or permits. According to the Northeast Fisheries Science Center commercial ownership database, 479 commercial fishing affiliate firms landed bluefish during the 2020–2022 period (the most recent and complete data available), with 473 of those commercial entities categorized as small businesses and 6 categorized as large businesses. Analyses indicate that bluefish revenues contributed less than two percent of the annual total gross receipts on average for those small businesses that landed bluefish in those years. For the recreational for-hire fishery, 412 for-hire affiliate firms generated revenues from recreational fishing for various species during 2020–2022. All of those business affiliates are categorized as small businesses, but it is not possible to derive the proportion of overall revenues for these for-hire firms resulting from fishing activities for an individual species such as bluefish. Nevertheless, given the popularity of bluefish as a recreational species in the Mid-Atlantic and New England, it is likely that revenues generated from bluefish may be somewhat important for many of these firms at certain times of the year.

Overall, proposed specifications for 2024 and projected specifications for 2025 are expected to provide similar fishing opportunities when compared to the 2023 fishing year. Although catch limits are decreasing in both the commercial and recreational sectors under these specifications, this change is not expected to substantially change overall fishing activity, result in catch overages or revenue losses to industry, or substantially impact the bluefish fishery as a whole. Harvest in both sectors has been decreasing in recent years; coastwide commercial landings have not exceeded 2.2 million lb (998 mt) in the last 3 years, and recreational harvest has averaged 11.54 million lb (5,234 mt), both lower than the proposed 2024 limits of 2.4 million lb (1,099 mt) and 11.96 million lb (5,425 mt), respectively. Additionally, this action is expected to provide similar fishing opportunities in the recreational sector compared to the previous year, as there are no proposed changes to the management measures such as recreational bag limits, which are most limiting to fishery behavior. Finally, state quota allocations are still changing, as 2024 is the third year of the phased-in quota re-allocation implemented by Amendment 7 to the Bluefish Fishery Management Plan. Therefore, regionally, there may be different amounts of commercial quota available. Often, fishing behavior and short-term landings are based on market conditions, which are not expected to substantially change as a result of these specifications. As such, this proposed action is not expected to have a substantial impact on the way the fishery operates or the revenue of small entities.

Overall, analyses indicate that the proposed specifications will not substantially change fishing effort, the risk of overfishing, prices/revenues, or fishery behavior. Therefore, the Council concluded, and NMFS agrees, that this action would not have a significant economic impact on a substantial number of small businesses. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This action would not establish any new reporting or record-keeping requirements.

This proposed rule contains no new information collection requirements under the Paperwork Reduction Act of 1995.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2023–25222 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 88, No. 220
Thursday, November 16, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FTPP–23–0008]

Proposed Posting and Posting of Stockyards

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) is taking action to post stockyards under the Packers and Stockyards Act (P&S Act). Specifically, we are proposing that 15 stockyards now operating subject to the P&S Act be posted. Also, we are posting 10 stockyards that were identified previously as operating subject to the P&S Act. We determined that the stockyards meet the definition of a stockyard under the P&S Act and, therefore, they have been posted.

DATES: For the proposed posting of stockyards, comments received on or before December 18, 2023 will be considered.

ADDRESSES: Interested persons are invited to submit comments concerning this notice. Comments may be submitted by any of the following methods:

- *Internet:* Go to *https://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Fax:* (202) 690–3207.
- *Mail, hand delivery, or courier:* Dora Malykin, USDA, AMS, 1400 Independence Avenue SW, Room 2097–S, Washington, DC 20250–3601.

Instructions: All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available for public inspection. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Donna A. Ash, Marketing Specialist, AMS, Packers, and Stockyards Division; Telephone: (202) 720–0222 or Email: *Donna.a.ash@usda.gov*.

SUPPLEMENTARY INFORMATION: AMS administers and enforces the P&S Act of 1921 (7 U.S.C. 181 *et seq.*). The P&S Act prohibits unfair, deceptive, and fraudulent practices by livestock market agencies, dealers, stockyard owners, meat packers, swine contractors, and live poultry dealers in the livestock, poultry, and meatpacking industries.

Section 302(a) of the P&S Act (7 U.S.C. 202(a)) defines the term ''stockyard'' as ''any place, establishment, or facility commonly known as stockyards, conducted, operated, or managed for profit or nonprofit as a public market for livestock producers, feeders, market agencies, and buyers, consisting of pens, or other enclosures, and their appurtenances, in which live cattle, sheep, swine, horses, mules, or goats are received, held, or kept for sale or shipment in commerce.''

Section 302(b) of the P&S Act (7 U.S.C. 202(b)) requires the Secretary of Agriculture to determine which stockyards meet this definition, and to notify the owner of the stockyard and the public of that determination by posting a notice in each designated stockyard. Once the Secretary provides notice to the stockyard owner and the public, the stockyard is subject to the provisions of Title III of the P&S Act (7 U.S.C. 201–203 and 205–217a) until the Secretary de-posts the stockyard by public notice. To post a stockyard, we assign the stockyard a facility number, notify the stockyard owner, and send an official posting notice to the stockyard owner to display in a public area of the stockyard. This process is referred to as ''posting.'' The date of posting is the date that the posting notices are physically displayed at the stockyard. A facility that does not meet the definition of a stockyard is not subject to the P&S Act and therefore cannot be posted. A posted stockyard can be ''de-posted,'' which occurs when the facility is no longer used as a stockyard.

We are hereby notifying stockyard owners and the public that the following 15 stockyards meet the P&S Act's definition of a stockyard and that we propose to designate these stockyards as posted stockyards.

Proposed facility No.	Stockyard name and location
AL–198	Rocking L Horse Sales LLC, Mount Hope, Alabama.
AL–199	Dennis Horse Sales, Audalusia, Alabama.
AR–185	Hilltop Acres Goat & Sheep Auction, LLC, Romance, Arkansas.
AR–186	Johnny Smith Livestock, Plumerville, Arkansas.
GA–238	Southern Blitz/Heart of Dixie Boer Goat Sale, Harlem, Georgia.
IN–169	Monroe Livestock Auction, LLC, Monroe, Indiana.
MO–290	Show Me Horse Sale, Barnett, Missouri.
MO–292	Lord S Nemo Auction, Kirksville, Missouri.
MO–291	Owensville Auction LLC, Owensville, Missouri.
MD–121	Wolfe Agricultural Actions, Inc., Thurmont, Maryland.
NY–180	Lakeview Sales Barn, Penn Yan, New York.
OH–161	BLT Livestock, Inc., Maryville, Ohio.
OK–226	D&D Auction Barn, LLC, Gans, Oklahoma.
TN–219	Prestige Horse Sales, LLC, Shelbyville, Tennessee.
VA–165	Cedar Grove Auctions, Charlotte, Virginia.

We are also notifying the public that the stockyards listed in the following table meet the P&S Act's definition of a stockyard and, therefore, we have posted these stockyards. On May 14, 2020, we published a notice in the **Federal Register** (85 FR 28928) proposing to post these 10 stockyards. Since we received no comments to our proposal, we assigned the stockyards a facility number and notified the owners of the stockyard facilities. Posting notices were sent to each stockyard owner to display in public areas of their stockyard. The table below reflects the date of posting for these stockyards.

Facility No.	Stockyard name and location	Date of posting
NY–178	Davis Livestock Sales, Inc., Gouverneur, New York	07/15/2020
NY–179	Argyle Livestock Station, LLC, Argyle, New York	07/15/2020
OK–266	Geary Livestock Market, LLC, Geary, Oklahoma	07/15/2020
OK–227	McDaniel Livestock Exchange LLC, Valliant, Oklahoma	07/15/2020
TX–358	Mort Livestock Exchange, Canton, Texas	07/16/2020
TX–359	Amarillo West Stockyards LLC, Wildorado, Texas	07/16/2020
PA–164	Double E. Auction Service LLC, Quarryville, Pennsylvania	07/16/2020
KY–190	Triple C. Auctions, Ewing, Kentucky	07/17/2020
FL–141	Cattleman's Market of Okeechobee LLC, Okeechobee, Florida	07/15/2020
ND–134	Bismarck Livestock Auction, LLC, Bismarck, North Dakota	07/15/2020

Authority: 7 U.S.C. 202.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–25248 Filed 11–15–23; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 18, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: National Veterinary Accreditation Program Application Form.

OMB Control Number: 0579–0297.

Summary of Collection: The Animal Health Protection Act, (APHA) of 2002 is the primary Federal law governing the protection of animal health. The APHA is contained in 7 U.S.C. 8301, *et seq., and* were created the Farm Security and Rural Investment Act of 2002. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Animal and Plant Health Inspection Service (APHIS) is the agency charged with carrying out this disease prevention mission. For APHIS to conduct all its disease prevention tasks, it utilizes APHIS-certified private veterinarians to work cooperatively with Federal and State animal health authorities on the Agency's behalf. These veterinarians obtain their certification through the APHIS National Veterinary Accreditation Program (NVAP) which has an application and renewal process.

Need and Use of the Information: APHIS will use VS form 1–36A, National Veterinary Accreditation Program Application Form to collect information to certify private veterinarians to work Federal and State animal health authorities to prevent disease and carry out disease surveillance on USDA's behalf. Applicants may appeal denial, revocation, or suspension of accredited status. The written appeal is prepared in letter format and signed by the denied veterinarian. If information from accredited veterinarians was collected less frequently or not collected, APHIS would lose access to professional and demographic data for more than 70,000 cooperators, and APHIS coverage of veterinary, plant, and agricultural activities would be proportionately reduced.

Description of Respondents: Business or other for-profit.

Number of Respondents: 24,820.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 9,929.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–25302 Filed 11–15–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No. RUS–23–Telecom–0023]

Publication of Depreciation Rates for Telecommunications Plant

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture (USDA) Rural Utilities Service (RUS) administers rural utilities programs, including the Telecommunications Program. Through this notice, RUS is announcing the

depreciation rates for telecommunication/broadband facilities and a new process for providing these rates going forward.

DATES: These rates are effective immediately and will remain in effect until superseded by subsequent rates as identified in the **SUPPLEMENTARY INFORMATION** section below. These rates are to be used in applying for financial assistance from RUS.

FOR FURTHER INFORMATION CONTACT: Laurel Leverrier, Assistant Administrator, Telecommunications Program, Rural Utilities Service, STOP 1590—Room 4121, 1400 Independence Avenue SW, Washington, DC 20250–1590. Telephone: (202) 720–9556.

SUPPLEMENTARY INFORMATION: RUS is publishing its median depreciation rates for telecommunication/broadband facilities. If an applicant for RUS financial assistance does not have depreciation rates approved by their respective Public Utilities Commission (PUC) or equivalent, these depreciation rates are to be used in the financial studies supporting the application and for determining the amortization period for any loan component. RUS will no longer publish these rates in the **Federal Register**. There will be an option in the RUS on-line application system that allows applicants to use PUC approved depreciation rates or default to the RUS median depreciation rates reflected in the system. The following chart comprises the median depreciation rates:

MEDIAN DEPRECIATION RATES

Code	Group	Letter	Type	Rate (%)
1000	1. Network & Access Equipment	a	Switching Equipment	9.30
1001	1. Network & Access Equipment	b	Routing Equipment	10.00
1002	1. Network & Access Equipment	c	Transport Equipment	10.00
1003	1. Network & Access Equipment	d	Access Equipment	10.00
1004	1. Network & Access Equipment	e	Video Equipment	9.61
1005	1. Network & Access Equipment	f	Power Equipment	10.00
1006	1. Network & Access Equipment	g	Satellite Equipment	9.26
1007	1. Network & Access Equipment	h	Other (specify)	10.00
2000	2. Outside Plant	a	Copper Cable—Aerial	6.00
2001	2. Outside Plant	b	Copper Cable—Buried	5.15
2002	2. Outside Plant	c	Copper Cable—Underground	5.00
2003	2. Outside Plant	d	Coaxial Cable—Aerial	6.00
2004	2. Outside Plant	e	Coaxial Cable—Buried	5.15
2005	2. Outside Plant	f	Coaxial Cable—Underground	5.00
2006	2. Outside Plant	g	Fiber Cable—Aerial	5.40
2007	2. Outside Plant	h	Fiber—Buried	5.00
2008	2. Outside Plant	i	Fiber—Underground Cable	5.00
2009	2. Outside Plant	j	Fiber—Submarine Cable	5.00
2010	2. Outside Plant	k	Conduit Systems	4.00
2011	2. Outside Plant	l	Ducts (Vacant)	5.00
2012	2. Outside Plant	m	Drops	5.00
2013	2. Outside Plant	n	Cabinets/underground vaults	5.00
2014	2. Outside Plant	o	Poles	6.35
2015	2. Outside Plant	p	Make-ready	5.00
2016	2. Outside Plant	q	Other (specify)	5.00
3000	3. Buildings	a	New Construction	3.30
3001	3. Buildings	b	Pre-Fab Huts	3.30
3002	3. Buildings	c	Improvements	3.30
3003	3. Buildings	d	Other (specify)	3.30
4001	4. Towers	a	Guyed Towers	5.00
4002	4. Towers	b	Lattice Towers	5.00
4003	4. Towers	c	Monopole/Self-Supporting Tower	5.00
4004	4. Towers	d	Wood poles	5.00
4005	4. Towers	e	Improvements	5.00
4006	4. Towers	f	Other (specify)	5.00
5000	5. Customer Premises Equipment	a	Video Set Top Boxes	12.00
5001	5. Customer Premises Equipment	b	Modems and Routers	12.00
5002	5. Customer Premises Equipment	c	Inside Wiring	10.40
5003	5. Customer Premises Equipment	d	Multi-Terminal Adapter (VoIP)	11.33
5004	5. Customer Premises Equipment	e	Smart Meters	11.00
5005	5. Customer Premises Equipment	f	Other (specify)	12.00
6000	6. Support Assets	a	Construction Vehicles	10.00
6001	6. Support Assets	b	Construction Equipment	10.00
6002	6. Support Assets	c	Motor Vehicles	17.00
6003	6. Support Assets	d	Special Purpose Vehicles	11.40
6004	6. Support Assets	e	Office Equipment	10.00
6005	6. Support Assets	f	Office Furniture	10.00
6006	6. Support Assets	g	Billing System	20.00
6007	6. Support Assets	h	Test Equipment	10.00
6008	6. Support Assets	i	Portable Generators	10.00
6009	6. Support Assets	j	Tools	10.00
6010	6. Support Assets	k	Other (specify)	10.00

Andrew Berke,

Administrator, Rural Utilities Service.

[FR Doc. 2023–25288 Filed 11–15–23; 8:45 am]

BILLING CODE 3410–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Maine Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Maine Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold virtual briefings on Thursday, December 14, 2023, and Thursday, January 11, 2024, both at 12 p.m. (ET) to hear testimony on the barriers to fully funding Maine's public defense services.

DATES: Thursday, December 14, 2023; at 12 p.m. (ET).

ADDRESSES: The meetings will be held via Zoom.

Zoom Link (Audio/Visual): https://tinyurl.com/5yr4dspy; password: USCCR–ME

Join by Phone (Audio Only): 1–833–435–1820 USA toll-free; Meeting ID: 161 655 9331#

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg, Designated Federal Official at *mtrachtenberg@usccr.gov* or via phone at 202–809–9618.

SUPPLEMENTARY INFORMATION: These committee meetings are available to the public through the registration link above. Any interested member of the public may listen to the meetings. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Mallory Trachtenberg at *mtrachtenberg@usccr.gov*. Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–202–809–9618.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meetings. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Maine Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *ebohor@usccr.gov.*

Agenda

I. Welcome & Roll Call
II. Discussion: Briefings on Barriers to Fully Funding Maine Public Defense Services
III. Public Comment
IV. Adjournment

Dated: November 13, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–25349 Filed 11–15–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2156]

Establishment of a Foreign-Trade Zone Under the Alternative Site Framework in Socorro, Texas

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the City of Socorro (the Grantee) made application to the Board (B–1–2023, docketed January 9, 2023) requesting the establishment of a foreign-trade zone under the ASF with a service area of the City of Socorro, Texas, adjacent to the Tornillo Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (88 FR 2603, January 17, 2023) and the application was processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopted the findings and recommendations of the examiners' report, and found that the requirements of the FTZ Act and the Board's regulations are satisfied;

Therefore, on November 9, 2023, the Board granted to the City of Socorro the privilege of establishing a foreign-trade zone, designated on the records of the Board as Foreign-Trade Zone No. 302, as described in the application, and subject to the FTZ Act and the Board's regulations, including section 400.13, and to the Board's standard 2,000-acre activation limit.

Dated: November 13, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2023–25350 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–827]

Certain Cased Pencils From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) has completed its administrative review of the antidumping duty order on certain cased pencils (cased pencils) from the People's Republic of China (China) for the period of review (POR) December 1, 2021, through November 30, 2022. We continue to find that the single entity Wah Yuen Stationery Co. Ltd./ Shandong Wah Yuen Stationery Co. Ltd. (Wah Yuen) as well as Tianjin Tonghe

Stationery Co., Ltd. (Tianjin Tonghe) and Ningbo Homey Union Co., Ltd. (Ningbo Homey) are part of the China-wide entity.

DATES: Applicable November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4929.

SUPPLEMENTARY INFORMATION:

Background

On September 5, 2023, Commerce published the *Preliminary Results* in the **Federal Register**.[1] We invited interested parties to comment on the *Preliminary Results*; however, no interested parties submitted comments. Accordingly, we made no changes to the *Preliminary Results* and no decision memorandum accompanies this **Federal Register** notice.

Scope of the Order [2]

The merchandise covered by the *Order* is certain cased pencils of any shape or dimension (except as described below) which are writing and/or drawing instruments that feature cores of graphite or other materials, encased in wood and/or man-made materials, whether or not decorated and whether or not tipped (*e.g.,* with erasers, *etc.*) in any fashion, and either sharpened or unsharpened. The pencils subject to the *Order* are currently classifiable under subheading 9609.10.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Specifically excluded from the scope of the *Order* are mechanical pencils, cosmetic pencils, pens, non-cased crayons (wax), pastels, charcoals, chalks, and pencils produced under U.S. patent number 6,217,242, from paper infused with scents by the means covered in the above-referenced patent, thereby having odors distinct from those that may emanate from pencils lacking the scent infusion. Also excluded from the scope of the *Order* are pencils with all of the following physical characteristics: (1) length: 13.5 or more inches; (2) sheath diameter: not less than one-and-one quarter inches at any point (before sharpening); and (3) core length: not more than 15 percent of the length of the pencil.

In addition, pencils with all of the following physical characteristics are excluded from the scope of the *Order:* novelty jumbo pencils that are octagonal in shape, approximately ten inches long, one inch in diameter before sharpening, and three-and-one eighth inches in circumference, composed of turned wood encasing one-and-one half inches of sharpened lead on one end and a rubber eraser on the other end.

Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise covered by the scope of the *Order* is dispositive.

China-Wide Entity

We find all companies for which a review was requested to be part of the China-wide entity, because they did not file no-shipment statements, separate rate applications, or separate rate certifications. Accordingly, Wah Yuen, Tianjin Tonghe, and Ningbo Homey are part of the China-wide entity. Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews, we did not conduct a review of the China-wide entity.[3] Accordingly, the rate previously established for the China-wide entity, 114.90 percent, is not changed as a result of this review.[4]

Assessment Rates

Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1). Because we determined that Wah Yuen, Tianjin Tonghe, and Ningbo Homey are not eligible for separate rates and are part of the China-wide entity, we intend to instruct CBP to apply an *ad valorem* assessment rate of 114.90 percent (*i.e.,* the China-wide entity rate) to all entries of subject merchandise during the POR that were exported by these companies.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results of review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided by section 751(a)(2)(C) of the Act: (1) for previously investigated or reviewed Chinese and non-Chinese exporters for which a review was not requested and that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate published for the most recently-completed period; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity; and (3) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction

[1] *See Certain Cased Pencils from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 60636 (September 5, 2023).

[2] *See Certain Cased Pencils from the People's Republic of China: Continuation of Antidumping Duty Order,* 88 FR 15673 (March 14, 2023); and *Antidumping Duty Order: Certain Cased Pencils from the People's Republic of China,* 59 FR 66909 (December 28, 1994) (*Order*).

[3] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[4] *See Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 26897 (May 11, 2015).

of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h) and 19 CFR 351.221(b)(5).

Dated: November 9, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–25290 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–878]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 29, 2023, the U.S. Department of Commerce (Commerce) published the notice of initiation and preliminary results of a changed circumstances review (CCR) of the antidumping duty (AD) order on certain corrosion-resistant steel from the Republic of Korea (Korea). For these final results, Commerce continues to find that Dongkuk Coated Metal Co., Ltd., following a corporate organizational change in June 2023 (hereinafter, Dongkuk CM), is the successor-in-interest to the pre-reorganization Dongkuk Steel Mill Co., Ltd. entity (hereinafter, Old Dongkuk Steel). Therefore, Dongkuk CM is entitled to Old Dongkuk Steel's AD cash deposit rate with respect to entries of the subject merchandise in the above-referenced proceeding.

DATES: Applicable November 16, 2023.

FOR FURTHER INFORMATION CONTACT: William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4868.

SUPPLEMENTARY INFORMATION:

Background

On September 29, 2022, Commerce published the *Initiation and Preliminary Results,*[1] finding that Dongkuk CM is the successor-in-interest to Old Dongkuk Steel, and should be assigned the same AD cash deposit rate assigned to Old Dongkuk Steel with respect to entries of subject merchandise in the above referenced proceeding.[2] In the *Initiation and Preliminary Results,* we provided all interested parties with an opportunity to comment and request a public hearing regarding our preliminary finding.[3] Dongkuk CM submitted comments agreeing with our preliminary finding in full, and we received no other comments from interested parties.[4] Additionally, we received no requests for a public hearing from interested parties.

Scope of the Order

The merchandise covered by the AD order is certain corrosion-resistant steel products from Korea. For a complete description of the scope, *see* the Preliminary Decision Memorandum.

Final Results of the Changed Circumstances Review

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no contrary comments from interested parties challenging our preliminary finding, Commerce continues to find that Dongkuk CM is the successor-in-interest to Old Dongkuk Steel and is entitled to the same AD cash deposit rate as Old Dongkuk Steel with respect to entries of subject merchandise in the above-noted proceeding. Consequently, Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced and/or exported by Dongkuk CM and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at the AD cash deposit rate in effect for Old Dongkuk Steel. This cash deposit requirement shall remain in effect until further notice.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Tariff Act of 1930, as amended, and 19 CFR 351.216 and 351.221(c)(3).

Dated: November 8, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–25354 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Corrosion-Resistant Steel Products from the Republic of Korea: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 88 FR 67243 (September 29, 2023) (*Initiation and Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *Id.,* 88 FR at 67243.

[3] *Id.,* 88 FR at 67245.

[4] *See* Dongkuk CM's Letter, ''Case Brief,'' dated October 11, 2023.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–823–817]

Prestressed Concrete Steel Wire Strand From Ukraine: Final Results of Antidumping Duty Administrative Review; 2020–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that PJSC Stalkanat (Stalkanat) did not make sales of prestressed concrete steel wire strand (PC strand) from Ukraine in the United States at less than normal value during the period of review, (POR) November 19, 2020, through May 31, 2022.

DATES: Applicable November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Laura Griffith, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6430.

SUPPLEMENTARY INFORMATION:

Background

On July 14, 2023, Commerce published the preliminary results of this administrative review covering one producer/exporter, Stalkanat.[1] We invited interested parties to comment on the *Preliminary Results.* For a complete description of the events that occurred

[1] *See Prestressed Concrete Steel Wire Strand from Ukraine: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Intent To Rescind, in Part; 2020–2022,* 88 FR 45134 (July 14, 2023) (*Preliminary Results*).

since the *Preliminary Results, see* the Issues and Decision Memorandum.[2]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The product covered by this *Order* is PC strand from Ukraine. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum and are listed in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Successor-in-Interest Analysis

Commerce initiated this administrative review with respect to Stalkanat and PJSC PA Stalkanat-Silur (Stalkanat-Silur), the entity that participated in the original investigation. We preliminarily determined that Stalkanat is the successor-in-interest to Stalkanat-Silur.[4] No parties commented on this issue in their briefs; accordingly, Commerce has determined that Stalkanat is the successor-in-interest to Stalkanat-Silur.[5]

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties, we have not made any changes to the weighted-average dumping margin for Stalkanat.

Final Results of Review

Commerce determines that the following weighted-average dumping margin exists for the period November 19, 2020, through May 31, 2022:

Producer and/or exporter	Weighted-average dumping margin (percent)
PJSC Stalkanat	0.00

Disclosure

Commerce normally discloses to interested parties the calculations performed in connection with the final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, there are no new calculations to disclose in accordance with 19 CFR 351.224(b) for these final results.

Assessment Rate

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. Because the rate assigned to Stalkanat (formerly Stalkanat-Silur) is zero, Commerce will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[6]

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by the mandatory respondent for which the company did not know that the merchandise it sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Stalkanat will be zero; (2) for merchandise exported by a company not covered in this administrative review but covered in a completed prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review or completed prior segment of this proceeding but the producer is, the cash deposit rate will be the company-specific rate established for the most recently-completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 19.30 percent, the rate established in the investigation of this proceeding.[7] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Prestressed Concrete Steel Wire Strand from Ukraine; 2020–2022,'' dated concurrently with and hereby adopted by this notice (Issues and Decision Memorandum).

[3] *See Prestressed Concrete Steel Wire Strand from Indonesia, Italy, Malaysia, South Africa, Spain, Tunisia, and Ukraine: Antidumping Duty Orders,* 86 FR 29998 (June 4, 2021) (*Order*).

[4] *See Preliminary Results.*

[5] While Commerce indicated its intent to rescind the review of Stalkanat-Silur in the *Preliminary Results,* rather than rescinding the review, Commerce determines that Stalkanat is the successor-in-interest to Stalkanat-Silur.

[6] As explained above, we determined that Stalkanat is the successor-in-interest to Stalkanat-Silur. Accordingly, we intend to issue assessment instructions covering entries produced and exported by either Stalkanat or Stalkanat-Silur during the POR at the rate established in these final results.

[7] *See Order.*

requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: November 9, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Changes Since the *Preliminary Results*
V. Final Successor-In-Interest Determination
VI. Discussion of the Issue
Comment: Whether Stalkanat's U.S. Sales Were *Bona Fide*
VII. Recommendation

[FR Doc. 2023–25351 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD531]

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of hybrid conference. Meetings of the North Pacific Fishery Management Council and its advisory committees.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will meet in Anchorage, AK.

DATES: The meetings will be held December 4, 2023 through December 12, 2023.

ADDRESSES: The meetings will be a hybrid conference. The in-person component of the meeting will be held at the Hilton Hotel, 500 W 3rd Ave., Anchorage, AK 99501, or join the meeting online through the links at *https://www.npfmc.org/current-or-next-council-meeting/.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Suite 400, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

Instructions for attending the meeting via web conference are given under Connection Information, below.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; email: *diana.evans@noaa.gov;* telephone: (907) 271–2809. For technical support, please contact our Council administrative staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Council's Scientific and Statistical Committee (SSC) will begin at 8 a.m. in the Aleutian room on Monday, December 4, 2023, and continue through Wednesday, December 6, 2023. The Council's Advisory Panel (AP) will begin at 8 a.m. in the Dilingham/Katmai room on Tuesday, December 5, 2023, and continue through Friday, December 8, 2023. The Council will begin at 8 a.m. in the Aleutian room on Thursday, December 7, 2023, and continue through Tuesday, December 12, 2023. The Finance Committee is a closed session and will meet Wednesday, December 6, 2023, from 8 a.m. to 12 p.m.; the Council Executive Session is a closed session and will meet on Wednesday, December 6, 2023, from 1 p.m. to 5 p.m.; both will meet at the North Pacific Fishery Management Council's offices; 1007 W 3rd Ave, Suite 400, Anchorage, AK 99501–2252. The Charter Halibut Management Committee will meet Wednesday, December 6, 2023, from 8 a.m. to 12 p.m. at the North Pacific Fishery Management Council's Conference Room; 1007 W 3rd Ave., Suite 400, Anchorage, AK 99501–2252. All times listed are Alaska Time.

Agenda

Monday, December 4, 2023, Through Wednesday, December 6, 2023

The SSC agenda will include the following issues:

(1) Administrative Issues including Inflation Reduction Act (IRA) funding workplan
(2) Bering Sea Aleutian Islands (BSAI) Groundfish specifications—review Bering Sea (BS) and Aleutian Islands (AI) Ecosystem Status Reports (ESR); Stock Assessment and Fishery Evaluation (SAFE) report; adopt Acceptable Biological Catch (ABC) and Over Fishing Limits (OFLs); Joint Groundfish Plan Team report; BSAI Groundfish Plan Team Report
(3) Gulf of Alaska (GOA) Groundfish specifications;—GOA ESR Report; SAFE report; adopt ABC/OFLs; GOA Plan Team report
(4) BS Fishery Ecosystem Plan (FEP) Climate Change Taskforce (CCTF)—review workplan and report

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3020* prior to the meeting, along with meeting materials.

In addition to providing ongoing scientific advice for fishery management decisions, the SSC functions as the Council's primary peer review panel for scientific information, as described by the Magnuson-Stevens Act section 302(g)(1)(e), and the National Standard 2 guidelines (78 FR 43066). The peer-review process is also deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines.

Tuesday, December 5, 2023, Through Friday, December 8, 2023

The Advisory Panel agenda will include the following issues:

(1) Administrative Issues
(2) Crab C Share recent participation requirement—Final Action
(3) Crab Facility Use Caps—Final Action
(4) Essential Fish Habitat (EFH) Fishery Management Plan (FMP) amendments—Initial/final action
(5) Crab FMP housekeeping amendment—Initial/final action
(6) GOA Tanner Crab protections—review discussion paper
(7) BS FEP CCTF Taskforce—review workplan and report
(8) BSAI Groundfish specifications—review BS and AI Ecosystem Status Reports; SAFE report; adopt ABC/OFLs; Joint Groundfish Plan Teams report; BSAI Groundfish Plan Team Report
(9) GOA Groundfish specifications;—GOA ESR Report; SAFE report; adopt ABC/OFLs; GOA Plan Team report
(10) 2024 Charter Halibut Management Measures—Final action; committee report
(11) Staff Tasking

Wednesday, December 6, 2023

The Charter Halibut Committee agenda will include: (a) 2024 management measures; (b) scheduling for a future tasking meeting; and (c) other business.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3022* prior to the meeting, along with meeting materials.

Thursday, December 7, 2023, Through Tuesday, December 12, 2023

The Council agenda will include the following issues. The Council may take appropriate action on any of the issues identified.

(1) B Reports (Executive Director including CCC update, IRA funding workplan, GOA Pacific cod allocation review, industry reports on 2023 crab avoidance; NMFS Management including Cook Inlet Salmon Secretarial FMP amendment, Final Observer Deployment Plan, year-end in-season management report, Aquaculture Opportunity Areas Request for Information; NOAA General Counsel (GC), NOAA Enforcement; Alaska Department of Fish and Game (ADF&G); United States Coast Guard (USCG); United States Fish and Wildlife Service (USFWS); Advisory Panel and SSC report)
(2) Crab C Share recent participation requirement—Final Action
(3) Crab Facility Use Caps—Final Action
(4) BSAI Groundfish specifications—review BS and AI Ecosystem Status Reports; SAFE report; adopt ABC/OFLs; Joint Groundfish Plan Teams report; BSAI Groundfish Plan Team Report Chum Salmon bycatch—preliminary review
(5) GOA Groundfish specifications;—GOA ESR Report; SAFE report; adopt ABC/OFLs; GOA Plan Team report
(6) EFH FMP amendments—Initial/final action
(7) Crab FMP housekeeping amendment—Initial/final action
(8) 2024 Charter Halibut Management Measures—Final action; committee report
(9) GOA Tanner Crab protections—review discussion paper
(10) BS FEP CCTF Taskforce—review workplan and report
(11) Staff Tasking

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://www.npfmc.org/upcoming-council-meetings.* For technical support, please contact our administrative staff, email: *npfmc.admin@noaa.gov.*

If you are attending the meeting in-person, please refer to the COVID avoidance protocols on our website, *https://www.npfmc.org/current-or-next-council-meeting/.*

Public Comment

Public comment letters will be accepted and should be submitted electronically through the links at *https://www.npfmc.org/current-or-next-council-meeting/.* The Council strongly encourages written public comment for this meeting, to avoid any potential for technical difficulties to compromise oral testimony. The written comment period is open from November 10, 2023, to December 1, 2023, and closes at 12 p.m. Alaska Time on Friday, December 1, 2023.

Although other non-emergency issues not on the agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25359 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD529]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council, NEFMC) will hold a three-day hybrid meeting with both in-person and remote participation to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday, and Thursday, December 5, 6, and 7, 2023, beginning at 9:30 a.m. on Tuesday and 9:00 a.m. on Wednesday and Thursday.

ADDRESSES: The meeting will be held at the Hotel Viking, One Bellevue Avenue, Newport, RI 02840; telephone (401) 847–3300; online at *www.hotelviking.com.* Join the webinar at *https://register.gotowebinar.com/register/8673787082024040282.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone (978) 465–0492; *www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492, ext. 113.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, December 5, 2023

After brief announcements, the Council will receive reports on recent activities from its Chair and Executive Director, the GARFO Regional Administrator, the NOAA Office of General Counsel, the Northeast Fisheries Science Center (NEFSC) Director, the Mid-Atlantic Fishery Management Council liaison, and representatives from the Atlantic States Marine Fisheries Commission (ASMFC), the U.S. Coast Guard, NOAA's Office of Law Enforcement, the Northeast Trawl Advisory Panel, and the U.S. Fish and Wildlife Service. The Council then will receive a progress report from its Risk Policy Working Group, which is continuing to work on revisions to the Council's Risk Policy Statement. Next, members of the public will have the opportunity to speak during an open comment period on issues that relate to Council business but are not included on the published agenda for this meeting. The Council asks the public to limit remarks to 3–5 minutes. These comments will be received both in person and through the webinar. A guide for how to publicly comment through the webinar is available on the Council website at *https://s3.amazonaws.com/nefmc.org/NEFMC-meeting-remote-participation_generic.pdf.*

After the lunch break, the Council will receive a report from the East Coast Climate Coordination Group about its first meeting on work following up on implementing recommendations from the East Coast Climate Change Scenario Planning Initiative. The Council will engage in a discussion about next steps. The Responsible Offshore Science Alliance (ROSA) will report on the alliance's mission, activities, and steps to support the Council's offshore wind efforts and streamline communications. The Habitat Committee report will follow. The Council will review its comments on the draft Wind Energy Areas for the Gulf of Maine (GOM) and discuss other GOM leasing/planning issues. It also will receive a presentation on other offshore wind and habitat-related updates. To close out the day, the Council will receive a NOAA General Counsel briefing on disclosure of financial interests and voting recusal regulations for regional fishery management council members.

Following the adjournment of official business, the Council will host a public outreach session to foster open lines of communication among Council members, staff, industry, and all meeting attendees.

Wednesday, December 6, 2023

The Council will begin the second day of its meeting with a presentation on the peer-reviewed results of the September 2023 Management Track Stock Assessments for Acadian redfish, Atlantic mackerel, northern and southern red hake, the Northeast skate complex, northern windowpane flounder, and spiny dogfish. Next, the Council's Scientific and Statistical Committee will provide overfishing limit (OFL) and acceptable allowable biological catch (ABC) recommendations for Gulf of Maine haddock, Acadian redfish, northern and southern windowpane flounder, white hake, northern and southern red hake, northern silver hake, southern whiting (silver and offshore hake combined), Atlantic sea scallops, and the Northeast skate complex. The Skate Committee report will follow. The Council will take final action on Framework 12 to the Northeast Skate Complex Fishery Management Plan (FMP), which was initiated to develop 2024–2025 fishery specifications and measures to expand possession of smooth and barndoor skates.

Following the lunch break, the Council will take final action on 2024–2026 specifications for the small-mesh multispecies (whiting) fishery. The Council then will hear from the Scallop Committee and take final action on Scallop Framework 38, which contains 2024 fishery specifications, 2025 default specifications, alternatives for increased vessel monitoring system (VMS) polling rates near closed area boundaries, and other measures. As the last item of business for the day, the Council will receive an update on a joint scallop/habitat action to potentially authorize scallop fishery access to the Habitat Closure Area on the Northern Edge of Georges Bank.

Thursday, December 7, 2023

The Council will lead off the third day of its meeting with the Groundfish Committee report, which will cover three items. First, the Council will take final action on Framework Adjustment 66 to the Northeast Multispecies (Groundfish) FMP, which includes (1) 2024–2025 total allowable catches for U.S./Canada shared resources on Georges Bank; (2) 2024–2025 specifications for Georges Bank yellowtail flounder, white hake, and Gulf of Maine haddock; (3) 2024–2026 specifications for Acadian redfish, northern windowpane, and southern windowpane; (4) a revised white hake rebuilding plan; (5) Atlantic halibut issues; (6) extending removal of the sector management uncertainty buffer for white hake and Gulf of Maine haddock until the next specifications cycle; and (7) modification of the scallop fishery accountability measure for Georges Bank yellowtail flounder for fishing years 2024 and 2025. Next, the Council will receive a progress report on Framework Adjustment 68 to the Groundfish FMP, which is being developed to revise the ABC control rules for groundfish. Finally, the Council will receive an update on the Atlantic Cod Management Transition Plan.

Following the lunch break, the Council will take final action on 2024 Council Priorities for all fishery management plans and other Council responsibilities. The Council then will close out the meeting with other business.

Although non-emergency issues not contained on this agenda may come before the Council for discussion, those issues may not be the subject of formal action during these meetings. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Executive Director Cate O'Keefe (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25358 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD527]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel will hold a public meeting.

DATES: The meeting will be held on Monday, December 4, 2023, from 3 p.m. until 6 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Summer Flounder, Scup, and Black Sea Bass Advisory Panel will meet to review and provided feedback on the Monitoring Committee's recommendations for 2024–2025 recreational management measures for summer flounder and scup and 2024 recreational management measures for black sea bass. The Advisory Panel will also receive a brief update on the Recreational Measures Setting Process Framework/Addenda. Additionally, the Advisory Panel will review recent analysis and stakeholder input on the commercial summer flounder minimum mesh regulations and exemptions (*i.e.,* minimum mesh size regulations, Small Mesh Exemption Program, and the flynet exemption), and provide feedback and recommendations on these issues. Input provided by the Advisory Panel will be considered during the December 2023 joint meeting of the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Management Board.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25357 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD522]

South Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the following: Mackerel Cobia Committee, Dolphin Wahoo Committee, Snapper Grouper Committee, Citizen Science Committee, Habitat and Ecosystem Committee, and the Southeast Data, Assessment and Review (SEDAR) Committee. The meeting week will also include a formal public comment session and a meeting of the Full Council.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, December 4, 2023, until 12 p.m. on Friday, December 8, 2023.

ADDRESSES: *Meeting address:* The meeting will be held at The Beaufort Hotel, 2440 Lennoxville Road, Beaufort, NC 28516; phone: (252) 728–3000. The meeting will also be available via webinar. See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including agendas, overviews, and briefing book materials will be posted on the Council's website at: *https://safmc.net/council-meetings/.* Webinar registration links for the meeting will also be available from the Council's website.

Public comment: Public comment on agenda items may be submitted through the Council's online comment form available from the Council's website at: *https://safmc.net/events/december-2023-council-meeting/.* Written comments will be accepted from November 17, 2023, until December 8, 2023. These comments are accessible to the public, part of the Administrative Record of the meeting, and immediately available for Council consideration. A formal public comment session will also be held during the Council meeting.

The items of discussion in the individual meeting agendas are as follows:

Council Session I, Monday, December 4, 2023, 8:30 a.m. Until 12 p.m. (Closed Session)

The Council will meet in Closed Session to receive a litigation brief from NOAA General Counsel and consider appointments to advisory panels, workgroups, and the Scientific and Statistical Committee (SSC) and Socio-Economic Panel (SEP).

Council Session I, Monday, December 4, 2023, 1:30 p.m. Until 5 p.m.

The Council will receive reports from NOAA Office of Law Enforcement, the U.S. Coast Guard, Council liaisons, and state agencies. The Council will also receive a report on Congressional activities relative to fisheries and reports from recent meetings of the Council's Executive Committee, SSC, and Outreach and Communications Advisory Panel (AP).

The Council will receive a presentation from NOAA Fisheries on the Southeast For-Hire Integrated Electronic Reporting (SEFHIER) Program and a presentation from NOAA Fisheries Southeast Fisheries Science Center on an update on the reliability of commercial discards.

Mackerel Cobia Committee, Tuesday, December 5, 2023, 8:30 a.m. Until 10 a.m.

The Committee will receive a report from the Mackerel Cobia AP, review public scoping comments for Amendment 13 to the Coastal Migratory Pelagics Fishery Management Plan addressing catch level adjustments for Spanish mackerel, and receive an update on plans to conduct port meetings for the mackerel fishery.

Dolphin Wahoo Committee, Tuesday, December 5, 2023, 10 a.m. Until 11 a.m.

The Committee will receive a report from the Dolphin Wahoo AP and an update on the Management Strategy Evaluation for Dolphin.

Snapper Grouper Committee, Tuesday, December 5, 2023, 11 a.m. Until 5 p.m., and Wednesday, December 6, 2023, 8:30 a.m. Until 3:45 p.m.

The Committee will receive a briefing on Exempted Fishing Permit applications, an update on amendments to the Snapper Grouper Fishery Management Plan under development, a System Management Plan Workgroup update, and a report from the Wreckfish Advisory Group and Sub-Committee relative to Amendment 48 addressing wreckfish management. The Committee will consider recommendations from the Snapper Grouper AP for Amendment 46 addressing a private recreational permit for the snapper grouper fishery and consider approving the amendment for public hearings.

The Committee will address Regulatory Amendment 36 addressing gag and black grouper vessel limits and on-demand gear for black sea bass and consider approving for public scoping, and consider Snapper Grouper AP recommendations for Amendment 55 addressing management measures for scamp and yellowmouth grouper. The Committee will discuss Regulatory Amendment 35 addressing red snapper management and re-consider submitting the amendment for Secretarial review, and discuss yellowtail snapper management. The Committee will receive an update on Best Fishing Practices Outreach and AP recommendations on topics not on the agenda.

Wednesday, December 6, 2023, 4 p.m.

Public comment will be accepted from individuals attending the meeting in person and via webinar on all items on the Council meeting agenda. The Council Chair will determine the amount of time provided to each commenter based on the number of individuals wishing to comment.

Citizen Science Committee, Thursday, December 7, 2023, 8:30 a.m.–10:30 a.m.

The Committee will review and approve updated research priorities for the Council's Citizen Science Program, receive an update on the SciFish platform and a demonstration, and an update on the Citizen Science Program.

Habitat and Ecosystem Committee, Thursday, December 7, 2023, 10:30 a.m. Until 12 p.m.

The Committee will receive a report from the Habitat Advisory Panel and address plans for the 5-year Essential Fish Habitat Review. The Committee will receive an update on the Habitat Blueprint and review the draft workplan and annual report outline. The

Committee will address coral management and provide guidance on the utilization of deepwater coral modelling for management and resubmission of Coral Amendment 10.

SEDAR Committee, Thursday, December 7, 2023, 1:30 p.m. Until 2:30 p.m.

The Committee will receive a report from the SEDAR Steering Committee, address Terms of Reference for the SEDAR assessment of Florida Keys/East Coast Florida and Gulf of Mexico hogfish (SEDAR 94), review the SEDAR schedule, and select species to consider for 2027 assessments.

Council Session II, Thursday, December 7, 2023, 2:30 p.m. Until 5 p.m. and Friday, December 8, 2023, 8:30 a.m. Until 12 p.m.

The Council will receive a litigation brief if needed, receive a staff report, and a report from the Council Coordination Committee. The Council will review Allocations Review Guidelines and consider approval, receive an update on stakeholder meetings planning, and receive a presentation on offshore wind activities. The Council will approve topics for a meeting of the Law Enforcement AP and receive reports from NOAA Fisheries Southeast Regional Office and the Southeast Fisheries Science Center. The Council will receive Committee reports, review its workplan, review upcoming meetings, and take action as necessary. The Council will discuss any other business as needed.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 13, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25356 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD524]

Marine Mammals; File No. 27670

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Iris Segura-Garcia, Ph.D., Harbor Branch Oceanographic Institution, Florida Atlantic University, 5600 US 1, Fort Pierce, FL 34946, has applied in due form for a permit to receive and import cetacean parts for scientific research.

DATES: Written comments must be received on or before December 18, 2023.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 27670 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 27670 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Erin Markin, Ph.D., or Shasta McClenahan, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to receive and import parts for research from up to 200 individual cetaceans of any species. Sources of samples may include animals in foreign countries stranded alive or dead or that died during rehabilitation, animals in captivity, and samples from other authorized persons. The parts would be used to understand cetaceans (1) foraging strategies when exposed to limited resources and/or disturbed habitats, (2) food web health, and (3) exposure to environmental toxicants and biomarkers of exposure and health effects. The permit would be valid for 5 years from the date of issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 13, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–25330 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD530]

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Exempted Fishing Permit Application

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Regional Administrator, West Coast Region, NMFS, announces receipt of an exempted fishing permit (EFP) application, and is considering issuance of an EFP that seeks exemption from the requirements at requiring vessel owners and operators to retain sablefish, rex sole, Pacific sanddab and California halibut when on a declared optimized retention bottom trawl or non-whiting midwater trawl trip. At this

time, NMFS is considering allowing participants in the EFP to add sablefish and rex sole to their Vessel Monitoring Plans' (VMP) allowable discard list. NMFS does not expect to add the other two species to this EFP because Pacific sanddab is already listed as an allowable discard, thus no exemption is needed, and NMFS intends to address California halibut discard rules through a future regulatory change rather than an EFP. NMFS requests public comment on the application.

DATES: Comments must be received by December 1, 2023.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2023–0143 by the following method:

• *Electronic Submissions:* Submit all public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2023–0143 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments. The EFP application will be available under Supporting and Related Materials through the same link.

• *Instructions:* Comments must be submitted by the above method to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Matt Dunlap, West Coast Region, NMFS, (206) 526–6119, *matthew.dunlap@noaa.gov.*

SUPPLEMENTARY INFORMATION: This action is authorized by the Pacific Coast Groundfish Fishery Management Plan and the regulations implementing the Magnuson-Stevens Fishery Conservation and Management Act at 50 CFR 600.745, which state that EFPs may be used to authorize fishing activities that would otherwise be prohibited.

On June 28, 2019 (84 FR 31146), at the recommendation of the Pacific Fishery Management Council (Council), NMFS published a final rule that authorized the use of electronic monitoring (EM) in place of human observers to meet requirements for 100-percent at-sea monitoring for catcher vessels in the groundfish trawl catch share fishery (Trawl Rationalization Program). EM video systems are used to record catch and discards by the vessel crew while at sea. Vessel operators are responsible for recording catch and discards in a logbook, which is then used to debit individual fishing quota (IFQ) accounts and cooperative allocations. The Council recommended, and NMFS implemented, a delay to the start of the regulatory program (86 FR 5525, October 6, 2021) until January 2024.

The EFP applicant, California Groundfish Collective, seeks to add sablefish, rex sole, Pacific sanddab and California halibut to the allowable discard list for EFP participants for 2024, just as these species have been allowable discards in the 2023 EM EFP. Extending the allowable discarding of sablefish and rex sole into 2024 via an EFP will provide data that could be used by the Council and NMFS to make informed decisions on refining EM discard regulations. NMFS does not expect to include Pacific sanddab in the EFP because that species is already an allowable discard in the regulations. NMFS expects to address California halibut discard rules via a future regulatory change, not an EFP. The EFP application is for approximately 20 trawl gear vessels that use EM. Additional EFP participants that join EM under the regulatory program may apply at a later date.

If approved, NMFS would issue the permits for the EFP project to the applicant and vessel owners or designated representatives as the ''EFP holder.'' NMFS intends to use an adaptive management approach in which NMFS may revise requirements and protocols to improve the program without issuing another **Federal Register** notice, provided that the modifications fall within the scope of the original EFP. NMFS would also accept additional applications to participate in the same, or similar, exempted fishing activity.

The Regional Administrator has made a preliminary determination that the application described above contains all of the required information and, at least in part, constitutes an activity appropriate for further consideration. After publication of this document in the **Federal Register**, and review and consideration of any public comments received, NMFS may approve and issue permits for the EFP project. NMFS may approve the application in its entirety or may make any alterations needed to achieve the goals of the EFP.

Authority: 16 U.S.C. 1801 *et seq.;* 50 CFR 600.745. This action is authorized by Pacific Coast Groundfish Fishery Management Plan and the regulations implementing the Magnuson-Stevens Fishery Conservation and Management Act at 50 CFR 600.745, which states that EFPs may be used to authorize fishing activities that would otherwise be prohibited.

Dated: November 13, 2023.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–25319 Filed 11–15–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No.–OS–2024–00040–FR]

Notice of Availability of Roundtable on Military Spouse Hiring Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: Notice of roundtable on military spouse hiring.

SUMMARY: The DoD is publishing this notice to announce the Roundtable on Military Spouse Hiring will take place pursuant to the 2023 National Defense Authorization Act (NDAA). This Roundtable will bring together stakeholders from the government, private sector, and military families, to discuss the landscape of opportunities and challenges surrounding military spouse hiring.

DATES: Thursday, November 16, 2023 from 9 a.m. to 3 p.m. Eastern Standard Time (EST).

ADDRESSES: Mark Center Conference Room 17, 4800 Mark Center Drive, Alexandria, VA 22311.

FOR FURTHER INFORMATION CONTACT: Josie Beets, *josie.e.beets.civ@mail.mil,* (202) 570–8977; mailing address: 4800 Mark Center Drive, Alexandria, VA 22311.

SUPPLEMENTARY INFORMATION: In compliance with the 2023 NDAA, section 578, USD(P&R) announces an industry roundtable on military spouse hiring.

Authority: Sec. 578, Public Law 117–263, Stat. 2395.

Purpose: The purpose of the roundtable is to bring together stakeholders from the government, private sector, and military families, to discuss the landscape of opportunities and challenges surrounding military spouse hiring, the resources available

within the DoD, and the role of industry. The roundtable seeks to foster dialogue and collaboration that can pave the way for military spouses to access fulfilling career opportunities while enhancing the talent pool for private entities and filling labor market gaps. The outcomes of this roundtable will be briefed to the Committees on Armed Services of the Senate and House of Representatives.

The Roundtable will include inputs and discussions from the Military Spouse Employment Partnership Annual Partner Meeting, where private industry along with military spouses, Federal agencies, and nonprofit partners gather to network, learn, and provide feedback on how to increase military spouse employment.

The roundtable will also include a meeting on November 16, 2023 from 9 a.m. to 3 p.m. EST on what the DoD can do to impact military spouse hiring both internally and in partnership with private entities. This conversation will focus on the DoD's existing resources for spouses, processes that need to change to increase DoD and Component hiring of spouses, and the capacity to increase support and awareness of available resources. Participants will include the USD (P&R), the Assistant Secretary for Manpower and Reserve Affairs of each Military Department, the Director of the Defense Human Resources Activity, other officials of the DoD the Secretary of Defense determines appropriate, and private entities that participate.

Written Statements: The public or interested organizations may submit written comments. Individuals submitting a written statement must submit their statement to Ms. Josie Beets at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section no later than November 20, 2023. Written statements received may be considered by the participants at a later date.

Dated: November 9, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25264 Filed 11–15–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Preparation of Related Services Personnel Serving Children With Disabilities Who Have High-Intensity Needs

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2024 for Personnel Development to Improve Services and Results for Children with Disabilities—Preparation of Related Services Personnel Serving Children with Disabilities who have High-Intensity Needs, Assistance Listing Number (ALN) 84.325R. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: November 16, 2023.

Deadline for Transmittal of Applications: January 16, 2024.

Deadline for Intergovernmental Review: March 15, 2024.

Pre-Application Webinar Information: No later than November 21, 2023, the Office of Special Education and Rehabilitative Services will post details on pre-recorded informational webinars designed to provide technical assistance to interested applicants. Links to the webinars may be found at *https://www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Louise Tripoli, U.S. Department of Education, 400 Maryland Avenue SW, Room 4A10, Washington, DC 20202. Telephone: (202) 245–7554. Email: *Louise.Tripoli@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in early intervention, special education, related services, and regular education to work with children, including infants, toddlers, and youth, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research, to be successful in serving those children.

Priorities: This competition includes one absolute priority and, within that absolute priority, one competitive preference priority. In accordance with 34 CFR 75.105(b)(2)(v), the absolute priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1462 and 1481)).

Absolute Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Preparation of Related Services Personnel Serving Children with Disabilities who have High-Intensity Needs.

Background:

The purpose of this priority is to prepare scholars in related services who are fully credentialed and licensed to serve children, including infants, toddlers, and youth, with disabilities (children with disabilities) who have high-intensity needs. The Department is committed to promoting equity for children with disabilities to access educational resources and opportunities, and a high priority for the Department is to increase the number of related services personnel, including increasing the number of multilingual personnel and personnel from racially and ethnically diverse backgrounds, who provide services to children with disabilities. To support these goals, under this absolute priority, the Department will fund high-quality projects that prepare related services personnel at the bachelor's degree, certification, master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in a variety of education settings, including natural environments (the home and community settings in which children with and without disabilities participate), early childhood

programs, classrooms, schools, and distance learning environments; including increasing the number of multilingual personnel and personnel from racially and ethnically diverse backgrounds. Projects will also prepare such personnel to support each child with a disability who has high-intensity needs in meeting high expectations and to have meaningful and effective collaborations with other providers, families, and administrators.

A shortage of related services personnel persists in all regions of the country and ultimately impedes the ability of children with disabilities to reach their full academic, social, and emotional potential (National Coalition on Personnel Shortages in Special Education, n.d.). In a national survey of Part C State coordinators, 98 percent of respondents indicated that they had shortages of personnel to work in their system, with the top three areas of shortage being speech-language pathologists (83 percent), physical therapists (80 percent), and occupational therapists (70 percent) (IDEA Infant and Toddler Coordinators Association, 2021). Other data substantiates this acute shortage in school-based settings with the majority of school districts reporting that they do not have enough related services personnel to meet the needs of students with disabilities (National Coalition on Personnel Shortages in Special Education, n.d.). These shortages are only expected to increase as the estimated demand for future related services professions is expected to exceed the supply (Bureau of Labor Statistics, 2023). The overall shortage in related services personnel is exacerbated by the substantial shortage of multilingual personnel, personnel with disabilities, and personnel from racially and ethnically diverse backgrounds prepared to enter the workforce (American Physical Therapy Association, 2020; American Speech-Language Hearing Association, 2019; National Association of School Psychologists, 2021). These shortages are of concern, as research indicates that increasing multilingual personnel, personnel with disabilities, and personnel from racially and ethnically diverse backgrounds can have positive impacts on all children. Multilingual children and children of color, with and without disabilities, demonstrate improved academic achievement and behavioral and social-emotional development when they receive services from multilingual personnel and personnel from racially and ethnically diverse backgrounds (Bryan, 2021; Carver-Thomas, 2018).

The need for related services personnel with the knowledge and skills to serve children with disabilities who have high-intensity needs is even greater. To effectively serve children with disabilities who have high-intensity needs, related services personnel require specialized or advanced skills and knowledge to work within a multidisciplinary team, collaboratively design and deliver evidence-based intensive individualized interventions, and provide interventions in person and through distance learning technologies in natural environments, classrooms, and schools that address the needs of these individuals (Boe et al., 2013; Browder et al., 2014; McLeskey & Brownell, 2015).

To enable related services personnel to provide efficient, high-quality, integrated, and equitable services, both in person and through distance learning technologies, personnel preparation programs need to embed content, practices, and extensive field or clinical experiences that are evidence-based and culturally and linguistically responsive into preservice training in early intervention settings, early childhood programs, and schools. Therefore, this priority aims to fund high-quality projects that prepare scholars in related services, including multilingual scholars, scholars with disabilities, and scholars from racially and ethnically diverse backgrounds, who are fully credentialed and licensed to enter the field and serve children with disabilities who have high-intensity needs.

Priority:

The purpose of this priority is to increase the number and improve the quality of related services personnel,[1] including multilingual personnel and personnel from racially and ethnically diverse backgrounds, who are fully credentialed and licensed to serve children with disabilities who have high-intensity needs.[2] The priority will fund high-quality projects that prepare scholars[3] in related services at the bachelor's degree, certification,[4] master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in natural environments, early childhood programs, classrooms, school settings, and in distance learning environments serving children with disabilities who have high-intensity needs.

Note: Projects may include individuals who are not funded as scholars, but are in degree programs (*e.g.,* general education, early childhood education, administration) that are cooperating with the grantee's project. These individuals may participate in the coursework, assignments, field or clinical experiences, and other opportunities required by the scholars' program of study (*e.g.,* speaker series, monthly seminars) if doing so does not diminish the benefit for project-funded scholars (*e.g.,* by reducing funds available for scholar support or limiting opportunities for scholars to participate in project activities).

Note: Projects that prepare scholars from two or more related services degree programs can qualify under this priority. Related services degree programs across more than one institution of higher education (IHE) may partner together within a project. Projects that prepare all scholars to be dually certified, including dually certified in a related service and special

[1] For the purposes of this priority, ''related services'' includes the following: speech-language pathology and audiology services; assistive technology services; sign language interpreting services; intervener services; psychological services; applied behavior analysis; physical therapy and occupational therapy; recreation, including therapeutic recreation; artistic and cultural services, including music, art, dance and movement therapy; social work services; counseling services, including rehabilitation counseling; and orientation and mobility services.

[2] For the purposes of this priority, ''high-intensity needs'' refers to a complex array of disabilities (*e.g.,* multiple disabilities, significant cognitive disabilities, significant physical disabilities, significant sensory disabilities, significant autism, significant emotional disabilities, or significant learning disabilities, including dyslexia) or the needs of children with these disabilities requiring intensive, individualized intervention(s) (*i.e.,* that are specifically designed to address persistent learning or behavior difficulties, implemented with greater frequency and for a more extended duration than is commonly available in a typical classroom or early intervention setting, or which require personnel to have knowledge and skills in identifying and implementing multiple evidence-based interventions).

[3] For the purposes of this priority, ''scholar'' means an individual who: (a) is pursuing a bachelor's, certification, master's, educational specialist, or clinical doctoral degree in related services; (b) receives scholarship assistance as authorized under section 662 of IDEA (34 CFR 304.3(g)); (c) will be eligible for a license, endorsement, or certification from a State or national credentialing authority following completion of the degree program identified in the application; and (d) will be able to be employed in a position that serves children with disabilities for a minimum of 51 percent of their time or case load.

[4] For the purposes of this priority, ''certification'' refers to programs of study for individuals with bachelor's, master's, educational specialist, or clinical doctoral degrees that lead to licensure, endorsement, or certification from a State or national credentialing authority following completion of the degree program that qualifies graduates to teach or provide services to children with disabilities. Programs of study that lead to a certificate of completion awarded from an institution of higher education (IHE), but do not lead to licensure, endorsement, or certification from a State or national credentialing authority, do not qualify.

education, can qualify under this priority.

Note: Applications that propose to prepare early intervention and special education personnel who do not provide related services are not eligible under this priority.

Note: Applicants under this priority may not submit the same proposal under Personnel Preparation of Special Education, Early Intervention, and Related Services Personnel at Historically Black Colleges and Universities, Tribally Controlled Colleges and Universities, and Other Minority Serving Institutions, ALN 84.325M. Applicants may submit substantively different proposals under ALN 84.325R and ALN 84.325M. The Office of Special Education Programs (OSEP) may fund applications out of rank order based on funding decisions across ALN 84.325R and ALN 84.325M in FY 2024 to ensure that similar personnel preparation projects are not funded within the same IHE across the ALN 84.325R and ALN 84.325M competitions.

Focus Areas:

Within this absolute priority, the Secretary intends to support projects under the following two focus areas: (A) Preparing Related Services Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs; and (B) Preparing Related Services Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.

Applicants must identify the specific focus area (*i.e.,* A or B) under which they are applying as part of the competition title on the application cover sheet (SF 424, line 12). Applicants may not submit the same proposal under both Focus Area A and B. However, applicants may submit substantively different proposals for Focus Areas A and B.

Note: OSEP may fund out of rank order high-quality applications to ensure that projects are funded in both Focus Area A and Focus Area B.

Focus Area A: Preparing Related Services Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs. This focus area is for projects that prepare related services personnel to provide services to infants, toddlers, and preschool children with disabilities who have high-intensity needs. In States where the certification age range is other than birth through five, applicants must propose a preparation project that complies with the State's certification requirements for related services personnel to work in early intervention or early childhood special education.

Focus Area B: Preparing Related Services Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs. This focus area is for projects that prepare related services personnel to work with school-age children with disabilities who have high-intensity needs.

Focus Areas A and B:

Applicants may, but are not required to, use up to the first 12 months of the project period and up to $100,000 awarded in the first budget period for planning, including enhancing an existing program, without enrolling scholars. If an applicant chooses to use the first year for program planning, then the applicant must provide sufficient justification for requesting program planning time and include the goals, objectives, key personnel and necessary collaborators, and intended outcomes of program planning in year one, a description of the proposed strategies and activities to be supported, and a timeline for the work. The proposed strategies may include activities such as—

(1) Updating coursework, group assignments, or extensive and coordinated field or clinical experiences in early intervention settings, early childhood programs, and schools needed to support preparation for related services personnel, including personnel from groups that are underrepresented in the field, including personnel with disabilities, multilingual personnel, and personnel from racially and ethnically diverse backgrounds, serving children with disabilities who have high-intensity needs;

(2) Building capacity (*e.g.,* hiring a field supervisor, providing professional development for faculty and field supervisors) of the project to prepare scholars, including scholars from groups that are underrepresented in the field, including scholars with disabilities, multilingual scholars, and scholars from racially and ethnically diverse backgrounds, to serve children with disabilities with high-intensity needs and their families;

(3) Purchasing needed resources (*e.g.,* additional intervention supplies, technology-based resources, or other specialized equipment to enhance interventions); or

(4) Establishing relationships with early intervention and early childhood programs or schools to serve as sites for field or clinical experiences needed to support the project. These sites may include high-need local educational agencies (LEAs),[5] high-poverty schools,[6] schools identified for comprehensive support and improvement,[7] and schools implementing a targeted support and improvement plan [8] for children with disabilities; early childhood and early intervention programs located within the geographic boundaries of a high-need LEA; and early childhood and early intervention programs located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State.

In addition to requesting up to $100,000 for planning, additional Federal funds may also be requested for scholar support and other grant activities occurring in year one of the project.

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to related services programs must provide, in their applications, information on how these new areas will be sustained once Federal funding ends.

Note: Project periods under this priority may be up to 60 months. Projects should be designed to ensure that all proposed scholars successfully complete the program within 60 months from the start of the project. The Secretary may reduce continuation awards for any project in which scholar

[5] For the purposes of this priority, ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children are from families with incomes below the poverty line.

[6] For the purposes of this priority, ''high-poverty school'' means a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified in section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data.

[7] For the purposes of this priority, ''school implementing a comprehensive support and improvement plan'' means a school identified for comprehensive support and improvement by a State under section 1111(c)(4)(D) of the ESEA that includes (a) not less than the lowest performing 5 percent of all schools in the State receiving funds under title I, part A of the ESEA; (b) all public high schools in the State failing to graduate one third or more of their students; and (c) public schools in the State described in section 1111(d)(3)(A)(i)(II) of the ESEA.

[8] For the purposes of this priority, ''school implementing a targeted support and improvement plan'' means a school identified for targeted support and improvement by a State that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system defined in section 1111(d)(2) of the ESEA.

recruitment is not on track or scholars are not on track to complete the program within the 60 months.

To be considered for funding under this absolute priority, all program applicants must meet the requirements contained in this priority.

To meet the requirements of this priority, an applicant must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how—

(1) The proposed project will address the need in the proposed preparation focus area to prepare related services personnel who are fully qualified to serve children with disabilities who have high-intensity needs;

(2) The proposed project will increase the number of personnel in the proposed preparation focus area who demonstrate the competencies [9] needed to—

(i) Promote high expectations and improve outcomes for children with disabilities who have high-intensity needs;

(ii) Provide intensive, evidence-based [10] individualized interventions in person and through distance learning technologies in a variety of early intervention, early childhood, and school settings (*e.g.,* natural environments; public schools, including charter schools; private schools; and other nonpublic education settings, including home education);

(iii) Provide culturally and linguistically responsive interventions and services;

(iv) Collaborate with diverse partners, including multilingual individuals, individuals and families from racially and ethnically diverse backgrounds, and individuals with disabilities, using a multidisciplinary team approach to address the individualized developmental, learning, and academic needs of children with disabilities who have high-intensity needs, and support their successful transitions from early childhood to elementary, elementary to secondary, or transition to postsecondary education and the workforce; and

(v) Exercise leadership to improve professional practice and services and education for children with disabilities who have high-intensity needs; and

(3) The applicant has successfully graduated students from their program, including students with disabilities, multilingual students, and students who are from racially, and ethnically diverse backgrounds, by including data disaggregated by disability status, race, national origin, and primary language(s), and the number of students who have graduated in the last five years.

(b) Demonstrate, in the narrative section of the application under ''Quality of project services,'' how—

(1) The project will conduct its planning activities, if the applicant elects to use up to the first 12 months of the project period and up to $100,000 awarded in the first budget period for planning;

(2) The project will recruit and retain scholars. To meet this requirement, the applicant must describe—

(i) The selection criteria the project will use to identify applicants for admission in the program;

(ii) The specific recruitment strategies the project will use to attract a diverse pool of applicants, including from groups that are traditionally underrepresented in the field, applicants with disabilities, multilingual applicants, and applicants from racially and ethnically diverse backgrounds; and

Note: Applicants should engage in focused outreach and recruitment to increase the number of applicants from groups that are traditionally underrepresented in the field, including applicants with disabilities, multilingual applicants, and applicants from racial and ethnic diversity backgrounds, but the selection criteria the applicant intends to use must ensure equal access and treatment of all applicants seeking admission to the program and must be consistent with applicable law, including Federal civil rights law.

(iii) The approach that will be used to mentor and support all scholars, including any specific approaches to supporting scholars from groups that are traditionally underrepresented in the field, including individuals with disabilities, multilingual scholars, and scholars from racially and ethnically diverse backgrounds, for retention and completion of the program within the project period and preparing them for careers in early intervention, special education, and related services; and

(3) The project will be designed to promote the acquisition of the competencies needed by related services personnel to support improved outcomes for children with disabilities with high-intensity needs. To address this requirement, the applicant must—

(i) Describe how the proposed components, such as coursework; field or clinical experiences in early intervention, early childhood, and school settings; work-based experiences; or other opportunities provided to scholars, and sequence of the project components will enable the scholars to acquire the competencies needed by personnel working with children with disabilities with high-intensity needs;

(ii) Describe how the proposed project will implement current evidence-based practices (EBPs) to prepare scholars to provide effective and equitable, evidence-based, and culturally and linguistically responsive instruction, interventions, and services that improve outcomes for children with disabilities with high-intensity needs, in a variety of early childhood and early intervention or educational settings, including in-person and remote settings; and

(iii) Describe how the proposed project will engage partners, including: multilingual individuals and individuals and families of color; public or private partnering agencies, schools, or programs; centers or organizations that provide services to children with disabilities and their families; and individuals with disabilities and their families, to inform and support project components.

(c) Demonstrate, in the narrative section of the application under ''Quality of the project personnel and management plan,'' how—

(1) The project director and other key project personnel are qualified to prepare scholars in the project's preparation focus area;

(2) The project director and other key project personnel will manage the components of the project; and

(3) The time commitments of the project director and other key project personnel are adequate to meet the objectives of the proposed project.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of resources,'' how—

(1) Information regarding the types of accommodations and resources available to fully support scholars' well-being and a work-life balance (*e.g.,* university and community mental health supports, counseling services, health resources, housing resources, child care) will be disseminated and how the project will support scholars to access those accommodations and resources on a timely basis, if needed, while the scholar is in the program;

[9] For the purposes of this priority, ''competencies'' means what a person knows and can do—the knowledge, skills, and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011).

[10] For the purposes of this priority, ''evidence-based'' means, at a minimum, evidence that demonstrates a rationale (as defined in 34 CFR 77.1), where a key project component (as defined in 34 CFR 77.1) included in the project's logic model (as defined in 34 CFR 77.1) is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes (as defined in 34 CFR 77.1).

(2) The types of accommodations and resources provided to support scholars' well-being and a work-life balance will be individualized based on scholars' cultural, academic, social emotional, and disability-related needs with the goal of supporting them to complete the program; and

(3) The budget is adequate for meeting the project objectives and mitigating financial burden to scholars in completing the program of study.

Note: Scholar support does not need to be uniform for all scholars and should be customized for individual scholars based on scholars' financial needs, including consideration of all costs associated with the cost of attendance, even if that means enrolling fewer scholars. Scholar support can include support for cost of attendance (*e.g.,* tuition and fees; university student health insurance; an allowance for books, materials, and supplies; an allowance for miscellaneous personal expenses; an allowance for dependent care, such as child care; and/or an allowance for room and board), travel in conjunction with training assignments including conference registration, and stipends to support scholars' completion of the program. Projections for scholar support should consider tuition increases and cost of living increases over the project period.

(e) Demonstrate, in the narrative section of the application under ''Quality of the project evaluation,'' how the applicant will—

(1) Evaluate how well the goals or objectives of the proposed project have been met. To meet this requirement, the applicant must describe—

(i) The outcomes to be measured for both the project and the scholars, particularly the acquisition of scholars' competencies; and

(ii) The evaluation methodologies, data collection methods, and data analyses that will be used; and

(2) Collect, analyze, and use data on scholars supported by the project to inform the project on an ongoing basis.

(f) Demonstrate, in the appendices or narrative under ''Required project assurances'' as directed, that the following requirements are met. The applicant must—

(1) Include in Appendix A of the application—

(i) Charts, tables, figures, graphs, screen shots, and visuals that provide information directly relating to the application requirements for the narrative. Appendix A should not be used for supplementary information. Please note that charts, tables, figures, graphs, and screen shots can be single-spaced when placed in Appendix A; and

(ii) A letter of support from a public or private partnering agency, school, or program, that states it will provide scholars with a field or clinical experience in a high-need LEA, a high-poverty school, a school implementing a comprehensive support and improvement plan, a school implementing a targeted support and improvement plan for children with disabilities, a State educational agency, an early childhood or early intervention program located within the geographical boundaries of a high-need LEA, or an early childhood or early intervention program located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State;

(2) Include in Appendix B of the application—

(i) A table that lists the project's required coursework and includes the course title, brief description, learning goals, and relevant State or national professional organization personnel standards for each course;

(ii) Four exemplar course syllabi required by the degree program that reflect EBPs across the areas of assessment; social, emotional, and behavior development and learning; inclusive practices; instructional strategies; and literacy, as appropriate, and consider the unique needs of children of color with disabilities and children with disabilities who are multilingual;

(3) Include in the application budget attendance by the project director at a three-day project directors' meeting in Washington, DC, during each year of the project; and

(4) Provide an assurance that—

(i) The project will meet the requirements in 34 CFR 304.23, particularly those related to (A) informing all scholarship recipients of their service obligation commitment; and (B) disbursing scholarships. Failure by a grantee to properly meet these requirements is a violation of the grant award that may result in the grantee being liable for returning any misused funds to the Department;

(ii) The project will meet the statutory requirements in section 662(e) through (h) of IDEA;

(iii) The project will be operated in a manner consistent with nondiscrimination requirements contained in Federal civil rights laws;

(iv) All the syllabi for the project's required coursework will be provided if requested by OSEP;

(v) At least 65 percent of the total award over the project period (*i.e.,* up to 60 months) will be used for scholar support;

(vi) Scholar support provided by the project (*e.g.,* tuition and fees; university student health insurance; an allowance for books, materials, and supplies; an allowance for miscellaneous personal expenses; an allowance for dependent care, such as child care; and an allowance for room and board) is not based on the condition that the scholar work for the grantee (*e.g.,* personnel at the IHE);

(vii) The project director, key personnel, and scholars will actively participate in learning opportunities (*e.g.,* webinars, briefings) supported by OSEP. This is intended to promote opportunities for participants to understand reporting requirements, share resources, and generate new knowledge by addressing topics of common interest to participants across projects including Department priorities and needs in the field;

(viii) The project website, if applicable, will be of high quality, with an easy-to-navigate design that meets government or industry-recognized standards for accessibility;

(ix) Scholar accomplishments (*e.g.,* public service, awards, publications, conference presentations) will be reported in annual and final performance reports; and

(x) Annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under 34 CFR 75.110. Data collection includes the submission of a signed, completed pre-scholarship agreement and exit certification for each scholar funded under an OSEP grant (see paragraph (f)(4)(i) of this priority). Applicants are encouraged to visit the Personnel Development Program Data Collection System website at *https://pdp.ed.gov/osep* for further information about this data collection requirement.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that address the following priority. Under 34 CFR 75.105(c)(2)(i), we award an additional 3 points to an application that meets the competitive preference priority. Applicants should indicate in the abstract if they are addressing the competitive preference priority.

This priority is:

Applications from New Potential Grantees (0 or 3 points).

(a) Under this priority, an applicant must demonstrate that the applicant (*e.g.,* the IHE) has not had an active discretionary grant under ALN 84.325R, ALN 84.325M, or ALN 84.325K funded in the last five years before the deadline date for submission of applications under this program (ALN 84.325R).

(b) For the purpose of this priority, a grant is active until the end of the grant's project or funding period, including any extensions of those periods that extend the grantee's authority to obligate funds.

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Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priorities in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $115,000,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2024, of which we intend to use an estimated $5,000,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2025 from the list of unfunded applications from this competition.

Estimated Range of Awards: $1,150,000–$1,250,000.

Estimated Average Size of Awards: $1,200,000.

Maximum Award: We will not make an award exceeding $1,250,000 per project for a project period of 60 months or an award that exceeds $350,000 for any single budget period.

Note: Applicants must describe, in their applications, the amount of funding being requested for each 12-month budget period.

Estimated Number of Awards: 20.

Project Period: Up to 60 months.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* Eligible applicants are IHEs and private nonprofit organizations.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2.a. *Cost Sharing or Matching:* Cost sharing or matching is not required for this competition.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *https://www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c), a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs, nonprofit organizations suitable to carry out the activities proposed in the application, and public agencies. The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee, consistent with 34 CFR 75.708(b)(2).

4. *Other General Requirements:*

a. Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

b. Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *www.federalregister.gov/content/pkg/FR-2022-12-07/pdf/2022-26554.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you limit the application narrative to no more than 40 pages and use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project will prepare personnel for fields in which shortages have been demonstrated; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(b) *Quality of project services (35 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(ii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services;

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services; and

(iv) The extent to which the proposed activities constitute a coherent, sustained program of training in the field.

(c) *Quality of project personnel and quality of the management plan (20 points).*

(1) The Secretary considers the quality of the project personnel and the quality of the management plan.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of key project personnel;

(ii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks; and

(iii) The extent to which the time commitments of the project director and principal investigator and other key

project personnel are appropriate and adequate to meet the objectives of the proposed project.

(d) *Adequacy of resources (20 points).*

(1) The Secretary considers the adequacy of resources of the proposed project.

(2) In determining the adequacy of resources of the proposed project, the Secretary considers the following factors:

(i) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization; and

(ii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the project evaluation (15 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project; and

(ii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions, and under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

6. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those

modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include (1) the percentage of preparation programs that incorporate scientifically based practices or EBPs into their curricula; (2) the percentage of scholars completing the preparation program who are knowledgeable and skilled in EBPs that improve outcomes for children with disabilities; (3) the percentage of scholars who exit the preparation program prior to completion due to poor academic performance; (4) the percentage of scholars completing the preparation program who are working in the area(s) in which they were prepared upon program completion; (5) the Federal cost per scholar who completed the preparation program; (6) the percentage of scholars who completed the preparation program and are employed in high-need districts; and (7) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

In addition, the Department will gather information on the following outcome measures: the number and percentage of scholars proposed by the grantee in their application that were actually enrolled and making satisfactory academic progress in the current academic year; the number and percentage of enrolled scholars who are on track to complete the training program by the end of the project's original grant period; and the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Glenna Wright-Gallo,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2023–25307 Filed 11–15–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Board for Education Sciences

AGENCY: National Board for Education Sciences, U.S. Department of Education, Institute of Education Sciences (IES).

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the agenda, time, and instructions to access or participate in the National Board for Education Sciences (hereafter referred to as NBES or Board) virtual meeting scheduled for December 4th and 5th, 2023. This notice provides information about the meeting to members of the public who may be interested in accessing the meeting and/or how to provide written comment(s).

ADDRESSES: The virtual meeting will be conducted via Microsoft Teams. Members of the public may access the meeting virtually and should contact the Designated Federal Official for access instructions.

DATES: The NBES meeting will be held on Monday, December 4th, 2023, from 10:00 a.m.–5:00 p.m. (EST) and Tuesday, December 5th, 2023, from 10:00 a.m.–3:00 p.m. (EST).

FOR FURTHER INFORMATION CONTACT: Ellie Pelaez, Designated Federal Official (DFO) for NBES, U.S. Department of Education, IES: 400 Maryland Avenue SW, PCP 4126–1, Washington, DC

20202, telephone: (202) 245–7274, email: *ellie.pelaez@ed.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is required by Section 1009(a)(2) of 5 U.S.C. Chapter 10 (Federal Advisory Committees).

Statutory Authority and Function: The Board is authorized by § 116 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9516). The Board is established as part of the U.S. Department of Education, IES, and shall, consistent with 20 U.S.C. 9514, 9515(b)–(c), and 9516 function as a board of directors for IES. The mission of IES is to provide national leadership in expanding fundamental knowledge and understanding of education from early childhood through postsecondary study, in order to provide parents, educators, students, researchers, policymakers, and the general public with reliable information about the condition and progress of education in the United States; educational practices that support learning and improve academic achievement and access to educational opportunities for all students; and the effectiveness of Federal and other education programs.

The Board's responsibilities are: (1) advise and consult with the Director of IES (Director) on the policies of IES; (2) consider and approve priorities proposed by the Director under 20 U.S.C. 9515 to guide the work of IES; (3) transmit approved priorities to the appropriate congressional committee (20 U.S.C. 9515(b)); (4) ensure that the priorities of IES and the National Education Centers are consistent with the mission of IES (20 U.S.C. 9515(c)); (5) review and approve procedures for technical and scientific peer review of the activities of IES; (6) advise the Director on the establishment of activities to be supported by IES, including the general areas of research to be carried out by the National Center for Education Research (NCER) and the National Center for Special Education Research (NCSER) (20 U.S.C. 9567); (7) present to the Director such recommendations as it may find appropriate for (a) the strengthening of education research, and (b) the funding of IES; (8) advise the Director on the funding of applications for grants, contracts, and cooperative agreements for research, after the completion of peer review; (9) review and regularly evaluate the work of IES, to ensure that scientifically valid research, development, evaluation, and statistical analysis are consistent with the standards for such activities under this title; (10) advise the Director on ensuring that activities conducted or supported by IES are objective, secular, neutral, and non-ideological, and are free of partisan political influence and racial, cultural, gender, or regional bias; (11) solicit advice and information from those in the educational field, particularly practitioners and researchers, to recommend to the Director topics that require long-term, sustained, systematic, programmatic, and integrated research efforts, including knowledge utilization and wide dissemination of research, consistent with the priorities and mission of IES; (12) advise the Director on opportunities for the participation in, and the advancement of, women, minorities, and persons with disabilities in education research, statistics, and evaluation activities of IES; (13) recommend to the Director ways to enhance strategic partnerships and collaborative efforts among other Federal and State research agencies; (14) recommend to the Director individuals to serve as Commissioners of the National Education Centers; and (15) make recommendations to the President with respect to the appointment of the Director.

Meeting Agenda: The agenda for the meeting is as follows: (1) Call to order and welcome by the Chairperson; (2) Member roll call; (3) Approval of meeting minutes from the September 11, 2023 meeting of the Board; (4) Board member approval of the meeting agenda; (5) Board member discussion of the process for reviewing reports from National Academies of Sciences, Engineering, and Medicine NASEM; (6) Responses to NASEM recommendations in *The Future of Education Research at IES* by NCSER Commissioner, Nathan Jones, and NCER Commissioner, Liz Albro, with Board discussion; (7) Responses to NASEM recommendations in *A Vision and Roadmap for Education Statistics* by National Center for Education Statistics (NCES) Commissioner, Peggy Carr, with Board discussion; (8) Reports from National Center for Education Evaluation and Regional Assistance (NCEE) Commissioner, Matt Soldner, and IES Deputy Director for Science, Anne Ricciuti; (9) discussion of upcoming policy legislation; (10) Establishment and planning for NBES Subcommittee for hiring an NBES Executive Director (11) Discussion of Board priorities; (12) Planning NBES meeting dates for the upcoming year; (13) Closing remarks.

Instructions for Accessing the Meeting: Members of the public interested in virtual access to this meeting may email the DFO listed in this notice no later than 11:59 p.m. Eastern Time (ET) on Monday, November 30th. The DFO will provide a link and instructions on how to access the meeting via Microsoft Teams.

Public Comment: Members of the public interested in submitting written comments related to the work of the NBES may do so by emailing the DFO listed in this notice no later than 11:59 p.m. ET on Monday, November 30th, 2023. Written comments should pertain to the mission and function of NBES.

Reasonable Accommodations: The virtual meeting is accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the DFO listed in this notice no later than November 30th, 2023.

Access to Records of the Meeting: The official minutes of this meeting will be available for public review on the IES website, *https://ies.ed.gov/director/board/index.asp,* no later than 90 days after the meeting. Pursuant to 5 U.S.C. 1009(b), the public may also inspect NBES records at the U.S. Department of Education, IES, 400 Maryland Avenue SW, Washington, DC 20202, Monday–Friday, 8:30 a.m. to 5:00 p.m. ET. Please email *ellie.pelaez@ed.gov* to schedule an appointment.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Section 116 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9516).

Mark Schneider,

Director, Institute of Education Sciences.

[FR Doc. 2023–25289 Filed 11–15–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology (PCAST)

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an open virtual meeting of the President's Council of Advisors on Science and Technology (PCAST). The Federal Advisory Committee Act (FACA) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Friday, December 1, 2023; 11:10 a.m. to 12:20 p.m. EST.

ADDRESSES: Information for viewing the livestream of the meeting can be found on the PCAST website closer to the meeting at: *www.whitehouse.gov/PCAST/meetings.*

FOR FURTHER INFORMATION CONTACT: Dr. Lara A. Campbell, Designated Federal Officer, PCAST, email: *PCAST@ostp.eop.gov;* telephone: (202) 881–9714.

SUPPLEMENTARY INFORMATION: PCAST is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from the White House, cabinet departments, and other Federal agencies. See the Executive order at *whitehouse.gov.* PCAST is consulted on and provides analyses and recommendations concerning a wide range of issues where understanding of science, technology, and innovation may bear on the policy choices before the President. The Designated Federal Officer is Dr. Lara A. Campbell. Information about PCAST can be found at: *www.whitehouse.gov/PCAST.*

Tentative Agenda: PCAST will hear from invited speakers on groundwater, including usage and reserves. There may also be a short discussion of the PCAST Advancing Nutrition Science Workshop held November 3, 2023. Additional information and the meeting agenda, including any changes that arise, will be posted on the PCAST website at: *www.whitehouse.gov/PCAST/meetings.*

Public Participation: The meeting is open to the public. The meeting will be held virtually for members of the public. It is the policy of the PCAST to accept written public comments no longer than 10 pages and to accommodate oral public comments whenever possible. The PCAST expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

The public comment period for this meeting will take place on December 1, 2023, at times specified in the meeting agenda. This public comment period is designed only for substantive commentary on PCAST's work, not for business marketing purposes.

Oral Comments: To be considered for the public speaker list at the meeting, interested parties should register to speak at *PCAST@ostp.eop.gov,* no later than 12 p.m. Eastern Time on November 22, 2023. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of up to 10 minutes. If more speakers register than there is space available on the agenda, PCAST will select speakers on a first-come, first-served basis from those who registered. Those not able to present oral comments may file written comments with the council.

Written Comments: Although written comments are accepted continuously, written comments should be submitted to *PCAST@ostp.eop.gov* no later than 12 p.m. Eastern Time on November 22, 2023, so that the comments can be made available to the PCAST members for their consideration prior to this meeting.

PCAST operates under the provisions of FACA, all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST website at: *www.whitehouse.gov/PCAST/meetings.*

Minutes: Minutes will be available within 45 days at: *www.whitehouse.gov/PCAST/meetings.*

Signed in Washington, DC, on November 9, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023–25272 Filed 11–15–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–150–000.

Applicants: Eastern Shore Natural Gas Company.

Description: § 4(d) Rate Filing: Supply Connection Service Rate Schedule Filing to be effective 1/1/2024.

Filed Date: 11/9/23.

Accession Number: 20231109–5066.

Comment Date: 5 p.m. ET 11/21/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 9, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25343 Filed 11–15–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–307–000]

Roundhouse Interconnect, LLC; Supplemental Notice That Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Roundhouse Interconnect, LLC includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal

Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502–6595 or *OPP@ferc.gov.*

Dated: November 9, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25345 Filed 11–15–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: November 16, 2023, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426, Open to the public.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* NOTE—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed online at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

1106TH—MEETING

[Open Meeting; November 16, 2023; 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD24–1–000	Agency Administrative Matters.
A–2	AD24–2–000	Customer Matters, Reliability, Security and Market Operations.
A–3	AD06–3–000	Market Update.
A–4	AD07–13–017	FY2023 Report on Enforcement.
	Electric	
E–1	ER22–2185–001, ER22–2185–000	Black Hills Colorado Electric, LLC.
E–2	ER20–1041–003	Wabash Valley Power Association, Inc.
E–3	EL21–78–000	PJM Interconnection, L.L.C.
E–4	ER23–2656–000	Louisville Gas and Electric Company and Kentucky Utilities Company.
	ER23–2662–000	Kentucky Utilities Company.
	ER21–894–000, ER21–895–000, ER21–896–000, ER21–897–000, ER21–900–000, ER21–904–000 (Consolidated).	Louisville Gas and Electric Company and Kentucky Utilities Company.
	ER21–894–002	Louisville Gas and Electric Company and Kentucky Utilities Company.
E–5	EC98–2–006, ER18–2162–005	Louisville Gas and Electric Company and Kentucky Utilities Company.
E–6	ER23–2893–000, TS23–8–000	Horus West Virginia I, LLC.
E–7	EL24–2–000	EverBright, LLC.
E–8	EL23–86–000	The Carlyle Group Inc. and NineDot Energy, LLC.
E–9	ER22–682–004, ER22–682–000, ER22–682–003.	Duke Energy Progress, LLC.
E–10	ER23–2033–001	ITC Midwest, LLC.

1106TH—MEETING—Continued

[Open Meeting; November 16, 2023; 10:00 a.m.]

Item No.	Docket No.	Company
E–11	ER23–1335–000	Ameren Illinois Company.
	Gas	
G–1	OR18–7–002	Epsilon Trading, LLC, Chevron Products Company, and Valero Marketing and Supply Company v. Colonial Pipeline Company.
	OR18–12–002	BP Products North America, Inc., Trafigura Trading LLC, and TCPU, Inc. v. Colonial Pipeline Company.
	OR18–17–002	TransMontaigne Product Services LLC v. Colonial Pipeline Company.
	OR19–1–001	Southwest Airlines Co. and United Aviation Fuels Corporation v. Colonial Pipeline Company.
	OR19–4–001	Phillips 66 Company v. Colonial Pipeline Company.
	OR19–16–001	American Airlines, Inc. v. Colonial Pipeline Company.
	OR19–20–000	Metroplex Energy, Inc. v. Colonial Pipeline Company.
	OR19–27–000	Gunvor USA LLC v. Colonial Pipeline Company.
	OR19–36–000	Pilot Travel Centers, LLC v. Colonial Pipeline Company.
	OR20–7–000, OR20–9–000 (consolidated)	Sheetz, Inc. v. Colonial Pipeline Company, Apex Oil Company, Inc. and FutureFuel Chemical Company v. Colonial Pipeline Company.
G–2	OR18–7–003	Epsilon Trading, LLC, Chevron Products Company, and Valero Marketing and Supply Company v. Colonial Pipeline Company.
	OR18–12–003	BP Products North America, Inc., Trafigura Trading LLC, and TCPU, Inc. v. Colonial Pipeline Company.
	OR18–17–003	TransMontaigne Product Services LLC v. Colonial Pipeline Company.
	OR19–1–002	Southwest Airlines Co. and United Aviation Fuels Corporation v. Colonial Pipeline Company.
	OR19–4–002	Phillips 66 Company v. Colonial Pipeline Company.
	OR19–16–002	American Airlines, Inc. v. Colonial Pipeline Company.
	OR19–20–001	Metroplex Energy, Inc. v. Colonial Pipeline Company.
	OR19–27–001	Gunvor USA LLC v. Colonial Pipeline Company.
	OR19–36–001	Pilot Travel Centers, LLC v. Colonial Pipeline Company.
	OR20–7–001	Sheetz, Inc. v. Colonial Pipeline Company.
	OR20–9–001 (consolidated)	Apex Oil Company, Inc. and FutureFuel Chemical Company v. Colonial Pipeline Company.
G–3	OMITTED.	
	Hydro	
H–1	P–3472–026	Aspinook Hydro, LLC.
H–2	P–15111–001	Saugerties Community Hydro, LLC.
H–3	P–2934–042	New York State Electric & Gas Corporation.
	Certificates	
C–1	CP22–502–000	Transcontinental Gas Pipe Line Company, LLC.
	CP22–503–000	Columbia Gas Transmission, LLC.
C–2	OMITTED.	
C–3	CP23–468–000	Virginia Electric and Power Company.
C–4	CP20–50–002	Tennessee Gas Pipeline Company, L.L.C.
C–5	CP22–501–000	Transcontinental Gas Pipe Line Company, LLC.
C–6	CP20–528–002, CP20–529–001	Stingray Pipeline Company, L.L.C.

A free webcast of this event is available through the Commission's website. Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The Federal Energy Regulatory Commission provides technical support for the free webcasts. Please call (202) 502–8680 or email *customer@ferc.gov* if you have any questions.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters but will not be telecast.

Issued: November 9, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–25400 Filed 11–14–23; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who

make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
None.		
Exempt:		
1. CP17–40–000	11–1–2023	Illinois Governor JB Pritzker.
2. CP22–2–000	11–8–2023	Oregon Legislature's Environmental Caucus.[1]
3. CP22–2–000	11–8–2023	FERC Staff.[2]

[1] Senator Michael Dembrow, Representative Mark Gamba, Representative Khanh Pham, Senator Jeff Golden, Representative Pam Marsh, Senator Janeen Sollman.

[2] Emailed comments from Robin Pasterski, and 34 others other individuals.

Dated: November 9. 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25342 Filed 11–15–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23–2638–001.

Applicants: NRG Business Marketing LLC.

Description: Tariff Amendment: Response to Request for Additional Information to be effective 8/16/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5151.

Comment Date: 5 pm ET 11/30/23.

Docket Numbers: ER23–2639–002.

Applicants: NRG Business Marketing LLC.

Description: Compliance filing: Response to Request for Additional Information to be effective 8/16/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5153.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER23–2641–001.

Applicants: NRG Power Marketing LLC.

Description: Tariff Amendment: Response to Request for Additional Information to be effective 8/1/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5159.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER23–2642–001.

Applicants: NRG Power Marketing LLC.

Description: Tariff Amendment: Response to Request for Additional Information to be effective 8/1/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5161.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER23–2842–001.

Applicants: Sunnyside Cogeneration Associates.

Description: Tariff Amendment: Supplement to MBR Application to be effective 9/15/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5138.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER23–2885–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment of NSA, SA No. 7076; Queue No. AD1–031 in Docket ER23–2885–000 to be effective 11/20/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5117.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–330–000.

Applicants: Arizona Public Service Company.

Description: Answer of Solar Energy Industries Association And Interwest Power Alliance Opposing Arizona Public Service Company's Expedited Action, et al.

Filed Date: 11/9/23.

Accession Number: 20231109–5190.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–340–000; ER24–341–000.

Applicants: Midcontinent Independent System Operator, Inc., Midcontinent Independent System Operator, Inc.

Description: Answer of Midcontinent Independent System Operator, Inc. Opposing Motions of DTE Electric Company for Extension of Time to Comment.

Filed Date: 11/9/23.

Accession Number: 20231109–5188.

Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–367–000.

Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–11–09_SA 4182 METC-Consumers Energy E&P (J2815) to be effective 11/2/2023.

Filed Date: 11/9/23.

Accession Number: 20231109–5017.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–368–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 4179 Osborne Grid, LLC GIA to be effective 11/2/2023.
Filed Date: 11/9/23.
Accession Number: 20231109–5025.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–369–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 4180 NextEra Energy Resources Surplus Interconnection GIA to be effective 1/8/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5029.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–370–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: 2024 TACBAA Update to be effective 1/1/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5041.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–371–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: City of Victorville Amended IFA WDT298 SA. 231 to be effective 1/9/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5056.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–372–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2023–11–09_SA 4187 Duke Energy IN-Galea Springs GIA (J1388) to be effective 1/9/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5063.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–373–000.
Applicants: Yellow Pine Solar Interconnect, LLC.
Description: Baseline eTariff Filing: Yellow Pine Solar Interconnect, LLC Shared Facilities Agreement to be effective 11/10/2023.
Filed Date: 11/9/23.
Accession Number: 20231109–5067.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–374–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Financial Transmission Rights Bilateral Agreement Reform to be effective 1/9/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5122.
Comment Date: 5 p.m. ET 11/30/23.

Docket Numbers: ER24–375–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA, SA No. 7130; Queue No. AF1–014 to be effective 1/9/2024.
Filed Date: 11/9/23.
Accession Number: 20231109–5157.
Comment Date: 5 p.m. ET 11/30/23.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH24–4–000.
Applicants: CMS Energy Corporation.
Description: CMS Energy Corporation submits FERC 65–B Notice of Exemption Notification.
Filed Date: 11/7/23.
Accession Number: 20231107–5166.
Comment Date: 5 p.m. ET 11/28/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 9, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25344 Filed 11–15–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11560–01–OEJECR;–EPA–HQ–OEJECR–2023–0101]

National Environmental Justice Advisory Council; Notification of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification for a public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the National Environmental Justice Advisory Council (NEJAC) will meet on the date and time described below. The meeting is open to the public. For additional information about registering to attend the meeting or to provide public comment, please see ''REGISTRATION'' under **SUPPLEMENTARY INFORMATION**. Pre-Registration is required.

DATES: The NEJAC will convene a virtual public meeting on Tuesday, December 5, 2023, at approximately 10 a.m. to 7:30 p.m., Eastern Time. The meeting discussions will focus on several topics including, but not limited to, updates on NEJAC recommendations related to air quality and community monitoring, PFAS, finance and investments and responses to community concerns brought forward in Puerto Rico. A public comment period relevant to current NEJAC charges and recommendations will be considered by the NEJAC at the meeting on Tuesday, December 5, 2023, (see **SUPPLEMENTARY INFORMATION**). Members of the public who wish to participate during the public comment period must register by 11:59 p.m., Eastern Time, November 28, 2023.

FOR FURTHER INFORMATION CONTACT: Paula Flores-Gregg, NEJAC Designated Federal Officer, U.S. EPA; email: *nejac@epa.gov;* telephone: (214) 665–8123. Additional information about the NEJAC is available at *https://www.epa.gov/environmentaljustice/national-environmental-justice-advisory-council.*

SUPPLEMENTARY INFORMATION: The Charter of the NEJAC states that the advisory committee ''will provide independent advice and recommendations to the Administrator about broad, cross-cutting issues related to environmental justice. The NEJAC's efforts will include evaluation of a broad range of strategic, scientific, technological, regulatory, community

engagement and economic issues related to environmental justice.''

Registration: Individual registration is required for the public meeting. No two individuals can share the same registration link. Information on how to register is located at *https://www.epa.gov/environmentaljustice/national-environmental-justice-advisory-council-meetings.* Registration to attend the meeting is available through the scheduled meeting days. The deadline to sign up to speak during the public comment period will close at 11:59 p.m., Eastern Time, November 28, 2023. When registering, please provide your name, organization, city and state, and email address. Please also indicate whether you would like to provide oral public comment during the meeting, or whether you are submitting written comments at time of registration.

A. Public Comment

The NEJAC is interested in receiving public comments relevant to the following charges:

(1) Cumulative Impacts Framework Charge

(2) Farmworker and Pesticides Charge

Individuals or groups making remarks during the oral public comment period will be limited to three (3) minutes. Please be prepared to briefly describe your comments; including your recommendations on what you want the NEJAC to advise the EPA to do. Submitting written comments for the record are strongly encouraged. You can submit your written comments in three different ways, (1.) by using the webform at *https://www.epa.gov/environmentaljustice/forms/national-environmental-justice-advisory-council-nejac-public-comment,* (2.) by sending comments via email to *nejac@epa.gov* and (3.) by creating comments in the Docket ID No. EPA–HQ–OA–2023–0101 at *http://www.regulations.gov.* Written comments can be submitted through December 19, 2023. More information about the NEJAC's current charges can be found here *https://www.epa.gov/environmentaljustice/national-environmental-justice-advisory-council-current-charges.*

B. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

For information about access or services for individuals requiring assistance, please contact Paula Flores-Gregg, at (214) 665–8123 or via email at *nejac@epa.gov.* To request special accommodations for a disability or other assistance, please submit your request at least fourteen (14) working days prior to the meeting, to give EPA sufficient time to process your request. All requests should be sent to the email or phone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Matthew Tejada,

Deputy Assistant Administrator for Environmental Justice, Office of Environmental Justice and External Civil Rights.

[FR Doc. 2023–25245 Filed 11–15–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11559–01–OA]

Farm, Ranch, and Rural Communities Advisory Committee; Notice To Establish Animal Agriculture and Water Quality Subcommittee and Solicitation of Nominations for Membership to the Animal Agriculture and Water Quality Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for nominations.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) invites nominations from a diverse range of qualified candidates to serve on a new subcommittee of the Farm, Ranch, and Rural Communities Advisory Committee (FRRCC), entitled the Animal Agriculture and Water Quality (AAWQ) subcommittee. The goal of the AAWQ subcommittee will be to provide recommendations that will inform the Agency's decisions regarding how to improve the implementation of the Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) Concentrated Animal Feeding Operation (CAFO) permitting program to more effectively reduce nutrients and other types of water pollutants from Animal Feeding Operations (AFOs), including determining whether any revisions to the regulations are warranted, and whether EPA can otherwise support the efforts of AFO operators to protect water quality.

DATES: To be considered for membership appointment to the AAWQ subcommittee, nominations should be submitted no later than January 2, 2024.

ADDRESSES: Nominations must be submitted electronically with the subject line ''AAWQ Membership 2023'' to *AAWQ@epa.gov.* General information regarding the AAWQ can be found on the EPA website at: *https://www.epa.gov/faca/frrcc.* General information about Federal Advisory Committees at EPA is available at: *www.epa.gov/faca.*

FOR FURTHER INFORMATION CONTACT:

Dr. Venus Welch-White, (202) 566–2369, Designated Federal Officer for both the FRRCC and AAQW at *AAWQ@epa.gov.* General information regarding the FRRCC can be found on the EPA website at *https://www.epa.gov/faca/frrcc.*

Dr. Venus Welch-White, Designated Federal Officer, AAWQ and Dr. Lauren Mosesso, Alternate Designated Federal Officer, AAWQ, can be reached at *AAWQ@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

On August 15, 2023, EPA responded to two petitions sent by environmental and community groups requesting that EPA revise its Clean Water Act (CWA) regulations for the National Pollutant Discharge Elimination System (NPDES) Concentrated Animal Feeding Operation (CAFO) program. Instead of initiating rulemaking at this time, as the petitions requested, EPA decided to conduct a comprehensive evaluation of the CAFO program to consider the most effective and efficient ways to reduce pollutants generated from CAFOs. EPA will establish a Federal Advisory Committee (FAC) subcommittee, called the Animal Agriculture and Water Quality (AAWQ) subcommittee, under the existing Farm, Ranch, and Rural Communities Committee (FRRCC). After engaging with the AAWQ and reviewing their recommendations, EPA will consider whether to revise its regulations or whether the issues discussed in the petitions can be more effectively addressed through non-regulatory initiatives.

EPA is currently seeking nominations for members to serve on the AAWQ subcommittee, who will be appointed for an estimated term of 12 to 18 months. Balanced and diverse representation is being sought from the following stakeholders across the geographic regions of the United States:

- Agricultural industry
- Environmental, community, and public health groups
- Local governments
- Research institutions
- States and Tribes

The AAWQ expects to hold meetings approximately four times per year over the course of 12 to 18 months. The first subcommittee meeting is anticipated to be held in-person at or near EPA Headquarters in Washington, DC, in the spring of 2024. Subsequent meetings and/or listening sessions may be held in Washington, DC, other parts of the

country, or virtually. In addition to the meetings, the minimum expected workload for members is approximately 5–10 hours per month, and potentially more depending on the responsibilities members choose to take on. Members will serve on the subcommittee in a voluntary capacity; however, EPA may provide reimbursement for travel expenses associated with official government business.

II. Eligibility To Serve on Subcommittee

Because of the nature of the issues to be discussed, it is the intent of the Agency for subcommittee members to have significant experience with (1) CAFO production area practices, (2) CAFO land application practices, and (3) effective means to limit pollution from CAFOs.

Topics that the AAWQ will discuss include, but are not limited to:

- Agricultural technology adoption and economics (*e.g.,* digesters, treat and discharge systems, nutrient management technologies).
- CWA NPDES program.
- Day-to-day operations of CAFOs, especially concerning land application, management, or off-site transport of manure, litter, and process wastewater.
- Development and implementation of agricultural conservation practices and technologies.
- Public health and environmental impacts of CAFOs.

EPA is seeking nominees for the AAWQ subcommittee who have demonstrated experience with the operations of animal agriculture practices and/or the impacts of animal feeding operations on public health and/or water quality. Nominations are sought from, but not limited to, AFO/CAFO operators; agricultural economists; agricultural producers, growers, and ranchers; nongovernmental organizations studying agricultural, public health, and environmental impacts; community members who reside adjacent to or near AFO/CAFO operations; academic researchers and/or extension agents; state, local, and tribal governments; and wastewater utilities. The membership of the AAWQ subcommittee will include a balanced representation of interested persons representing the geographic diversity of the Unites States. Individuals will be generally appointed to serve on the AAWQ subcommittee as ''Representative'' members and are thus expected to represent the points of view of a particular group (*e.g.,* a community, organization, or industry), rather than provide independent judgment and expertise. Other Federal agencies, and members of other sectors, as warranted, may be invited to attend, offer expertise, or provide presentations at committee meetings as non-members.

Nominees must be able to volunteer approximately 5–10 hours per month to the AAWQ subcommittee's activities, including participation in virtual workgroup meetings and preparation of text for the subcommittee's Final Report.

In accordance with Executive Order 14035 (June 25, 2021) and consistent with law, EPA values and welcomes opportunities to increase diversity, equity, inclusion, and accessibility on its Federal advisory committees. EPA's Federal advisory committees have a workforce that reflects the diversity of the American people.

III. Nominations To Serve on Subcommittee

Any interested person or organization may submit the names of qualified persons, including themselves. Nominations must be submitted electronically with the subject line ''AAWQ Membership 2023'' to *AAWQ@epa.gov.* To be considered, all nominations should include the information requested below:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), business address, email address, and daytime telephone number(s).
- A brief statement describing the nominee's interest, relevant experience, and availability in serving on the AAWQ subcommittee, as well as: (1) The nominee's ability to serve as a ''Representative'' member and represent the point of view of a group (*e.g.,* a community, organization, or industry) rather than provide independent judgment and expertise; and (2) whether the nominee has any prior/current service on Federal advisory committees, and, if so, the number of years.
- Résumé or curriculum vitae detailing the nominee's background, experience, and qualifications, and any other relevant materials.

Other sources, in addition to this **Federal Register** notice, may be utilized in the solicitation of nominees. EPA expressly values diversity, equity, and inclusion, and encourages the nominations of interested individuals from diverse backgrounds. Individuals may self-nominate.

Venus Welch-White,

Senior Advisor to EPA Senior Advisor for Agriculture, Office of the Administrator, U.S. EPA.

[FR Doc. 2023–25363 Filed 11–15–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEJECR–2023–0326; FRL 10605–01–OA]

Release of Achieving Health and Environmental Protection Through EPA's Meaningful Involvement Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Draft policy; notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on a draft policy that updates the EPA's 2003 Public Involvement Policy. The revised draft policy promotes an EPA-wide approach to meaningful involvement that can be tailored for program and regional needs and outlines practices that EPA staff can use as they design and provide opportunities for meaningful involvement.

DATES: Comments must be received on or before January 16, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OEJECR–2023–0326, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Agency Website: https://www.epa.gov/environmentaljustice/epas-meaningful-involvement-policy.* Follow the online instructions for submitting comments.
- *Email: MeaningfulInvolvementPolicy@epa.gov.*
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Environmental Justice and External Civil Rights Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

Instructions: All submissions received must include the Docket ID No. for this draft policy. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Stacey Lobatos, Office of Environmental Justice and External Civil Rights (Mail Code 2201A), Environmental Protection Agency, William Jefferson Clinton Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460; phone number: 202–564–8579, email address: *MeaningfulInvolvementPolicy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How can I get copies of the Draft Policy document and other related information?

You may access this document electronically at *https://www.epa.gov/environmentaljustice/epas-meaningful-involvement-policy* or at *https://www.federalregister.gov.* EPA established an official public docket under Docket ID No. EPA–HQ–OEJECR–2023–0326 which is accessible electronically at *https://www.regulations.gov* that will also contain copies of this **Federal Register** notice. The public docket does not include CBI or other information whose disclosure is restricted by statute.

B. What should I consider as I prepare my comments for the EPA?

1. *Tips for preparing your comments.* When preparing and submitting your comments, see Tips for Effective Comments at *https://www.epa.gov/dockets.* Please note that once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Please also consider the following questions while drafting comments:

- How can the EPA's Meaningful Involvement Approach support meaningful involvement without putting an extra burden on the public, and communities with environmental justice concerns specifically?
- How could the adapted Public Participation Spectrum be enhanced?
- Are there other examples of meaningful public involvement that the EPA should consider in this policy?

2. *Submitting CBI.* Do not submit CBI information to the EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Michael S. Regan,

Administrator.

[FR Doc. 2023–25273 Filed 11–15–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11552–01–OMS]

National and Governmental Advisory Committees to the U.S. Representative to the Commission for Environmental Cooperation (CEC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Committee Act, the Environmental Protection Agency (EPA) gives notice of a public meeting of the National Advisory Committee (NAC) and the Governmental Advisory Committee (GAC). The NAC and GAC provide advice to the EPA Administrator on a broad range of environmental policy, technology, and management issues. NAC and GAC members represent academia, business/industry, non-governmental organizations, and State, local and Tribal governments. The purpose of this meeting is to provide advice to the EPA Administrator on exemplary cities in North America with strong climate governance, nature-based solutions, environmental justice engagement and other matters related to the Commission for Environmental Cooperation.

DATES: December 7, 2023, from 12:30 p.m.–4:30 p.m. (EST). A copy of the agenda will be posted at *www.epa.gov/faca/nac-gac.*

ADDRESSES: The meeting will be held at the EPA Headquarters, William Jefferson Clinton East Building, Great Lakes Conference Room, 1201 Constitution Avenue NW, Washington, DC 20004.

The meeting will be conducted in a hybrid environment and is open to the public with limited access available on a first-come, first-served basis. Members of the public wishing to participate in the video/teleconference, should contact Oscar Carrillo at *carrillo.oscar@epa.gov* by November 29, 2023. Requests to make oral comments or submit written public comments to the NAC and GAC should also be directed to Oscar Carrillo at least five business days prior to the meeting. To ensure adequate time for processing, requests for accessibility and/or accommodations for individuals with disabilities should be directed to Oscar Carrillo at the email address listed above at least 10 days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Oscar Carrillo, Federal Advisory Committee Management and Oversight Division, Office of Inclusive Excellence, Office of Mission Support (1601M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–0347; email address: *carrillo.oscar@epa.gov.*

SUPPLEMENTARY INFORMATION: The NAC and GAC are Presidential Federal advisory committees that advise the U.S. Government via the EPA Administrator on trade and environment matters related to the Environmental Cooperation Agreement (ECA), which entered into force at the same time as the United States-Mexico Canada Agreement (USMCA). The NAC and GAC were created in 1994 and operate in accordance with the Federal Advisory Committee Act. Establishment of the committees is authorized under article 11 of the ECA.

Oscar Carrillo,

Program Analyst.

[FR Doc. 2023–25346 Filed 11–15–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0004; FR ID 184855]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 16,

2024. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–0004.

Title: Sections 1.1307 and 1.1311, Guidelines for Evaluating the Environmental Effects of Radiofrequency Exposure.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal government.

Number of Respondents and Responses: 233,596 Respondents; 233,596 Responses.

Estimated Time per Response: 0.0833 hours (5 minutes)–20 hours.

Frequency of Response: On occasion reporting requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this Information collection is contained in 47 U.S.C. 154, 302, 303, and 307.

Total Annual Burden: 26,005 hours.

Total Annual Costs: $1,958,335.

Needs and Uses: The Commission will submit this revision of a currently approved information collection to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three-year clearance.

This information collection is a result of responsibility placed on the FCC by the National Environmental Policy Act (NEPA) of 1969. NEPA requires that each federal agency evaluate the impact of ''major actions significantly affecting the quality of the human environment.'' It is the FCC's opinion that this is the most efficient and reasonable method of complying with NEPA with regard to the environmental issue of radiofrequency radiation from FCC-regulated transmitters.

To account for rule changes implemented by 2019 rulemaking item FCC 19–126, ET Docket Nos. 03–137 and 13–184, the Commission had previously estimated the burden to respondents for the collection of information in two components: the recurring annual burden, and the one-time burden of transitioning to the rule changes for existing parties. The period for transition to those rule changes has now passed, and so the Commission has now revised its estimates to remove consideration of the one-time transition burden. To update burden estimates based on the most recently available data, the Commission has also adjusted the total number of respondents/responses, the total annual hourly burden, and the total annual costs from the previous estimates, based on licensing data for calendar year 2022.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–25295 Filed 11–15–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 185218]

Open Commission Meeting Wednesday, November 15, 2023

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, November 15, 2023, which is scheduled to commence at 10:30 a.m. in the Commission Meeting Room of the Federal Communications Commission, 45 L Street NE, Washington, DC.

While attendance at the Open Meeting is available to the public, the FCC headquarters building is not open access and all guests must check in with and be screened by FCC security at the main entrance on L Street. Attendees at the Open Meeting will not be required to have an appointment but must otherwise comply with protocols outlined at: *www.fcc.gov/visit.* Open Meetings are streamed live at: *www.fcc.gov/live* and on the FCC's YouTube channel.

Item No.	Bureau	Subject
1	WIRELINE COMPETITION	*TITLE:* Preventing Digital Discrimination (GN Docket No. 22–69). *SUMMARY:* The Commission will consider a Report and Order and Further Notice of Proposed Rulemaking to establish a framework to facilitate equal access to broadband internet access service by preventing digital discrimination of access and seek additional comment on matters pertaining to the Commission's administration of Section 60506 of the Infrastructure Investment and Jobs Act and our efforts to facilitate equal access.
2	WIRELINE COMPETITION	*TITLE:* Empowering Survivors of Domestic Violence (WC Docket No. 22–238), Lifeline and Link Up Reform Modernization (WC Docket No. 11–42), Affordable Connectivity Program (WC Docket No. 21–450). *SUMMARY:* The Commission will consider a Report and Order that would adopt rules to implement the Safe Connections Act of 2022 to help survivors of domestic violence and similar crimes separate lines from shared mobile accounts that include their abusers, protect the privacy of calls made by survivors to domestic abuse hotlines, and support survivors who face financial hardship through the Commission's affordability programs.
3	CONSUMER & GOVERNMENTAL AFFAIRS.	*TITLE:* Understanding Impacts of Artificial Intelligence on Robocalls and Robotexts (CG Docket No. 23–362). *SUMMARY:* The Commission will consider a Notice of Inquiry seeking to better understand the implications of Artificial Intelligence technologies as part of the Commission's ongoing efforts to protect consumers from unwanted and illegal telephone calls and text messages under the Telephone Consumer Protection Act (TCPA).
4	WIRELINE COMPETITION	*TITLE:* Protecting Consumers from SIM Swapping and Port-Out Fraud (WC Docket No. 21–341).

Item No.	Bureau	Subject
		SUMMARY: The Commission will consider a Report and Order and Further Notice of Proposed Rulemaking that would adopt rules to protect consumers from SIM swap and port-out fraud, two fraudulent practices that bad actors use to take control of consumers' cell phones, and would also seek comment on whether to harmonize the Commission's existing requirements governing customer access to customer proprietary network information with the new SIM change authentication and protection measures in the Report and Order.
5	WIRELINE TELE-COMMUNICATIONS	*TITLE:* Amending Amateur Radio Rules for Greater Flexibility in Data Communications (WT Docket No. 16–239). *SUMMARY:* The Commission will consider a Report and Order and Further Notice of Proposed Rulemaking that would eliminate the symbol rate (also known as baud rate) limitation and establish a bandwidth limitation that would provide flexibility to use modern digital emissions, thereby promoting innovation and experimentation in the amateur service. The item would also propose removal of the baud rate limitation in several additional bands.
6	WIRELINE COMPETITION	*TITLE:* Reducing Regulatory Requirements for Rural Provider of Long-Distance Access Service (WC Docket No. 22–407). *SUMMARY:* The Commission will consider a Declaratory Ruling and Memorandum Opinion and Order that would grant the Minnesota Independent Equal Access Corporation (MIEAC) relief from dominant carrier regulation with respect to its provision of centralized equal access (CEA) service, and regulate MIEAC as a non-dominant competitive LEC for this service going forward. In light of declining demand, intervening exchange access service regulatory reforms, and technological changes in the voice services marketplace generally, dominant carrier regulation of MIEAC's CEA service is no longer necessary to serve the public interest.
7	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.
8	ENFORCEMENT.	
9	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.

* * * * *

The meeting will be webcast at: *www.fcc.gov/live.* Open captioning will be provided as well as a text only version on the FCC website. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Press Access—Members of the news media are welcome to attend the meeting and will be provided reserved seating on a first-come, first-served basis. Following the meeting, the Chairwoman may hold a news conference in which she will take questions from credentialed members of the press in attendance. Also, senior policy and legal staff will be made available to the press in attendance for questions related to the items on the meeting agenda. Commissioners may also choose to hold press conferences. Press may also direct questions to the Office of Media Relations (OMR): *MediaRelations@fcc.gov.* Questions about credentialing should be directed to OMR.

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live.*

Federal Communications Commission.

Dated: November 8, 2023.

Marlene Dortch,

Secretary.

[FR Doc. 2023–25297 Filed 11–15–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0761; FR ID 184483]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 16, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should

advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0761.

Title: Section 79.1, Closed Captioning of Video Programming, CG Docket No. 05–231.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Individuals or households; and Not-for-profit entities.

Number of Respondents and Responses: 68,007 respondents; 510,514 responses.

Estimated Time per Response: 0.5 (30 minutes) to 30 hours.

Frequency of Response: Annual, monthly, on occasion, and ongoing reporting requirements; Third party disclosure requirement; Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this obligation is found at section 713 of the Communications Act of 1934, as amended, 47 U.S.C. 613, and implemented at 47 CFR 79.1.

Total Annual Burden: 766,435 hours.

Annual Cost Burden: $35,324,172.00.

Needs and Uses: The Commission seeks to extend existing information collection requirements in its closed captioning rules (47 CFR 79.1), which require that, with some exceptions, all new video programming, and 75 percent of ''pre-rule'' programming, be closed captioned. The existing collections include petitions by video programming providers, producers, and owners for exemptions from the closed captioning rules, responses by commenters, and replies; complaints by viewers alleging violations of the closed captioning rules, responses by video programming distributors (VPDs) and video programmers, recordkeeping in support of complaint responses, and compliance ladder obligations in the event of a pattern or trend of violations; recordkeeping of monitoring and maintenance activities; caption quality best practices procedures; making video programming distributor contact information available to viewers in phone directories, on the Commission's website and the websites of video programming distributors (if they have them), and in billing statements (to the extent video programming distributors issue them); and video programmers filing of contact information and compliance certifications with the Commission.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–25271 Filed 11–15–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS23–19]

Appraisal Subcommittee; Notice of Meeting; Cancellation

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting; cancellation.

The Open Meeting, which was published in accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, at 88 FR 77320, November 9, 2023 and scheduled for Wednesday, November 15, 2023 at 10:00 a.m. ET, has been cancelled.

James R. Park,

Executive Director.

[FR Doc. 2023–25281 Filed 11–15–23; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS23–18]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of Special Closed Meeting.

SUPPLEMENTARY INFORMATION: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) met for a Special Closed Meeting on this date.

Location: Virtual meeting via Webex.

Date: November 8, 2023.

Time: 11:15 a.m. ET.

Action and Discussion Item: Personnel Matter.

The ASC convened a Special Closed Meeting to discuss a personnel matter. No action was taken by the ASC.

James R. Park,

Executive Director.

[FR Doc. 2023–25283 Filed 11–15–23; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2023–N–13]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: Contractor Workforce Inclusion Good Faith Efforts—60-day notice of submission of information collection for approval from Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Housing Finance Agency (FHFA or the Agency) is seeking public comments concerning the renewal of an information collection known as ''Contractor Workforce Inclusion Good Faith Efforts,'' which has been assigned control number 2590–0016 by the Office of Management and Budget (OMB). FHFA intends to submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on January 31, 2024.

DATES: Interested persons may submit comments on or before January 16, 2024.

ADDRESSES: Submit comments to FHFA, identified by ''Proposed Collection; Comment Request: 'Contractor Workforce Inclusion Good Faith Efforts, (No. 2023–N–13)' '' by any of the following methods:

- *Agency Website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by *email* to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the agency.
- *Mail/Hand Delivery:* Federal Housing Finance Agency, Office of General Counsel, 400 Seventh Street SW, Washington, DC 20219, Attention: Proposed Collection; Comment Request: ''Contractor Workforce Inclusion Good Faith Efforts, (No. 2023–N–13).''

We will post all public comments we receive without change, including any

personal information you provide, such as your name and address, email address, and telephone number, on the FHFA website at *https://www.fhfa.gov.*

Copies of all comments received will be available for examination by the public through the electronic comment docket for this PRA Notice also located on the FHFA website.

FOR FURTHER INFORMATION CONTACT: Takisha Koonce, Office of Minority and Women Inclusion, *Takisha.Koonce@fhfa.gov,* (202) 649–3740; Brent Burris, Associate General Counsel, *Brent.Burris@fhfa.gov,* (202) 731–1083; or Angela Supervielle, Senior Counsel, *Angela.Supervielle@fhfa.gov,* (202) 649–3973 (these are not toll-free numbers); Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

A. Paperwork Reduction Act

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice [1] in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection of information to OMB for approval. FHFA's collection of information set forth in this document is titled ''Contractor Workforce Inclusion Good Faith Efforts'' (assigned control number 2590–0016 by OMB). To comply with the PRA requirement, FHFA is publishing notice of a proposed three-year extension of this collection of information, which is due to expire on January 31, 2024.

B. Background

Section 342(a)(1)(A) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act) requires FHFA and certain other Federal agencies each to establish an Office of Minority and Women Inclusion (OMWI) responsible for all matters of the agency relating to diversity in management, employment, and business activities.[2] Section 342(c)(1) requires the OMWI Director at each agency to develop and implement standards and procedures to ensure, to the maximum extent possible, the fair inclusion and utilization of minorities, women, and minority- and women-owned businesses in all business and activities of the agency at all levels, including procurement, insurance, and all types of contracts. Section 342(c)(2) requires that the OMWI Director include in the agency's procedures for evaluating contract proposals and hiring service providers a component that gives consideration to the diversity of an applicant, to the extent consistent with applicable laws. That statutory provision also requires that each agency's procedures include a written statement that a contractor shall ensure, to the maximum extent possible, the fair inclusion of women and minorities in the workforce of the contractor and, as applicable, subcontractors.

Further, section 342(c)(3)(A) of the Dodd-Frank Act requires that each agency's standards and procedures include a procedure for determining whether an agency contractor or subcontractor has failed to make a good faith effort to include minorities and women in its workforce. If the OMWI Director determines that a contractor or subcontractor has failed to make such a good faith effort, section 342(c)(3)(B)(i) provides that the OMWI Director shall recommend to the agency administrator that the contract be terminated. Section 342(c)(3)(B)(ii) provides that, upon receipt of such a recommendation, the agency administrator may either terminate the contract, make a referral to the Office of Federal Contract Compliance Programs (OFCCP) of the Department of Labor, or take other appropriate action.

As a means of implementing the requirements of section 342(c) of the Dodd-Frank Act, FHFA developed a Minority and Women Inclusion Clause (MWI Clause) that it includes in Agency contracts with a dollar value greater than $150,000. The MWI Clause requires a contractor to confirm its commitment to equal opportunity in employment and contracting, and to implement that commitment by ensuring, to the maximum extent possible consistent with applicable law, the fair inclusion of minorities and women in its workforce. The MWI Clause also requires that a contractor include the substance of the MWI Clause in all subcontracts with a dollar value greater than $150,000 awarded under the contract. (Hereinafter, contractors that are subject to the MWI Clause and subcontractors that are subject to a similar clause required to be included in a subcontract are referred to as ''covered'' contractors and subcontractors.)

Finally, the MWI Clause requires a contractor to provide, when requested by FHFA, documentation demonstrating that the covered contractor, as well as any covered subcontractor, has made a good faith effort to ensure the fair inclusion of minorities and women in its workforce. The MWI Clause provides that such documentation may include, but is not limited to: (1) the contractor's total number of employees, and the number of minority and women employees, by race, ethnicity, and gender (*e.g.,* an EEO–1 Employer Information Report (Form EEO–1)); (2) a list of the subcontracts the contractor awarded including the dollar amount, date of the award, and the ownership status of the subcontractor by race, ethnicity, and/or gender; (3) information similar to that required under the first item above for each subcontractor; and (4) the contractor's plan to ensure that minorities and women have appropriate opportunities to enter and advance within its workforce, including outreach efforts (hereinafter, a ''workforce inclusion plan''). A request for documentation by FHFA pursuant to this provision of the MWI Clause constitutes a ''collection of information'' within the meaning of the PRA.

On March 9, 2018, FHFA finalized its ''Policy Establishing Procedures to Determine Compliance by Contractors with the Minority and Women Inclusion Clause'' (Good Faith Efforts Policy (GFEP)), which establishes a process to determine whether covered contractors or subcontractors are making good faith efforts to ensure the fair inclusion of minorities and women in their respective workforces. The GFEP ensures transparency, clarity, and consistency in the good faith effort review process. Covered contractors agree to provide documentation of the good faith effort they have made in support of this commitment within 10 business days after a request from FHFA. According to the GFEP, ''OMWI will rely on the conclusions of a prior GFE review if OMWI conducted that review within the past two fiscal years.''

C. Need for and Use of the Information Collection

The purpose of this information collection is to fulfill the requirements of section 342(c) of the Dodd-Frank Act. The collected information allows FHFA's OMWI Director to determine whether covered contractors and subcontractors have complied with their contractual obligations to make good faith efforts to ensure, to the maximum extent possible consistent with

[1] Following the close of this notice's 60-day comment period, FHFA will publish a second notice with a 30-day comment period as required by 44 U.S.C. 3507(b) and 5 CFR 1320.10(a).

[2] 12 U.S.C. 5452.

applicable law, the fair inclusion of minorities and women in their respective workforces.

D. Burden Estimate

FHFA estimates that the average annual burden imposed on all respondents by this information collection over the next three years will be 725 hours. Because, as explained below, the amount of burden imposed upon a contractor by this information collection will differ depending upon whether the contractor has 50 or more employees, FHFA has based its total burden estimate on two separate sets of calculations—(1) one for contractors and subcontractors with 50 or more employees (30 hours); and (2) another for contractors and subcontractors with fewer than 50 employees (695 hours).

FHFA includes the MWI Clause in Agency contracts with a dollar value greater than $150,000. Under the MWI Clause, FHFA may also request information about covered subcontractors' ownership status, workforce demographics, and workforce inclusion plans. Contractors would request this information from their covered subcontractors, who, because the substance of the MWI Clause would be included in their subcontracts, would have a contractual obligation to keep records and report data as required under the MWI Clause.

FHFA data on the dollar value of contracts awarded by the Agency from the beginning of fiscal year 2020 through fiscal year 2023 shows that 165 contractors were subject to the MWI Clause. FHFA believes that 85 of those contractors have 50 or more employees, while 80 contractors have fewer than 50 employees. FHFA estimates that no more than two subcontracts with a dollar value of $150,000 or more were awarded by Agency contractors during that same time period. Both of those subcontractors have 50 or more employees each. Thus, over the preceding three years, a total of 167 contractors and subcontractors were subject to the MWI Clause—87 of which have 50 or more employees and 80 of which have fewer than 50 employees.

Based on these figures, FHFA estimates that, on average over the next three years, 87 contractors and subcontractors with 50 or more employees and 80 contractors or subcontractors with fewer than 50 employees will be subject to the MWI Clause at any given time. As mentioned above, the GFEP provides that OMWI will rely on the conclusions of a prior GFE review if OMWI conducted that review within the past two fiscal years. Accordingly, a covered contractor or subcontractor is required to submit new information only once within any three-year period.

(1) Documentation Submitted by Contractors With 50 or More Employees

FHFA estimates that the average annual burden on contractors with 50 or more employees will be 30 hours (0 recordkeeping hours + 30 reporting hours). Because Federal contractors with 50 or more employees are already required to maintain the same types of records that may be requested pursuant to the MWI Clause under regulations implementing Title VII of the Civil Rights Act of 1964 [3] and Executive Order 11246 (E.O. 11246),[4] this information collection does not impose additional recordkeeping burdens on such contractors and subcontractors. FAR 52.222–26, Equal Opportunity, requires that such contractors' contracts and subcontracts include a clause implementing E.O. 11246. OFCCP regulations require each contractor with 50 or more employees and a Federal contract or subcontract of $50,000 or more to maintain records on the race, ethnicity, gender, and EEO–1 job category of each employee.[5] OFCCP regulations also require each such contractor to: (1) demonstrate that it has made a good faith effort to remove identified barriers, expand employment opportunities, and produce measurable results; [6] and (2) develop and maintain a written program summary describing the policies, practices, and procedures that the contractor uses to ensure that applicants and employees received equal opportunities for employment and advancement.[7] In lieu of creating and maintaining a separate workforce inclusion plan to submit in satisfaction of the MWI Clause, a contractor or subcontractor with 50 or more employees could submit the written program summary that it is already required to maintain under the OFCCP regulations to demonstrate its good faith efforts to ensure the fair inclusion of minorities and women in its workforce.

With respect to reporting burden, FHFA estimates that it will take each contractor or subcontractor with 50 or more employees approximately one hour to retrieve, review, and submit the documentation specified in the MWI Clause. Thus, the estimate of the triennial burden upon contractors or subcontractors with 50 or more employees associated with reporting requirements under this information collection is 87 hours (87 respondents × 1 hour per respondent) and the annual burden is 30 hours.

(2) Documentation Submitted by Contractors With Fewer Than 50 Employees

FHFA estimates that the average annual burden on contractors and subcontractors with fewer than 50 employees will be 695 hours (667 recordkeeping hours + 28 reporting hours).

OFCCP regulations require contractors with fewer than 50 employees to maintain records on the race, ethnicity, and gender of each employee.[8] FHFA believes that such contractors also keep EEO–1 job category information in the normal course of business, despite the fact that they are not required by law to do so. However, contractors or subcontractors with fewer than 50 employees may not have the type of written program summary that is required of larger contractors under the OFCCP regulations or any similar document that could be submitted as a workforce inclusion plan under the MWI Clause. Accordingly, such contractors or subcontractors may need to create a workforce inclusion plan to comply with the MWI Clause.

In order to estimate the burden associated with creating a workforce inclusion plan, FHFA considered the OFCCP's burden estimates for the time needed to develop the written program summaries required under its regulations.[9] In its OMB Supporting Statement, the OFCCP estimated that a contractor with 1 to 100 employees would take approximately 73 hours to create an initial written program summary. While the OFCCP regulations require contractors to perform time-consuming quantitative analyses when developing their written program summaries, such analyses would not be required in connection with the creation of a workforce inclusion plan. For this reason, FHFA believes that a contractor could develop a workforce inclusion plan in about one-third of the time that it would take to develop the written program summary required under the OFCCP regulations.

FHFA estimates that a contractor or subcontractor with fewer than 50 employees would spend approximately 25 hours creating a workforce inclusion plan for the first time. It is likely that,

[3] 42 U.S.C. 2000e, *et seq.*

[4] E.O. No. 11246, 30 FR 12319 (Sept. 28, 1965).

[5] *See* 41 CFR 60–1.7.

[6] *See* 41 CFR 60–2.17.

[7] *See* 41 CFR 60–2.31.

[8] *See* 41 CFR 60–3.4.

[9] *See* PRA Supporting Statement for the OFCCP Recordkeeping and Requirements-Supply and Service Program, OMB Control No. 1250–0003, at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201906-1250-001.*

going forward, many small contractors and subcontractors will simply submit updated versions of workforce inclusion plans that they have submitted previously. For purposes of this burden estimate, however, FHFA has assumed that all small contractors and subcontractors will need to create a new plan every time they are required to submit information under the MWI clause. This results in an estimated average triennial recordkeeping burden on all contractors and subcontractors with fewer than 50 employees over the next three years of 2,000 hours (80 respondents × 25 hours per respondent), with an annual burden of 667 hours.

As with larger entities, FHFA estimates that it will take each contractor and subcontractor with fewer than 50 employees approximately one hour to retrieve, review, and submit the documentation specified in the MWI Clause. Thus, FHFA estimates that the average triennial reporting burden on all contractors and subcontractors with fewer than 50 employees will be 80 hours (80 respondents × 1 hour per respondent), with an annual burden of 28 hours.

E. Comment Request

FHFA requests written comments on the following: (1) whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Shawn Bucholtz,

Chief Data Officer, Federal Housing Finance Agency.

[FR Doc. 2023–25333 Filed 11–15–23; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL LABOR RELATIONS AUTHORITY

Senior Executive Service Performance Review Board

AGENCY: Federal Labor Relations Authority.

ACTION: Notice.

SUMMARY: The Federal Labor Relations Authority (FLRA) publishes the names of the persons selected to serve on its SES Performance Review Board (PRB). This notice supersedes all previous notices of the PRB membership.

DATES: Effective November 16, 2023.

ADDRESSES: Written comments about this notice can be mailed to the Human Resources Division Office, Federal Labor Relations Authority, 1400 K Street NW, Washington, DC 20424.

FOR FURTHER INFORMATION CONTACT: Michael Jeffries, Executive Director, Federal Labor Relations Authority, 1400 K St. NW, Washington, DC 20424, (771) 444–5801, *mjeffries@flra.gov.*

SUPPLEMENTARY INFORMATION: Section 4314(c) of Title 5, U.S.C. requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The PRB shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on the FLRA's PRB.

PRB Chairman:

—Michael Jeffries, Executive Director, FLRA, and PRB Chairman

PRB Members:

—Charlotte Dye, Deputy General Counsel, FLRA

—Kimberly Moseley, Executive Director, Federal Service Impasses Panel, FLRA

—Timothy Curry, Deputy Associate Director, Accountability and Workforce Relations, Workforce Policy and Innovation, U.S. Office of Personnel Management

—Joseph Panteloglous, Director, Human Resources Division, FLRA (Ex Officio).

Dated: November 13, 2023.

Thomas Tso,

Solicitor and Federal Register Liaison, Federal Labor Relations Authority.

[FR Doc. 2023–25329 Filed 11–15–23; 8:45 am]

BILLING CODE 7627–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010955–011.

Agreement Name: ACL/H–L Reciprocal Space Charter and Sailing Agreement.

Parties: Atlantic Container Line, A.B.; Hapag-Lloyd AG.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment converts the agreement from a reciprocal space charter to a one-way space charter, narrows the geographic scope, adjusts the amount of space to be chartered, and revises the amount of notice required to resign from the agreement. The amendment also changes the name of the agreement and restates the agreement.

Proposed Effective Date: 12/18/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1184.

Agreement No.: 012312–004.

Agreement Name: Grimaldi Euromed S.p.A./Mitsui O.S.K. Lines Ltd./Nissan Motor Car Carrier Co. Space Charter Agreement.

Parties: Grimaldi Euromed S.p.A.; Mitsui O.S.K. Lines Ltd; Nissan Motor Car Carrier Co. Ltd.

Filing Party: Rebecca Fenneman; Jeffrey/Fenneman Law and Strategy PLLC.

Synopsis: The Amendment adds Nissan Motor Car Carrier as a party to the Agreement, changes the Grimaldi entity that is Party to the Agreement, adds the trade between the United States and Japan to the geographic scope, and changes the name of the Agreement to reflect the addition of NMCC.

Proposed Effective Date: 11/7/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/183.

Agreement No.: 201210–003.

Agreement Name: Port of NY/NJ—Port Authority/Marine Terminal Operators Agreement.

Parties: APM Terminals Elizabeth, LLC; Port Liberty Bayonne LLC; Maher Terminals LLC; Port Liberty New York LLC; Port Newark Container Terminal LLC; Red Hook Container Terminal, LLC.

Filing Party: Carol Lambos; The Lambos Firm LLP.

Synopsis: The Amendment reflects the name changes of member companies GCT Bayonne LP and GCT New York LP to Port Liberty Bayonne LLC and Port Liberty LLC respectively, and adds Red Hook Container Terminal LLC to the agreement.

Proposed Effective Date: 12/18/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/2135.

Agreement No.: 201410.

Agreement Name: CMA CGM/Maersk A/S Vessel Sharing Agreement USEC/Caribbean/Central America Service.

Parties: Maersk A/S; CMA CGM S.A.

Filing Party: Draughn Arbona; CMA CGM.

Synopsis: The Agreement authorizes the Parties to share vessels with one another and cooperate on a weekly liner service in the Trade between ports in Jamaica, Venezuela, Colombia, Honduras and Guatemala and the inland and coastal points served by such ports, on one hand, and ports on the U.S. East Coast and the inland and coastal points served by such ports, on the other hand.

Proposed Effective Date: 12/20/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/84527.

Agreement No.: 201411.

Agreement Name: NPDL/PFLG Slot Charter Agreement.

Parties: Neptune Pacific Direct Line Pte. Ltd.; Pacific Forum Line (Group) Limited.

Filing Party: David Monroe; GKG Law, P.C.

Synopsis: The Agreement authorizes NPDL to charter space to PFLG in the trade between and among ports in Australia, American Samoa, Samoa and Tonga.

Proposed Effective Date: 11/7/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/84528.

Dated: November 9, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023–25282 Filed 11–15–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Serious Medical Procedure Request (SMR) Form (Office of Management and Budget #: 0970–0561)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families' (ACF) Office of Refugee Resettlement is requesting a 3-year extension of the Serious Medical Procedure Request (SMR) Form (Office of Management and Budget (OMB) #0970–0561, expiration February 29, 2024). Revisions are proposed to the currently approved form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF's ORR places unaccompanied children in their custody in care provider programs until unification with a qualified sponsor. Care provider programs are required to provide children with a range of services including medical, dental, and mental healthcare. Children identified as having a serious medical or dental condition may require a procedure while in ORR custody to maintain and promote their health and wellbeing. Procedures requiring general anesthesia, surgeries, and invasive diagnostic procedures (*e.g.,* cardiac catheterization, invasive biopsy, amniocentesis) require advance ORR approval. Before ORR can approve, data must be collected on the SMR form and submitted to ORR by the care provider program (*e.g.,* care provider program's contact information, child demographics, authorized consenter, unification status) and the lead surgeon (*e.g.,* reason for the procedure, potential risks/complications/adverse outcomes if the procedure is not performed, timing, recovery timeframe, planned follow-up procedures, hospital points of contact). ORR will waive the completion of the SMR form if it is deemed to be in the best interest of the child (*e.g.,* during a hospitalization or emergency department visit, related to a medical emergency).

The form is used as a worksheet for care provider program staff and surgeons to compile information that would otherwise have been collected during the health evaluation. Once completed, care provider program staff upload the form and supporting documentation into ORR's secure, electronic data record system and send an email notification to ORR staff that the SMR packet is ready for review.

ORR has incorporated changes to the form to streamline the flow of data collection, clarify intent and purpose of the form and fields, improve data quality, and ensure alignment with ORR program policies. The overall estimated time per form has increased by 1 minute and has been adjusted to reflect a decrease by 1 minute for care provider program staff and an increase by 2 minutes for surgeons.

Respondents: Care provider program staff, surgeons.

Annual Burden Estimates

There are currently about 250 programs that use the SMR form. Over the past 2 years, an annual average of 115 SMR forms were submitted across all programs. For each form, a care provider program staff member completes page 1, and a surgeon completes pages 2 and 3.

ESTIMATED REPORTING TIME FOR RESPONDENTS

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SMR Form	Care Provider Program Staff.	250	1.38	.07	24.15	8
	Surgeons	250	1.38	.17	58.65	20
Total Annual Burden Estimate.						28

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SMR Form	Care Provider Program Staff.	250	1.38	.08	27.6	9

Authority: 6 U.S.C 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996]).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–25322 Filed 11–15–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Voluntary Agencies Matching Grant Program Data Reporting (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing to collect data from grantee agencies participating in the Voluntary Agencies Matching Grant Program. Client data collected will include enrollment information, demographics, and program outcomes.

DATES: *Comments due within 30 days of publication.* Office of Management and Budget (OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This Matching Grant Program data collection is designed to satisfy the statutory requirements of the Immigration and Nationality Act (INA). Section 412(a)(3) of INA (8 U.S.C. 1522(a)(3)) requires that the Director of ORR make a periodic assessment of the needs of refugees for assistance and services and the resources available to meet those needs. In addition, section 412(a)(7) of the INA (8 U.S.C. 1522(a)(7)) requires ORR to develop a system to monitor the assistance provided under the Refugee Act that includes evaluation of the effectiveness of the program and data collection on the services provided and the results achieved. ORR proposes collecting both case-level and client-level data elements at multiple points in time, which will allow the ORR Director to better understand client demographics, services utilized, and the outcomes achieved by clients enrolled in the Matching Grant Program. Data elements include biographical information, progress made toward achieving self-sufficiency, and employment status. The data collected will inform evidence-based policy making and program design.

Respondents: National resettlement agencies participating in the Matching Grant Program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent (3 years)	Average burden hours per response	Total burden hours (3 years)	Annual burden hours
Voluntary Agencies Matching Grant Program Data Reporting—Data System Updates	10	1	60	600	200
Voluntary Agencies Matching Grant Program Data Reporting—Monthly Uploads	10	36	16	5,760	1,920
Total estimated annual burden					2,120

Authority: 8 U.S.C. 412(a)(3) and 412(a)(7).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–25352 Filed 11–15–23; 8:45 am]

BILLING CODE 4184–89–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Runaway and Homeless Youth Prevention Demonstration Prevention Plans (New Collection)

AGENCY: Family and Youth Services Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Family and Youth Service Bureau (FYSB) is proposing to collect comprehensive Prevention Plans from grant recipients that have been awarded funding for a new prevention demonstration project to design and implement prevention and intervention services tailored to prevent at-risk youth from experiencing homelessness.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: On September 29, 2023, FYSB awarded funding for the first time to Runaway and Homeless Youth-Prevention Demonstration Program (RHY–PDP) projects to design and deliver community-based demonstration initiatives to prevent youth from experiencing homelessness. Through the development and coordination of partnerships with youth and young adults, community organizations, and private and public agencies, the RHY–PDP grantees will: (1) design and develop a comprehensive community-based prevention plan to prevent youth homelessness; (2) identify young people at risk of experiencing homelessness; and (3) implement robust, holistic prevention services tailored for youth and young adults to respond to the diverse needs of youth who are at risk of homelessness and their families. The RHY–PDP has two phases with the first phase serving as a 6-month timeline for grant recipients to develop and submit a comprehensive prevention plan to prevent youth homelessness.

The Prevention Plans can include:

- Grantee definition of prevention
- Summary of risk and protective factors for youth experiencing homelessness
- How grantees will identify at-risk youth to include existing data to assist in identification
- Referral strategies for youth
- Explanation of the process of how youth with lived experience and community partners co-designed the prevention plan
- List of prevention interventions
- All related goals and performances measures planned
- List of community partners and their roles.

FYSB will utilize the Prevention Plans to provide technical assistance to grantees, as needed, and will post the Prevention Plans to the FYSB website for grantees' peer-to-peer learning.

Respondents: All grant recipients that receive a RHY–PDP grant for the prevention demonstration.

Total Burden Estimates: FYSB awarded 11 grants in September 2023 and anticipates awarding a second cohort next year. The number of respondents reflects a potential second cohort of grant recipients that would also be required to submit the Prevention Plan.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
FYSB RHY–PDP Prevention Plan	26	1	60	1,560

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 343 of the Runaway and Homeless Youth Act authorizes the award of grants for research, evaluation, demonstration, and service projects (34 U.S.C. 11243).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–25308 Filed 11–15–23; 8:45 am]

BILLING CODE 4182–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Rural Health Policy, Community, and Collaboration Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Supplemental funding for the National Rural Health Policy, Community, and Collaboration Program.

SUMMARY: HRSA provided supplemental funds to the sole award recipient of the National Rural Health Policy, Community, and Collaboration Program.

FOR FURTHER INFORMATION CONTACT: Alexa Ofori, Senior Advisor, Federal Office of Rural Health Policy, HRSA, at *aofori@hrsa.gov* and (301) 945–3986.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The National Rural Health Association (NRHA). The purpose of this program is to identify, engage, educate, and collaborate with rural stakeholders on national rural health policy issues and promising practices in an effort to improve the health of people living in rural communities nationwide.

Amount of Non-Competitive Award: One award for $520,000.

Project Period: August 1, 2023, to July 31, 2024.

CFDA Number: 93.155.

Award Instrument: Supplement.

Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Supplemental award amount
U16RH03702	National Rural Health Association	Leawood, KS	$520,000

Justification: The supplement provides funds to NRHA, the recipient of the National Rural Health Policy, Community, and Collaboration Program, to enhance technical assistance activities for rural health care facilities and rural communities to better respond to emergent rural health issues, to track rural provider and patient issues, and to further support rural behavioral health resource needs through partnerships with key stakeholders. These activities align with the goals of the program by creating resources, supporting the development of educational materials, and increasing collaboration among key stakeholders to support rural health needs.

Carole Johnson,

Administrator.

[FR Doc. 2023–25315 Filed 11–15–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Faculty Loan Repayment Program, OMB No. 0915–0150—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 18, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Faculty Loan Repayment Program OMB No. 0915–0150—Revision.

Abstract: HRSA administers the Faculty Loan Repayment Program (FLRP). FLRP provides health professionals from disadvantaged backgrounds based on environmental and/or economic factors the opportunity to enter into a contract with the Department of Health and Human Services to receive repayment of qualifying educational loans in exchange for a minimum of 2 years of service as a full-time or part-time faculty member at an eligible health professions school. The applicant completes and submits an electronic application that identifies for the Secretary of Health and Human Services that the applicant comes from an economically or environmentally disadvantaged background who has a contract with an eligible health professions school to serve as a full-time or part-time faculty member for a minimum of 2 years and has qualifying outstanding educational loans. In addition, for each undergraduate and/or graduate loan for which repayment is sought, the applicant is required to submit loan documentation verifying the establishment of the educational loan(s) and lender account statements, promissory notes including the original date, and current balance of the outstanding educational loan(s). The sole change in this version of the ICR from previous ICR versions is that there is an increase in the estimated burden hours related to an increased number of respondents/applicants to the FLRP.

A 60-day notice published in the **Federal Register** on September 5, 2023, vol. 88, No. 170; pp. 60693–94. There were no public comments.

Need and Proposed Use of the Information: The information collected will be used to evaluate applicants' eligibility to participate in the FLRP and to monitor FLRP related activities.

Likely Respondents: FLRP applicants and institutions providing employment to the applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Eligible Applications	215	1	215	1.00	215.00
Institution/Loan Repayment Employment Form	*215	1	215	1.00	215.00
Authorization to Release Information Form	215	1	215	0.25	53.75
Disadvantaged Background Form	215	1	215	0.20	43.00
Total	860				526.75

* Respondents for this form is the institution on behalf of the applicant.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–25317 Filed 11–15–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be partially open to the public as indicated below. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be partially closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: February 14–15, 2024.

Open: February 14, 2024, 10:00 a.m. to 4:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments.

Open session will be videocast from this link: https://videocast.nih.gov/watch=52772.

Closed: February 14, 2024, 4:00 p.m. to 5:30 p.m.

February 15, 2024, 9:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6001 Executive Boulevard, Room 1131, Rockville, Maryland 20852 (Virtual Meeting).

Contact Person: David Owens, Ph.D., Director of Extramural Activities (Acting), National Institute of Neurological Disorders and Stroke, NIH 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, (301) 496–9248, *owensd@ninds.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: November 7, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–25260 Filed 11–15–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2023–0001]

Agency Information Collection Activities: Request for Comment on Secure Software Development Attestation Common Form

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments.

SUMMARY: The Cyber Supply Chain Risk Management (C–SCRM) Program Management Office (PMO) within Cybersecurity and Infrastructure Security Agency (CISA) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance. CISA previously published this information collection request (ICR) in the **Federal Register** on April 27, 2023, for a 60-day public comment period. 110 comments were received by CISA. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until December 18, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

This process is conducted in accordance with 5 CFR 1320.10.

FOR FURTHER INFORMATION CONTACT: Shon Lyublanovits, 888–282–0870, *central@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In response to incidents such as the Colonial Pipeline and Solar Winds attacks, on May 12, 2021, President Biden signed Executive Order 14028 [1] on *Improving the Nation's Cybersecurity.* This order outlines over 55 actions [2] federal agencies need to take to improve cybersecurity. These actions range from developing strategies for critical software use to directly removing certain software products that do not comply with revamped standards. The objective of the executive order is to bolster the cybersecurity of federal systems. This Executive order addresses seven key points:

- Remove barriers to cyber threat information sharing between government and the private sector
- Modernize and implement more robust cybersecurity standards in the Federal Government
- Improve software supply chain security
- Establish a Cybersecurity Safety Review Board
- Create a standard playbook for responding to cyber incidents
- Improve detection of cybersecurity incidents on Federal Government networks
- Improve investigative and remediation capabilities

Section 4 of the E.O. observed, ''The development of commercial software often lacks transparency, sufficient focus on the stability of the software to resist attack, and adequate controls to prevent tampering by malicious actors.'' To address these concerns, the Executive Order required the National Institute of Standards and Technology (NIST) to issue guidance including standards, procedures, or criteria to strengthen the security of the software supply chain.

To put this guidance into practice, the Executive Order, through the Office of Management and Budget (OMB), requires agencies to only use software provided by software producers who can attest to complying with Federal Government-specified secure software development practices, as described in NIST Special Publication (SP) 800–218 Secure Software Development Framework.[3] OMB implemented this requirement through OMB memorandum M–22–18 dated September 14, 2022.[4] Specifically, M–22–18 requires agencies to ''obtain a self-attestation from the software producer before using the software.'' (Enhancing the Security of the Software Supply Chain through Secure Software Development Practices, Page 6, Sep. 14, 2022)

A copy of the current draft of the self attestation form is available at *https://www.cisa.gov/resources-tools/resources/secure-software-self-attestation-common-form.*

On June 9, 2023, OMB subsequently updated M–22–18 with M–23–16, ''Update to Memorandum M–22–18, Enhancing the Security of the Software Supply Chain through Secure Software Development Practices.'' M–23–16 states that ''Agencies must collect attestations for critical software subject to the requirements of M–22–18 and this memorandum no later than three months after the M–22–18 attestation common form released by the Cybersecurity and Infrastructure Security Agency (CISA) (hereinafter 'common form') is approved by OMB under the Paperwork Reduction Act (PRA). Six months after the common form's PRA approval by OMB, agencies must collect attestations for all software subject to the requirements delineated in M–22–18, as amended by this memorandum.'' (Update to Memorandum M–22–18, Enhancing the Security of the Software Supply Chain through Secure Software Development Practices, page 2, June 9, 2023) Per M–22–18, as amended by M–23–16, this requirement applies to agencies' use of software developed after the effective date of M–22–18 (Sep. 14, 2022), as well as use of existing software that is modified by major version changes after the effective date of M–22–18 (September 14, 2022). CISA's common self-attestation form does not preclude agencies from adding agency-specific requirements to the minimum requirements in CISA's common self-attestation form. However, any agency specific attestation requirements, modification and/or supplementation of these common forms will require clearance by OMB/OIRA under the PRA process and are not covered by this notice.

II. Responses

CISA received 110 comments in response to the 60-day public notice for the secure software self-attestation common form which concluded the 26th of June 2023. Comments can be found at *regulations.gov* under docket number CISA–2023–0001.[5] Summaries of the comments and CISA responses can be found at: *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. As result of public comment, CISA has changed the draft self attestation common form described in the 60-day notice in the following manner:

- Added the citations to the appropriate NIST Guidance under ''What is the Purpose of Filling out this form'' to now read: ''to issue guidance ''identifying practices that enhance the security of the software supply chain.'' The NIST Secure Software Development Framework (SSDF), SP 800–218, and the NIST Software Supply Chain Security Guidance (these two documents, taken together, are hereinafter referred to as ''NIST Guidance'') include a set of practices that create the foundation for developing secure software.'' ''
- Included references to M–23–16 throughout.
- Under ''What is the Purpose of Filling out this Form?'' edited the ''and'' to ''or'' in the list of software that requires self-attestation.
- Edited the software products and components that are not in scope for M–22–18, as amended by M–23–16, and do not require self attestation to now read:

1. ''Software developed by Federal agencies;
2. Open source software that is freely and directly obtained by a federal agency; or
3. Software that is freely obtained and publicly available.''

This aligns with M–23–16. This changes is also reflected in the Form on page 8.

- Under ''Filling Out the Form,'' added ''When the software producer chooses to verify conformance with the minimum requirements by a certified FedRAMP Third Party Assessor Organization (3PAO) or other 3PAO approved in writing by an appropriate agency official, the software producer must attach the assessment in lieu of a signed attestation. The 3PAO must use relevant NIST Guidance, which

[1] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/05/12/executive-order-on-improving-the-nations-cybersecurity/.*

[2] *https://www.natlawreview.com/article/2021-cybersecurity-recap-government-contractors-and-what-to-expect-2022-part-1-4.*

[3] *https://doi.org/10.6028/NIST.SP.800-218.*

[4] *https://www.whitehouse.gov/wp-content/uploads/2022/09/M-22-18.pdf.*

[5] *https://www.federalregister.gov/documents/2023/04/27/2023-08823/agency-information-collection-activities-request-for-comment-on-secure-software-development.*

includes all elements outlined in this form, as part of the assessment baseline. To rely upon a third-party assessment, the software producer must check the appropriate box in Section III and attach the assessment to the form. The producer need not sign the form in this instance.''

• Modified language under ''Additional Information'' to clarify that an agency may still use the producer's software if the producer identifies the practices to which they cannot attest, documents practices they have in place to mitigate associated risks, and submits a plan of actions and milestones (POA&M) to the agency.

• Added additional language (in italics) under ''Additional Information'' to include: ''Software producers may be asked by agencies to provide additional attestation artifacts or documentation, such as a Software Bill of Materials (SBOMs) or documentation from *a certified FedRAMP third party assessor organization (3PAO) or other 3PAO approved in writing by an appropriate agency official*.''

• Under ''Additional Information,'' removed ''If the relevant software has been verified by a certified FedRAMP third party assessor organization (3PAO) or other 3PAO approved in writing by an appropriate agency official, and the assessor used relevant NIST guidance, the software producer does not need to submit a signed attestation. However, relevant documentation from the 3PAO is required.''

• Moved the minimum attestation reference to the appendix.

• Added ''Version 1.0'' to the form.

• Added ''Revised Attestation'' in the case of necessary corrections or edits.

• In Section I, on page 8, added that additional pages can be attached to the attestation if more lines are needed to appropriately list all relevant products.

• Removed Product Line from Type of Attestation due to confusion. Product line presents problem such as when a new product is added. Also removed ''product line'' in the file name structure example on page 3.

• Modified the language on page 8 to now read: ''Note: In signing this attestation, software producers are attesting to adhering to the secure software development practices outlined in Section III.'' This clarifies the practices to which software producers are attesting.

• Removed First Name, Last Name and modified to just Name.

• Under Requirement #2 in Section III, modified to remove redundancies and now reads: ''The software producer has made a good-faith effort to maintain trusted source code supply chains by employing automated tools or comparable processes to address the security of internal code and third-party components and manage related vulnerabilities.'' This modification is also reflected in the reference table in the appendix.

• Removed duplicative requirement previously listed under 3). This modification is also reflected in the reference table in the appendix.

• Modified minimum requirement regarding provenance to now read: ''The software producer maintains provenance for internal code and third-party components incorporated into the software.'' This modification is also reflected in the reference table in the appendix.

• Modified minimum requirement regarding security vulnerabilities to now read:

○ ''(4) The software producer employs automated tools or comparable processes that check for security vulnerabilities. In addition:

(a) The software producer operates these processes on an ongoing basis and, at a minimum, prior to product, version, or update releases;

(b) The software producer has a policy or process to address discovered security vulnerabilities prior to product release; and

(c) The software producer operates a vulnerability disclosure program and accepts, reviews, and addresses disclosed software vulnerabilities in a timely fashion and according to any timelines specified in the vulnerability disclosure program or applicable policies.''

A redundant ''and'' was removed under section 4(a). These modifications are also reflected in the reference table in the appendix.

• Added ''To the best of my knowledge'' after ''I attest'' in both instances in the attestation section (Section III).

• Modified signature line to clarify signature of CEO or COO is acceptable; it now reads: ''Signature of CEO or COO and Date (YYYY–MM–DD).'' This modification is also reflected in the instructions on page 3.

• Added ''OR'' between CEO signature and 3PAO certification option and modified ''I attest that the referenced software has been verified by a certified FedRAMP Third Party Assessor Organization (3PAO) or other 3PAO approved in writing by an appropriate agency official has evaluated our conformance to all elements in this form'' to ''A certified FedRAMP Third Party Assessor Organization (3PAO) or other 3PAO approved in writing by an appropriate agency official has evaluated our conformance to all elements in this form. The 3PAO used relevant NIST Guidance, which includes all elements outlined in this form, as the assessment baseline. The assessment is attached.''

• Under Attachment(s) removed: ''Please check the appropriate boxes below, if applicable: There are addendums and/or artifacts attached to this self-attestation form, the title and contents of which are delineated below the signature line. I attest the referenced software has been verified by a certified FedRAMP Third Party Assessor Organization (3PAO) or other 3PAO approved in writing by an appropriate agency official, and the Assessor used relevant NIST Guidance, which includes all elements outlined in this form, as the assessment baseline. Relevant documentation is attached.''

• Removed ''Title of Individual signing on behalf of the organization.''

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Secure Software Development Attestation.

OMB Number: 1670–NEW.

Frequency: Annually.

Affected Public: Business-Software Producers.

Estimated Number of Respondents per Initial Submission: 16,688.

Estimated Number of Respondents per Resubmission: 8,344.

Estimated Number of Responses per Respondent per Initial Submission: 3.

Estimated Number of Responses per Respondent per Resubmission: 1.

Estimated Time for Initial Submission per Respondent: 3 hours and 20 minutes.

Estimated Time for Resubmission per Respondent: 1 hour and 50 minutes.

Total Annualized Hours for Initial Submission: 83,432 hours.

Total Annualized Hours for Resubmission: 7,647 hours.

Estimated Number of Respondents per POA&M Development: 14,105.

Estimated Number of Responses per Respondent per POA&M Development: 1.

Estimated Time for POA&M Development per Respondent: 6 Hours.

Total Annualized Hours for POA&M Development: 84,630 hours.

Estimated Cost to Public: $13,264,954.

Robert J. Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2023–25251 Filed 11–15–23; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2023–0012]

Notice of President's National Infrastructure Advisory Council Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of open *Federal Advisory Committee Act* (FACA) meeting; request for comments.

SUMMARY: CISA is publishing this notice to announce the following President's National Infrastructure Advisory Council (NIAC) meeting.

DATES: *Meeting Registration:* Registration is required to attend the meeting and must be received no later than 5 p.m. eastern standard time (EST) on December 6, 2023. For more information on how to participate, please contact *NIAC@cisa.dhs.gov.*

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5 p.m. EST on December 6, 2023.

Written Comments: Written comments must be received no later than 5 p.m. EST on December 6, 2023.

Meeting Date: The NIAC will meet on December 12, 2023, from 1 p.m. to 4 p.m. EST. The meeting may close early if the council has completed its business.

ADDRESSES: The National Infrastructure Advisory Council's open session will be held in-person at 1650 Pennsylvania Ave. NW, Washington, DC; however, members of the public may participate via teleconference only. Requests to participate will be accepted and processed in the order in which they are received. For access to the conference call bridge, information on services for individuals with disabilities, or to request special assistance, please email *NIAC@cisa.dhs.gov* by 5 p.m. EST on December 6, 2023. The NIAC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Celinda Moening at *NIAC@cisa.dhs.gov* as soon as possible.

Comments: The council will consider public comments on issues as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials for potential discussions during the meeting will be available for review at *https://www.cisa.gov/niac* by December 5, 2023. Comments should be submitted by 5:00 p.m. EST on December 6, 2023 and must be identified by Docket Number CISA–2023–0012. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Please follow the instructions for submitting written comments.
- *Email: NIAC@cisa.dhs.gov.* Include the Docket Number CISA–2023–0012 in the subject line of the email.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the Docket Number for this action. Comments received will be posted without alteration to *www.regulations.gov,* including any personal information provided. You may wish to read the Privacy & Security Notice which is available via a link on the homepage of *www.regulations.gov.*

Docket: For access to the docket and comments received by the National Infrastructure Advisory Council, please go to *www.regulations.gov* and enter docket number CISA–2023–0012.

A public comment period will take place from 2:30 p.m. to 2:40 p.m. Speakers who wish to participate in the public comment period must email *NIAC@cisa.dhs.gov* to register. Speakers should limit their comments to 3 minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, depending on the number of speakers who register to participate.

FOR FURTHER INFORMATION CONTACT: Celinda Moening, 571–532–4119, *NIAC@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NIAC is established under section 10 of E.O. 13231 issued on October 16, 2001, as amended and continued under the authority of E.O. 14109, dated September 30, 2023. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. Ch. 10 (Pub. L. 117–286). The NIAC provides the President, through the Secretary of Homeland Security, advice on the security and resilience of the Nation's critical infrastructure sectors.

Agenda: The National Infrastructure Advisory Council will meet in an open session on Tuesday, December 12, 2023, from 1 p.m. to 4 p.m. EST to discuss NIAC activities. The open session will include: (1) a period for public comment; (2) a keynote address on critical infrastructure security and resilience; (3) a report to the Council from the NIAC's Electrification Subcommittee; (4) deliberation and vote on Electrification Subcommittee recommendations; and (5) Additional Topics Discussion.

Dated: November 13, 2023.

Celinda E. Moening,

Alternate Designated Federal Officer, National Infrastructure Advisory Council, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2023–25348 Filed 11–15–23; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[CIS No. 2758–23; DHS Docket No. USCIS–2023–0014]

RIN 1615–ZC07

Implementation of a Family Reunification Parole Process for Ecuadorians

AGENCY: Department of Homeland Security.

ACTION: Notice of implementation of a family reunification parole process for Ecuadorians.

SUMMARY: This notice announces the U.S. Department of Homeland Security's (DHS) creation and implementation of a family reunification parole (FRP) process for Ecuadorians. Under this process, certain Ecuadorian principal beneficiaries of an approved Form I–130, Petition for Alien Relative, and their immediate family members, will be issued advance authorization to travel to the United States to seek a discretionary grant of parole into the United States for a period of up to three years, rather than remain outside the United States while awaiting availability of their immigrant visas. This process will allow family members to reunite in the United States while they wait for their immigrant visas to become available. This process is voluntary and intended to provide an additional lawful, safe, and orderly avenue for migration from Ecuador to the United States as an alternative to irregular migration to help relieve pressure at the Southwest Border (SWB) and to reunite families, consistent with U.S. national security interests and foreign policy priorities. The process complements other efforts to collaboratively manage migration in the Western Hemisphere and at the SWB as the U.S. Government (USG) continues to implement its broader, multi-pronged, regional strategy to address the challenges posed by irregular migration.

DATES: DHS will begin using the Form I–134A, Online Request to be a

Supporter and Declaration of Financial Support, for this process on November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Rená Cutlip-Mason, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 800–375–5283.

SUPPLEMENTARY INFORMATION:

I. Background

This notice describes the implementation of a new parole process for certain Ecuadorian nationals and their immediate family members,[1] including the eligibility criteria and filing process. The parole process is intended to reunite families more quickly and offer an alternative to dangerous irregular migration routes through North and Central America to the United States by providing an avenue for certain Ecuadorians and their immediate family members to lawfully enter the United States in a safe and orderly manner.

The USG is committed to implementing a comprehensive framework to collaboratively manage migration with its partners in the Western Hemisphere.[2] Executive Order (E.O.) 14010 called for a four-pronged approach, including: addressing the root causes of irregular migration; managing migration throughout the region collaboratively with other nations and stakeholders; restoring and enhancing the U.S. asylum system and the process for migrants at the SWB to access this system; and creating and expanding lawful pathways for migrants to enter the United States and seek protection.[3]

In July 2021, the National Security Council (NSC) published the *U.S. Strategy for Addressing the Root Causes of Migration in Central America.*[4] This strategy outlined a comprehensive framework within which federal government agencies would work collaboratively to address the root causes of irregular migration through Central America, noting long-standing political instability, insecurity, and climate change in the region. Also in July 2021, the NSC published the *Collaborative Migration Management Strategy,* which described U.S. strategy to collaboratively manage migration through Central America.[5] Further, in March 2022, DHS published an interim final rule (IFR) intended to allow U.S. immigration officials to consider more promptly the asylum claims of noncitizens encountered at or near the SWB while ensuring the fundamental fairness of the asylum process.[6] In June 2022, through the Los Angeles Declaration on Migration and Protection (L.A. Declaration), the United States, along with several countries in the Western Hemisphere, committed to strengthen national, regional, and hemispheric efforts to create the conditions for safe, orderly, humane, and regular migration, and signaled their intent to work together to expand access to regular pathways for migrants and international protection, including through family reunification options, where appropriate and feasible, in accordance with national legislation.[7]

A critical component of this migration framework is the creation and expansion of access to lawful pathways through which migrants can come to the United States as one means of reducing irregular migration flows. On October 12, 2022, the United States announced a parole process for certain Venezuelan nationals and their immediate family members to lawfully enter the United States in a safe and orderly manner.[8] The process for Venezuelans was designed to immediately address the humanitarian need and the increasing number of encounters of Venezuelan nationals at the SWB.[9] Implementation of the parole process for Venezuelans was dependent on Mexico continuing to accept the return of Venezuelan nationals seeking to irregularly enter the United States between the ports of entry (POEs), and the announcement made clear that Venezuelans who did not avail themselves of this process, and who instead entered the United States without authorization, would be subject to expulsion or removal.[10] In January 2023, DHS implemented similar parole processes for Cubans, Haitians, and Nicaraguans, and their immediate family members, to address the increasing numbers of encounters of nationals of those countries at the SWB, and announced changes to the existing parole process for Venezuelans to allow for its continued operation.[11]

On May 12, 2023, following the termination of the Centers for Disease Control and Prevention's (CDC) Title 42 public health Order, DHS and the Department of Justice (DOJ) implemented a joint final rule, *Circumvention of Lawful Pathways,* which incentivizes migrants to avail themselves of identified lawful, safe, and orderly pathways into the United States, or otherwise to seek asylum or other protection in another country through which they travel.[12] That rule reflects the position that an increase in the availability of lawful pathways paired with consequences for migrants who do not avail themselves of such pathways can encourage the use of lawful pathways and undermine transnational criminal organizations (TCOs), such as smuggling operations.[13]

In addition, DHS and the Department of State (State) have collaborated on a number of efforts to address the challenges of irregular migration by expanding access to lawful pathways, including: restarting and expanding eligibility criteria to the Central American Minors (CAM) Program [14] and

[1] Throughout this notice, ''immediate family members'' is used as a shorthand for the derivative beneficiary spouse and children of a principal beneficiary. *See* INA sec. 203(d), 8 U.S.C. 1153(d); *see also* INA sec. 101(b)(1), 8 U.S.C. 1101(b)(1) (defining ''child,'' in general, as meaning ''an unmarried person under twenty-one years of age'').

[2] *See generally* Executive Order (E.O.) 14010, *Creating a Comprehensive Regional Framework to Address the Causes of Migration, To Manage Migration Throughout North and Central America, and To Provide Safe and Orderly Processing of Asylum Seekers at the United States Border* (Feb. 2, 2021) *https://www.govinfo.gov/content/pkg/FR-2021-02-05/pdf/2021-02561.pdf; see also* NSC, *Collaborative Migration Management Strategy* (July 2021) *https://www.whitehouse.gov/wp-content/uploads/2021/07/Collaborative-Migration-Management-Strategy.pdf.*

[3] *See* E.O. 14010 at secs. 2, 4.

[4] *See* National Security Council (NSC), *U.S. Strategy for Addressing the Root Causes of Migration in Central America* (July 2021), *https://www.whitehouse.gov/wp-content/uploads/2021/07/Root-Causes-Strategy.pdf.*

[5] *See* NSC *Collaborative Migration Management Strategy* (July 2021), *https://www.whitehouse.gov/wp-content/uploads/2021/07/Collaborative-%20Migration-%20Management-%20Strategy.*

[6] Procedures for Credible Fear Screening and Consideration of Asylum, Withholding of Removal, and CAT Protection Claims by Asylum Officers, 87 FR 18078 (Mar. 29, 2022).

[7] The White House, *Los Angeles Declaration on Migration and Protection* (June 10, 2022), *https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/10/los-angeles-declaration-on-migration-and-protection/.*

[8] Implementation of a Parole Process for Venezuelans, 87 FR 63507 (Oct. 19, 2022).

[9] *See id.*

[10] *Id.*

[11] *See* Implementation of a Parole Process for Cubans, 88 FR 1266 (Jan. 9, 2023); Implementation of a Parole Process for Haitians, 88 FR 1243 (Jan. 9, 2023); Implementation of a Parole Process for Nicaraguans, 88 FR 1255 (Jan. 9, 2023); Implementation of Changes to the Parole Process for Venezuelans, 88 FR 1279 (Jan. 9, 2023).

[12] 88 FR 31314 (May 16, 2023).

[13] *See id.* at 31325.

[14] The United States announced in March 2021 that the CAM Program would reopen and continue with processing for cases that were closed in 2018 when the program was terminated. *See* U.S. Department of State, Restarting the Central American Minors Program, March 10, 2021, *https://www.state.gov/restarting-the-central-american-minors-program/* (last visited Aug. 3, 2023). In June 2021, the United States announced the program would be expanded by increasing the categories of eligible U.S.-based relatives who can request access for their children in Northern Central America (NCA). *See* U.S. Department. of State, Joint

Continued

expanding refugee processing in South and Central America, including by working to establish Safe Mobility Offices (SMOs) in key locations.[15] USG efforts have also expanded access to H–2 temporary nonimmigrant worker visas for noncitizens in the region while enhancing worker protections.[16]

Consideration of noncitizens for parole on a case-by-case basis under the process outlined here will meaningfully contribute to the broader USG strategy of expanding access to lawful pathways to noncitizens who may otherwise undertake an irregular migration journey to the United States.

II. Parole Authority

The Secretary of Homeland Security (the Secretary) has the discretionary authority under the Immigration and Nationality Act (INA) to parole an applicant for admission ''into the United States temporarily under such reasonable conditions as [the Secretary] may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit.'' [17] Parole is not an admission of the noncitizen to the United States, and a parolee remains an ''applicant for admission'' during the period of parole in the United States.[18] DHS sets the duration of the parole based on the purpose for granting the parole request and may impose reasonable conditions on parole.[19] DHS may terminate parole upon notice in its discretion at any time.[20] By regulation, parolees may apply for and be granted employment authorization to work lawfully in the United States.[21]

Past Secretaries have similarly exercised parole authority to establish other family reunification parole processes administered by U.S. Citizenship and Immigration Services (USCIS). For example, Cuban Family Reunification Parole (CFRP) as established in 2007, allows U.S. citizens (USCs) and lawful permanent residents (LPRs) to request parole for certain eligible family members in Cuba who are beneficiaries of approved Forms I–130.[22] If parole is authorized, these family members may come to the United States and seek parole before their immigrant visa priority dates are current.[23] Similarly, in 2014, Haitian Family Reunification Parole (HFRP) was established, which allows USCs and LPRs to request parole for certain eligible family members in Haiti who are beneficiaries of approved Form I–130s, who may subsequently come to the United States and seek parole before their immigrant visa priority dates are current.[24] On July 10, 2023, DHS announced the implementation of four new FRP processes for certain nationals from Colombia, El Salvador, Guatemala, and Honduras, and their immediate family members, who have approved family-based petitions filed on their behalf by a U.S.C. or LPR.[25] On August 11, 2023, DHS announced updates to modernize the CFRP and HFRP processes by adopting the new, mostly

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Statement by the U.S. Department of State and U.S. Department of Homeland Security on the Expansion of Access to the Central America Minors Program, June 15, 2021, *https://www.state.gov/joint-statement-by-the-u-s-department-of-state-and-u-s-department-of-homeland-security-on-the-expansion-of-access-to-the-central-american-minors-program/* (last visited Aug. 3, 2023). In April 2023, the United States announced enhancements to the CAM Program, including updates to certain eligibility criteria for program access. *See* Bureau of Population, Refugees, and Migration; Central American Minors Program, 88 FR 21694 (Apr. 11, 2023).

[15] *See* DHS, Fact Sheet, U.S. Government Announces Sweeping New Actions to Manage Regional Migration (Apr. 27, 2023), *https://www.dhs.gov/news/2023/04/27/fact-sheet-us-government-announces-sweeping-new-actions-manage-regional-migration;* U.S Department of State, U.S.-Colombia Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 4, 2023), *https://www.state.gov/u-s-colombia-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/*. DHS has previously announced the intention to establish Regional Processing Centers (RPCs) but will now refer to them as Safe Mobility Offices (SMOs) following the launch of the *MovilidadSegura.org* website and announcements with hosting countries. *See* The White House, Joint Statement from the United States and Guatemala on Migration (Jun 1, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/01/joint-statement-from-the-united-states-and-guatemala-on-migration/; See* United States Department of State, U.S.-Colombia Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 4, 2023), *https://www.state.gov/u-s-colombia-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/; See* The White House, Readout of Principal Deputy National Security Advisor Jon Finer's Meeting with Colombian Foreign Minister Alvaro Leyva (June 11, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/11/readout-of-principal-deputy-national-security-advisor-jon-finers-meeting-with-colombian-foreign-minister-alvaro-leyva/; See* United States Department of State, U.S.-Costa Rica Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 12, 2023), *https://www.state.gov/u-s-costa-rica-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/; See* The Department of State, Announcement of Safe Mobility Office in Ecuador, Oct. 19, 2023, *https://www.state.gov/announcement-of-safe-mobility-office-in-ecuador/*.

[16] While focusing attention on improvements to recruitment practices and educating workers on their rights in the NCA countries and labor conditions in the United States, the United States Government has been engaging in efforts to substantially increase the number of H–2 temporary workers from NCA countries. As part of these efforts, the Secretary of Homeland Security, in consultation with the Secretary of Labor, has exercised the authority given by Congress to allocate additional H–2B temporary non-agricultural worker visas under the supplemental cap. Most recently, on December 15, 2022, DHS and DOL jointly published a temporary final rule increasing the number of H–2B nonimmigrant visas by up to 64,716 for the entirety of FY 2023. *See* Exercise of Time-Limited Authority to Increase the Numerical Limitation for FY 2023 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers, 87 FR 76816 (Dec. 15, 2022). 20,000 of these H–2B visas are reserved for nationals of El Salvador, Guatemala, Honduras, and Haiti. *Id.* DHS and DOL similarly exercised this authority in other recent FYs, with specific allocations for NCA countries. *See* Exercise of Time-Limited Authority To Increase the Numerical Limitation for Second Half of FY 2022 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers, 87 FR 30334 (May 18, 2022) (authorizing the issuance of no more than 35,000 additional H–2B visas during the second half of FY 2022, of which 11,500 H–2B visas were reserved for nationals of El Salvador, Guatemala, Honduras, and Haiti); Exercise of Time-Limited Authority to Increase the Fiscal Year 2022 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers, 87 FR 4722 (Jan. 28, 2022) (DHS and DOL authorized an additional 20,000 H–2B visas, of which 6,500 were reserved for nationals of the NCA countries and Haiti); Exercise of Time-Limited Authority to Increase the Fiscal Year 2021 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers, 86 FR 28198 (May 25, 2021) (DHS and DOL authorized a total of 22,000 supplemental visas, of which 6,000 visas were reserved for nationals of the NCA countries).

[17] INA sec. 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A); *see also* 6 U.S.C. 202(a)(4) (charging the Secretary with the responsibility for ''[e]stablishing and administering rules . . . governing . . . parole'').

[18] INA secs. 101(a)(13)(B) and 212(d)(5)(A), 8 U.S.C. 1101(a)(13)(B) and 1182(d)(5)(A).

[19] *See* 8 CFR 212.5(c).

[20] *See* 8 CFR 212.5(e).

[21] *See* 8 CFR 274a.12(c)(11).

[22] *See* Cuban Family Reunification Parole Program, 72 FR 65588 (Nov. 21, 2007) (Noting that granting parole to eligible aliens under the CFRP Program serves the significant public benefit of enabling the United States to meet its commitments under the Migration Accords as well as ''reducing the perceived need for family members left behind in Cuba to make irregular and inherently dangerous attempts to arrive in the United States through unsafe maritime crossings, thereby discouraging alien smuggling as a means to enter the United States,'' and stating that whether to parole a particular alien ''remains, however, a case-by-case, discretionary determination.'').

[23] *Id.*

[24] *See* Implementation of Haitian Family Reunification Parole Program, 79 FR 75581 (Dec. 18, 2014) (''By expanding existing legal means for Haitians to immigrate, the HFRP Program serves a significant public benefit by promoting safe, legal, and orderly migration to the United States. Furthermore, it supports U.S. goals for Haiti's long-term reconstruction and development.'').

[25] *See* Implementation of a Family Reunification Parole Process for Colombians, 88 FR 43591 (July 10, 2023); Implementation of a Family Reunification Parole Process for Salvadorans, 88 FR 43611 (July 10, 2023); Implementation of a Family Reunification Parole Process for Guatemalans, 88 FR 43581 (July 10, 2023); Implementation of a Family Reunification Parole Process for Hondurans, 88 FR 43601 (July 10, 2023).

online, processing steps implemented for the four new FRP processes.[26]

III. The FRP Process for Ecuadorians

As in all other FRP processes, the FRP process for Ecuadorians will allow U.S.C. and LPR petitioners who have been invited to file a request and initiate this process for certain eligible family members to receive advance authorization to travel to the United States to seek parole at an interior POE (*i.e.,* an airport). Individuals who are eligible to be considered for parole under this process include nationals of Ecuador who are principal beneficiaries of approved Form I–130 family-based immigrant petitions, as well as their immediate family members, who are outside the United States and who have not yet received an immigrant visa. This process requires that the Form I–130 petitioner first receive an invitation to be able to initiate the process on behalf of the Form I–130 principal beneficiary and their immediate family members. As in other FRP processes, this invitation requirement will allow DHS to adjust the number of invitations issued based on the resources available to process requests and to achieve desired policy objectives. If U.S. Customs and Border Protection (CBP) issues an advance authorization to travel to a beneficiary, the beneficiary will be permitted to travel to the United States to be considered for a discretionary grant of parole on a case-by-case basis at an interior POE. Noncitizens paroled into the United States under this FRP process will generally be paroled for up to three years, consistent with the other FRP processes. If paroled into the United States, parolees will be able to request employment authorization while they wait for their immigrant visa to become available and to apply for adjustment of status to that of an LPR once an immigrant visa becomes available to them. As with all parole requests, under this FRP process for Ecuadorians, parole will be authorized only on a discretionary, case-by-case, and temporary basis upon a demonstration of urgent humanitarian reasons or significant public benefit, as well as a demonstration that the beneficiary warrants a favorable exercise of discretion. Noncitizens paroled into the United States under this process may request additional periods of parole. DHS will determine whether an additional period is warranted, on a case-by-case basis, for urgent humanitarian reasons or significant public benefit.

IV. Justification for the Process—Significant Public Benefit

As noted above, section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A), confers upon the Secretary the discretionary authority to parole noncitizens ''into the United States temporarily under such reasonable conditions as [the Secretary] may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit.''

The case-by-case parole of noncitizens who are beneficiaries of approved family-based immigrant visa petitions under this process will, in general, provide a significant public benefit by furthering the USG's holistic migration management strategy, specifically by: (1) promoting family unity; (2) furthering important foreign policy objectives; (3) providing a lawful and timely alternative to irregular migration; (4) reducing strain on limited U.S. resources; and (5) addressing root causes of migration through economic stability and development supported by increased remittances.

A. Promoting Family Unity

The case-by-case parole of noncitizens under this FRP process will provide the significant public benefit of promoting family unity by providing a more expeditious pathway for USCs and LPRs to reunite in the United States with their family members from Ecuador. Currently, nationals of Ecuador with approved family-based petitions often wait many years before their immigrant visas can be issued and they can travel to the United States to apply for admission as immigrants.[27] While they wait for an immigrant visa to be issued, security concerns and uncertainty in their home country, combined with a desire to reunify with family in the United States, could cause many to choose irregular migration in the absence of an alternative, near-term path to come to the United States for family reunification.

By facilitating quicker reunification of USCs and LPRs with their family members in the United States, this FRP process will improve the social and economic stability and well-being of these families as well as their communities at large. Additionally, facilitating reunification in the short-term through a lawful, safe, and orderly pathway will provide the significant public benefit of promoting the expeditious reception and integration of arriving noncitizens into American society. New arrivals will be introduced sooner to the networks built by family members living in the United States, providing them an opportunity to familiarize themselves with the United States, establish stable financial foundations, find housing and transportation, and enroll in school and find childcare for their children as they wait for their immigrant visas to become available.

[26] *See* Implementation of Changes to the Cuban Family Reunification Parole Process, 88 FR 54639 (Aug. 11, 2023); Implementation of Changes to the Haitian Family Reunification Parole Process, 88 FR 54635 (Aug. 11, 2023).

[27] For example, under the October 2023 Department of State Visa Bulletin, an Ecuadorian unmarried son or daughter of a U.S.C.—F1 Preference Relative category—will only have an immigrant visa available to them if their relative filed the Form I–130 on their behalf more than 8 years ago. *See* DOS, Visa Bulletin for October 2023, Number 82, Volume X (Oct. 2023), *https://travel.state.gov/content/travel/en/legal/visa-law0/visa-bulletin/2024/visa-bulletin-for-october-2023.html.* However, these dates are not predictive. Due to increases in volume of Form I–130 filings, an Ecuadorian unmarried son or daughter of a U.S.C. for whom a Form I–130 is filed today will likely have an even longer wait before an immigrant visa becomes available.

B. Furthering Important Foreign Policy Objectives

The United States has been engaging with international partners to manage irregular migration through various lines of effort, including bringing together leaders from nations across the Western Hemisphere to endorse the L.A. Declaration,[28] joining Colombia and Panama to ramp up efforts to address irregular flows through the Darién,[29] establishing SMOs in key locations throughout the Western Hemisphere,[30] joining Mexico to announce and develop a humanitarian plan on migration,[31] issuing a trilateral statement with Canada and Spain to announce our intent to partner together to deepen engagement in Latin America,[32] and, most recently, announcing full support for an initiative that the Government of Mexico plans to start in southern Mexico to offer new refugee and labor pathways.[33] A central theme of all these efforts is, as further articulated below, expanding and strengthening access to lawful pathways for migration. Many countries have cooperated extensively, at great financial, staffing, and domestic political costs, to: (1) create and expand access to lawful pathways in their respective countries, (2) increase enforcement measures along the migratory routes, and (3) introduce policies that seek to reduce irregular migration from or through their countries. In turn, regional partner countries have consistently requested that the United States expand and strengthen access to lawful pathways, even following implementation of the parole processes for nationals of Cuba, Haiti, Nicaragua, and Venezuela. Implementation of this FRP process is one response to such requests and, thereby, will build goodwill with regional partners and secure cooperation and strengthen bilateral relations in furtherance of U.S. national interests.

This process is not only responsive to the requests and interests of key foreign partners—and necessary for addressing migration issues requiring coordination between two or more governments—it is also fully aligned with larger foreign policy objectives of this Administration and fits within a framework of carefully negotiated actions by multiple governments, as reflected in the L.A. Declaration and the aforementioned actions.[34] The L.A. Declaration acknowledges the endorsees' shared responsibility on migration and commitment to strengthen national, regional, and hemispheric efforts to create the conditions for safe, orderly, humane, and regular migration.[35] All 21 countries that endorsed the declaration reaffirmed their shared commitment to strengthening and expanding regular pathways and promoting principles of safe, orderly, humane, and regular migration.[36] As such, it is the view of the United States that this process advances the Administration's foreign policy goals by demonstrating U.S. partnership and U.S. commitment to the shared goals of addressing migration through the hemisphere, both of which are essential to maintaining strong relationships with key partners to manage migration collaboratively.

The USG further intensified its international engagement in Spring 2023 as the date on which the CDC Title 42 public health Order[37] would terminate neared and DHS anticipated a significant potential further increase in irregular migration.[38] For instance, on April 11, 2023, consistent with the spirit of the L.A. Declaration, in anticipation of the end of the Title 42 public health Order, and at the request of the United States, the United States, jointly with the Governments of Panama and Colombia, committed to three goals—a counter-human smuggling effort in both the land and maritime domain; an expansion of lawful pathways as an alternative to irregular migration; and increased economic investment in impacted border communities—as part of a coordinated 60-day campaign and sustained cooperation beyond the initial two-month campaign to reduce irregular migration.[39] Implementing this process fulfills one of the commitments the United States made with its regional partners to, among all three governments, ''[o]pen new lawful and flexible pathways for tens of thousands of migrants and refugees as an alternative to irregular migration.''[40]

The United States also continues to encourage regional governments to continue to expand lawful pathways for migrants, including providing legal status to migrants residing in their countries, as well as to establish removal programs. Colombia, for example, has given 10-year temporary protected status to approximately 2.5 million Venezuelans, allowing them to work, study, and access public services.[41] Partner countries have also taken actions to forgive existing migrant overstay fines, effectively removing one of the largest barriers to regularization.

[28] *See* The White House, Los Angeles Declaration on Migration and Protection, June 10, 2022, *https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/10/los-angeles-declaration-on-migration-and-protection/.*

[29] *Trilateral Joint Statement,* April 11, 2023, *https://www.dhs.gov/news/2023/04/11/trilateral-joint-statement.*

[30] *See* The White House, Joint Statement from the United States and Guatemala on Migration (June 1, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/01/joint-statement-from-the-united-states-and-guatemala-on-migration/;* United States Department of State, U.S.-Colombia Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 4, 2023), *https://www.state.gov/u-s-colombia-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/;* The White House, Readout of Principal Deputy National Security Advisor Jon Finer's Meeting with Colombian Foreign Minister Alvaro Leyva (June 11, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/11/readout-of-principal-deputy-national-security-advisor-jon-finers-meeting-with-colombian-foreign-minister-alvaro-leyva/;* United States Department of State, U.S.-Costa Rica Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 12, 2023), *https://www.state.gov/u-s-costa-rica-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/.*

[31] *See* The White House, Mexico and United States Strengthen Joint Humanitarian Plan on Migration, May 2, 2023, *https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/02/mexico-and-united-states-strengthen-joint-humanitarian-plan-on-migration/.*

[32] *See* DHS, Trilateral statement on joint commitment to Latin America, May 3, 2023, *https://www.dhs.gov/news/2023/05/03/trilateral-statement-joint-commitment-latin-america.*

[33] *See* The White House, Statement from National Security Advisor Jake Sullivan on Legal Pathways Initiative with Mexico, July 28, 2023, *https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/28/statement-from-national-security-advisor-jake-sullivan-on-legal-pathways-initiative-with-mexico/.*

[34] The White House, *Los Angeles Declaration on Migration and Protection* (June 10, 2022), *https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/10/los-angeles-declaration-on-migration-and-protection/.*

[35] *Id.*

[36] *Id.*

[37] *See* Public Health Determination and Order Regarding Suspending the Right to Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease Exists, 87 FR 19941, 19941–42 (Apr. 6, 2022) (describing the CDC's recent Title 42 public health Orders, which ''suspend[ ] the right to introduce certain persons into the United States from countries or places where the quarantinable communicable disease exists in order to protect the public health from an increased risk of the introduction of COVID–19'').

[38] *See* 88 FR 11704, 11704–08 (Feb. 23, 2023) (describing ''concern about the possibility of a surge in irregular migration upon, or in anticipation of, the eventual lifting of the Title 42 public health Order''); CNN, Southern border braces for a migrant surge with Title 42 set to expire this week, May 8, 2023, *https://www.cnn.com/2023/05/08/us/title-42-expires-border-immigration/index.html.*

[39] *Trilateral Joint Statement,* Apr. 11, 2023, *https://www.dhs.gov/news/2023/04/11/trilateral-joint-statement.*

[40] *See id.*

[41] *See* Secretary Antony J. Blinken and Secretary of Homeland Security Alejandro Mayorkas at a Joint Press Availability—U.S. Department of State (''Blinken-Mayorkas Joint Press Availability''), Apr. 27, 2023, *https://www.state.gov/secretary-antony-j-blinken-and-secretary-of-homeland-security-alejandro-mayorkas-at-a-joint-press-availability/.*

Brazil's ''Operation Welcome'' helped over 100,000 Venezuelans voluntarily resettle in places where they have greater economic opportunity.[42] Mexico and Canada are increasing the number of people that they welcome on a humanitarian basis.[43]

Expanding cooperation with Ecuador can help achieve migration goals within Ecuador, regionally, and around the globe.[44] Ecuador is committed to diminishing the flow of irregular migrants from Ecuador northward by imposing additional visa requirements for certain nationalities,[45] providing life-saving assistance to Venezuelan and Colombian refugees and migrants within its borders, and strengthening its border security and controls.[46] Ecuador, along with Costa Rica, Belize, and Peru, is undertaking efforts to regularize migrants from Venezuela and Nicaragua.[47] Ecuador's program for Venezuelans in the country has provided an opportunity for stability and integration for more than 500,000 displaced Venezuelans.[48] Furthermore, establishing an FRP process for certain nationals of Ecuador furthers the USG's efforts to set up SMOs in Ecuador. As part of ongoing negotiations over the establishment of SMOs in Ecuador, the Government of Ecuador has repeatedly emphasized the critical importance of lawful pathways to the United States for nationals of Ecuador, including labor and family reunification pathways.[49] After months of negotiations, on October 19, the USG and the Government of Ecuador announced the establishment of SMOs in Ecuador to guide migrants and refugees towards lawful migration pathways.[50]

C. Lawful Alternative to Irregular Migration

In addition to existing lawful pathways, implementation of this FRP process will provide another lawful, safe, and orderly alternative to irregular migration in the near term. In Fiscal Year 2023 (FY23), CBP encounters with Ecuadorians totaled 117,487 as compared to 24,936 encounters in FY22, a 371% increase.[51] In FY21, CBP encountered a total of 97,074 Ecuadorian nationals, and in all of FY20, CBP encountered 12,892 Ecuadorian nationals.[52] Economic insecurity and high levels of poverty, food insecurity, and sexual and gender-based violence, coupled with the desire to reunite with family members already in the United States, are driving migrants from Ecuador to the United States.[53]

Some beneficiaries of approved family-based immigrant visa petitions may have to wait many years for an immigrant visa to become available.[54] While beneficiaries of this FRP process will still need to wait to apply to become an LPR, it will allow certain noncitizens to spend part of that waiting time with family in the United States. The process will create a lawful, safe, and orderly pathway to travel to the United States for certain nationals of Ecuador and their immediate family members, who have already followed established channels to begin seeking lawful status in the United States, whose immigrant visa petitions have been approved, and who are waiting for an immigrant visa to become available. The availability of this FRP process could discourage beneficiaries whose immigrant visas are not expected to become available soon from engaging in irregular migration by providing a hope and expectation that they will soon have access to a reasonably foreseeable, safe, and orderly alternative to irregular migration.

D. Reducing Strain on Limited U.S. Resources

Increases in irregular migration from Ecuador have strained DHS's reception and processing capacity at the SWB. From FY20 to FY23, encounters of Ecuadorians at the SWB totaled approximately 252,389.[55] By establishing a lawful pathway for some nationals of Ecuador and their immediate family members, on a case-by-case basis, to be paroled into the United States before an immigrant visa becomes immediately available to them, this FRP process is expected to reduce the number of irregular migrants encountered at the SWB. This would thereby provide a significant public benefit by reducing the strain on border reception and processing capacity, including by diverting the processing of noncitizens to interior POEs.

Paroling noncitizens through this process will be significantly less resource-intensive than processing individuals who irregularly migrate. Noncitizens who arrive through this FRP process will generally not require placement in DHS custody or removal proceedings, preserving space and resources for managing irregular migration.

Furthermore, by establishing a meaningful, near-term lawful pathway that certain noncitizens, if found to be eligible on a case-by-case basis, may choose to use in lieu of attempting to

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[42] *See id.*

[43] *See id.*

[44] U.S. Department of State, Integrated Country Strategies—Ecuador, Apr. 20, 2023, *https://www.state.gov/wp-content/uploads/2022/07/ICS_WHA_Ecuador_Public-1.pdf.*

[45] Ministry of Foreign Affairs of Ecuador, LISTA DE PAÍSES QUE DEBEN PRESENTAR VISA AL INGRESAR AL ECUADOR, *https://www.cancilleria.gob.ec/2020/06/30/lista-de-paises-que-deben-presentar-visa-al-ingresar-al-ecuador/* (last visited Sept. 21, 2023). Ecuador passed new legislation imposing additional visa requirements on nationals arriving from Chad, Guinea-Bissau, Kyrgyzstan, Mauritania, Sierra Leone, Sudan, and South Sudan. The new law went into effect on August 3, 2023, and since then, all new travelers from the seven countries must have visas prior to arrival in Ecuador. These additional nationalities follow Ecuador's late 2022 decision to add visa requirements for nationals arriving from Albania, Tajikistan, and Uzbekistan.

[46] *Id.*

[47] *See supra* note 41.

[48] The White House, Readout of Los Angeles Declaration Implementation Launch, Sept. 27, 2023, *https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/27/readout-of-los-angeles-declaration-implementation-launch/.*

[49] *See, e.g.,* The Department of State, Quito PRM Regional Refugee Coordinator Report, 23 QUITO 648, July 21, 2023. Gustavo Manrique: ''Dialogamos con EE.UU. para que los migrantes puedan tener una reunificación familiar'' (Gustavo Manrique: ''We are in dialogue with the U.S. so that migrants can have family reunification''), July 10, 2023, *https://www.ecuavisa.com/noticias/politica/gustavo-manrique-dialogamos-con-ee-uu-para-que-los-migrantes-puedan-tener-una-reunificacion-familiar-YK5509735.*

[50] The Department of State, Announcement of Safe Mobility Office in Ecuador, Oct. 19, 2023, *https://www.state.gov/announcement-of-safe-mobility-office-in-ecuador/.*

[51] CBP, Nationwide Encounters, *https://www.cbp.gov/newsroom/stats/nationwide-encounters* (last visited Nov. 2, 2023).

[52] *Id.*

[53] Genevieve Glatsky and José María León Cabrera, *Security is the Main Worry as Ecuador Votes on Sunday. Here's What to Know,* New York Times, Aug. 20, 2023, *https://www.nytimes.com/2023/08/20/world/americas/ecuador-election-assassination-explainer.html;* Genevieve Glatsky and José María León Cabrera, *How Narco Traffickers Unleashed Violence and Chaos in Ecuador,* New York Times, Aug 17, 2023, *https://www.nytimes.com/2023/08/17/world/americas/ecuador-drug-trafficking-election.html?searchResultPosition=16;* Gonzalo Solano and Michael Weissenstein, *More Ecuadorians move to US, spared many others' hurdles,* Associated Press, Apr. 2, 2023, *https://apnews.com/article/ecuador-migrants-migration-us-immigration-policy-86a8009efa8d357e7cb4dc0cff40fb52;* Vincent Ricci, *More Ecuadorians leaving for US amid 'burst in migration,'* Aljazeera, Sep. 23, 2021, *https://www.aljazeera.com/news/2021/9/23/more-ecuadorians-leaving-for-us-amid-burst-in-migration;* Adriana Pérez and Alfredo Corchado, *A heartbreaking exodus: More people from Ecuador feel forced to migrate to the U.S.,* The Dallas Morning News, Aug. 13, 2021, *https://www.dallasnews.com/news/immigration/2021/08/13/a-heartbreaking-exodus-more-people-from-ecuador-feel-forced-to-migrate-to-the-us/.*

[54] *See* William Kandel, Congressional Research Service, *U.S. Family-Based Immigration Policy* (Feb. 9, 2018), *https://crsreports.congress.gov/product/pdf/R/R43145;* DOS, Visa Bulletin for October 2023, Number 82, Volume X (Oct. 2023), *https://travel.state.gov/content/travel/en/legal/visa-law0/visa-bulletin/2024/visa-bulletin-for-october-2023.html.*

[55] CBP, Nationwide Encounters, *https://www.cbp.gov/newsroom/stats/nationwide-encounters* (last visited Nov. 2, 2023).

enter the United States irregularly, the process could redirect such intending migrants away from irregular migratory routes that funnel money into TCOs. TCOs engaged in human smuggling along the route from the Northern Central America region to the United States earn hundreds of millions to billions of dollars each year from smuggling activities associated with irregular migration.[56] TCOs exploit irregular migration for financial gain, either by charging migrants to cross the border, forcing migrants to carry contraband as they cross, or forcing and coercing migrants into a sex or labor trafficking situation.[57] This money can then be used to fund additional human smuggling, drug trafficking, and human trafficking, to buy weapons, or to engage in other illicit activities in the region, all of which are competing priorities for limited U.S. border resources to confront and manage.[58] This FRP process is expected to reduce the number of irregular migrants who may be exploited by TCOs engaged in human smuggling, serving a significant public benefit.

DHS anticipates that this process will help minimize the burden on communities, state and local governments, and non-governmental organizations along the SWB. Beneficiaries will be required to fly at their own expense to an interior POE, rather than arriving at the SWB and transiting through border communities. Beneficiaries will only be authorized to come to the United States if they have a U.S.-based supporter who has agreed to receive them and provide basic needs, including housing support. Beneficiaries will also be immediately eligible to apply for employment authorization, enabling them to support themselves.

E. Addressing Root Causes of Migration Through Remittances

The case-by-case parole into the United States of noncitizens under this FRP process will also serve a significant public benefit by aiding U.S. efforts to address economic insecurity in Ecuador, which is a key factor that drives out-migration.[59] Unlike many noncitizens who irregularly migrate, noncitizens who are paroled into the United States through this process will be immediately eligible to apply for employment authorization that, if granted, they may maintain throughout the duration of their parole period, allowing them to support themselves and to contribute to the U.S. economy through the labor they provide, taxes they pay, and consumption of goods or payment of rent and utilities in their new U.S. communities.[60] Noncitizens with employment authorization also typically enjoy higher wages than those without employment authorization, providing them with the resources to send additional money to their home country as remittances.[61]

Additional remittances sent back to Ecuador, together with other efforts to improve the investment climate and infrastructure in the country and address security concerns, may promote economic development and address some of the root causes of migration.[62] In total, remittances sent to Ecuador amounted to $603.97 million in 2021, a significant contribution to development in communities in Ecuador.[63] Remittances provide a crucial financial lifeline that enhances economic development and promotes economic stability for many individuals, families, and communities in Ecuador, impacting individual decisions on whether to leave the country. In the absence of timely alternative options for lawful pathways, such as parole under this process, and the additional remittances that are anticipated to result from implementation of this process, noncitizens are more likely to turn to irregular migration in the short-term.

V. Eligibility

A. Petitioners

Invitations to participate in this process will be issued to certain petitioners who have an approved Form I–130 filed on behalf of an Ecuadorian principal beneficiary. Invitations will be issued based on operational capacity, the expected period of time until the principal beneficiary's immigrant visa becomes available, and in a manner calibrated to best achieve the policy aims of this process as described in this Notice. Petitioners who have an approved [64] Form I–130 filed on behalf of an Ecuadorian principal beneficiary outside the United States should ensure that their mailing address and other contact information are up to date with State's National Visa Center (NVC), as this is the information that will be used to issue invitations. The invitations will provide information about how the petitioner may file a request with USCIS that initiates this FRP process on behalf

[56] Homeland Security Operational Analysis Center, *Human Smuggling and Associated Revenues: What Do or Can We Know About Routes from Central America to the United States* (2019), *https://www.rand.org/content/dam/rand/pubs/research_reports/RR2800/RR2852/RAND_RR2852.pdf; see also* DHS, *Fact Sheet: Counter Human Smuggler Campaign Update* (Oct. 6, 2022), *https://www.dhs.gov/news/2022/10/06/fact-sheet-counter-human-smuggler-campaign-update-dhs-led-effort-makes-5000th.*

[57] DHS's Efforts to Disrupt Transnational Criminal Organizations in Central America: Hearing before the Subcommittee on Oversight, Management, and Accountability of the Committee of Homeland Security of the House of Representatives, 117th Cong. (2021).

[58] *Id.*

[59] U.S. Department of State, Integrated Country Strategies—Ecuador, Apr. 20, 2023, *https://www.state.gov/wp-content/uploads/2022/07/ICS_WHA_Ecuador_Public-1.pdf;* Gonzalo Solano and Michael Weissenstein, *More Ecuadorians move to US, spared many others' hurdles,* Associated Press, Apr. 2, 2023, *https://apnews.com/article/ecuador-migrants-migration-us-immigration-policy-86a8009efa8d357e7cb4dc0cff40fb52;* Vincent Ricci, *More Ecuadorians leaving for US amid 'burst in migration,'* Aljazeera, Sept. 23, 2021, *https://www.aljazeera.com/news/2021/9/23/more-ecuadorians-leaving-for-us-amid-burst-in-migration;* Adriana Pérez and Alfredo Corchado, *A heartbreaking exodus: More people from Ecuador feel forced to migrate to the U.S.,* The Dallas Morning News, Aug. 13, 2021, *https://www.dallasnews.com/news/immigration/2021/08/13/a-heartbreaking-exodus-more-people-from-ecuador-feel-forced-to-migrate-to-the-us/.*

[60] *See generally, e.g.,* National Academies of Sciences, Engineering, and Medicine, ''The Economic and Fiscal Consequences of Immigration'' (2017), *https://nap.nationalacademies.org/catalog/23550/the-economic-and-fiscal-consequences-of-immigration;* Chair Cecilia Rouse, Lisa Barrow, Kevin Rinz, and Evan Soltas, The White House Blog: The Economic Benefits of Extending Permanent Legal Status to Unauthorized Immigrants (Sept. 17, 2021), *https://www.whitehouse.gov/cea/blog/2021/09/17/the-economic-benefits-of-extending-permanent-legal-status-to-unauthorized-immigrants/.*

[61] George J. Borjas, ''The Earnings of Undocumented Immigrants,'' National Bureau of Economic Research (Mar. 2017), *https://www.nber.org/papers/w23236* (providing that noncitizens without authorization to work earn less than those with employment authorization).

[62] Pew Research Center, *Remittances from Abroad are major economic assets for some developing countries* (Jan. 29, 2018), *https://www.pewresearch.org/fact-tank/2018/01/29/remittances-from-abroad-are-major-economic-assets-for-some-developing-countries/; see also* NSC, *U.S. Strategy for Addressing the Root Causes of Migration in Central America* (July 2021) *https://www.whitehouse.gov/wp-content/uploads/2021/07/Root-Causes-Strategy.pdf;* Atlas of Sustainable Development Goals, *Remittances: a lifeline for many economies,* The World Bank (2020) *https://datatopics.worldbank.org/sdgatlas/goal-17-partnerships-for-the-goals/.*

[63] Statista, Personal remittances paid in Ecuador from 1999 to 2021, *https://www.statista.com/statistics/1390805/personal-remittances-paid-ecuador/#:~:text=The%20personal%20remittances%20paid%20in,have%20been%20subject%20to%20fluctuation* (last visited July 6, 2023). *See also* The World Bank, Data, GDP (current US$)—Ecuador, *https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?end=2021&locations=EC&start=2019* (last visited July 31, 2023), which indicates that the 2021 GDP for Ecuador was 106.17 billion US dollars.

[64] In certain circumstances, such as if the beneficiary is no longer eligible for the Form I–130 (*e.g.,* the petitioner is no longer an LPR or U.S.C.), parole would be denied, and the Form I–130 approval would be revoked. If DHS revokes Form I–130 approval, the beneficiary will no longer be eligible for an immigrant visa. DHS will make these determinations on a case-by-case basis and will provide a written notice.

of an Ecuadorian principal beneficiary of an approved Form I–130, and separate requests for any immediate family members of the principal beneficiary. As part of the request process, the petitioner will be required to provide evidence of their income and assets and commit to provide financial support to the beneficiary named in the request for the length of their parole by submitting Form I–134A online. Petitioners will also be required to provide evidence to verify the family relationships between the principal beneficiary of the Form I–130 and all immediate family members of the principal beneficiary for whom the petitioner will be filing a request under this process. As part of the review process, the petitioner must pass security and background vetting, including for public safety, national security, human trafficking, and exploitation concerns.

B. Beneficiaries

A beneficiary is a national of Ecuador (or their immediate family member of any nationality) who is outside the United States and who may be considered for a discretionary grant of parole under this FRP process. To be considered for a discretionary issuance of advance authorization to travel to the United States to seek a discretionary grant of parole at the POE under this process, a beneficiary must:

- Be outside the United States;
- Be the principal beneficiary (or a derivative beneficiary spouse or child) [65] of an approved Form I–130, Petition for Alien Relative;
- Be a national of Ecuador or be a non-Ecuadorian derivative beneficiary spouse or child [66] of an Ecuadorian principal beneficiary;
- Have a petitioning relative in the United States who received an invitation to initiate this FRP process on the beneficiary's behalf by filing a Form I–134A;
- Have a U.S.-based petitioning relative who filed a Form I–134A on the beneficiary's behalf that USCIS has vetted and confirmed;
- Have not yet been issued an immigrant visa at the time the invitation is issued to the petitioning relative; and
- Have an unexpired passport valid for international travel, or possess alternative acceptable documentation as described in the invitation letter issued to the petitioning relative.

In addition, each beneficiary must undergo and pass national security and public safety vetting and must demonstrate that they otherwise merit a favorable exercise of discretion by DHS. This includes vetting by CBP prior to issuance of advance authorization to travel to an interior POE to seek parole, as well as additional vetting and collection of additional biometrics at the POE by CBP upon inspection, as described in the section of this Notice that details the processing steps for this FRP process. CBP will consider a beneficiary's previous immigration history, encounters with USG entities, and the results of screening and vetting when determining eligibility to be issued advance authorization to travel to the United States, as well as when determining, on a case-by-case basis, whether to grant parole to the beneficiary at the POE. When making these discretionary approvals of advance authorization to travel and parole determinations, DHS will consider a beneficiary to be ineligible for this process if the beneficiary has:

- Crossed irregularly into the United States, between POEs, after November 16, 2023, except DHS will not consider a beneficiary to be ineligible based on a single instance of voluntary departure pursuant to section 240B of the INA, 8 U.S.C. 1229c, or withdrawal of their application for admission pursuant to section 235(a)(4) of the INA, 8 U.S.C. 1225(a)(4);
- Been interdicted at sea [67] after November 16, 2023; or
- Been ordered removed from the United States within the prior five years or is subject to a bar to admissibility based on a prior removal order.[68]

DHS also will consider other factors in making discretionary determinations consistent with long-standing policy and practice.

Each beneficiary must demonstrate that a grant of parole is warranted based on urgent humanitarian reasons or significant public benefit, and that the beneficiary merits a favorable exercise of discretion in order for CBP to grant parole upon arrival at the POE. Each beneficiary must also comply with all additional requirements, including vaccination requirements and other public health guidelines.

Participation in this process is not limited to those beneficiaries currently living in Ecuador. However, as noted above, beneficiaries must be outside the United States to participate in the process. In order to use the advance authorization to travel to the United States, the beneficiary must have sufficient documentation (*e.g.,* international passport) to travel on a commercial airline. Beneficiaries under the age of 18 to whom CBP issues advance authorization to travel under this process may be subject to additional screening and/or travel parameters in coordination with U.S. authorities to ensure appropriate travel arrangements and coordination with their parent(s) or legal guardian(s). This FRP process does not affect CBP's legal obligations regarding the identification and processing of unaccompanied children.[69]

A potential beneficiary of this process who enters the United States between POEs after November 16, 2023, rather than being considered for parole under this process, will be ineligible for this process, except as indicated above, and will be processed under Title 8 of the U.S. Code and face appropriate consequences. For example, they may be subject to potential criminal prosecution,[70] expedited removal proceedings,[71] or removal proceedings under section 240 of the INA, 8 U.S.C. 1229a. In addition, potential beneficiaries who enter the United States between POEs may become ineligible for adjustment of status [72] or for an immigrant visa [73] as a result of

[65] *See* INA sec. 203(d), 8 U.S.C. 1153(d); *see also* INA sec. 101(b)(1), 8 U.S.C. 1101(b)(1) (defining ''child,'' in general, as meaning ''an unmarried person under twenty-one years of age''). If a principal beneficiary married or had a child after USCIS approved the underlying Form I–130, that spouse or unmarried child under 21 may in some circumstances become a derivative beneficiary and may be eligible for parole based on their relationship to the principal beneficiary. Such ''add-on derivatives'' are included within the term ''derivative'' in this notice.

[66] Certain non-Ecuadorians may use this process if they are a derivative beneficiary of an Ecuadorian principal beneficiary and traveling with that Ecuadorian beneficiary.

[67] For purposes of this notice, ''interdicted at sea'' refers to migrants directly interdicted by the U.S. Coast Guard from vessels subject to U.S. jurisdiction or vessels without nationality, or migrants transferred to the U.S. Coast Guard.

[68] *See, e.g.,* INA sec. 212(a)(9)(A), 8 U.S.C. 1182(a)(9)(A).

[69] *See* 6 U.S.C. 279(g)(2) (defining ''unaccompanied alien child'').

[70] INA secs. 275 and 276, 8 U.S.C. 1325 and 1326 (for illegal entry and reentry, respectively).

[71] INA sec. 235(b)(1)(A)(i), 8 U.S.C. 1225(b)(1)(A)(i).

[72] INA sec. 245(a), 8 U.S.C. 1255(a) (requiring adjustment of status applicants to be inspected and admitted or inspected and paroled, as well as be admissible); INA sec. 245(c)(2), 8 U.S.C. 1255(c)(2) (adjustment of status applicants are ineligible if they are in unlawful immigration status on the date of filing the application for adjustment of status or fail to maintain continuously a lawful status since entry into the United States); INA sec. 212(a), 8 U.S.C. 1182(a) (grounds of inadmissibility that, absent the granting of an available waiver, render applicants for adjustment of status ineligible).

[73] INA sec. 221(g), 8 U.S.C. 1201(g) (immigrant visa applicants are ineligible for immigrant visas if inadmissible under INA sec. 212(a), 8 U.S.C. 1182(a)); INA sec. 212(a), 8 U.S.C. 1182(a) (grounds of inadmissibility that render applicants for immigrant visas ineligible).

entering without inspection and not having been admitted or paroled.[74]

C. Processing Steps

This FRP process will be implemented in light of lessons learned from the original CFRP and HFRP programs and will build on technological advancements and efficiencies developed since the inception of CFRP and HFRP. All steps of the process, except certain medical requirements, and the ultimate parole determination made in person, on a case-by-case basis, by CBP at the POE, will generally be completed online, including individualized, case-by-case identity and eligibility determinations and robust security vetting.

Step 1: Invitation Sent to Petitioner

An invitation may be sent to a petitioner who has filed an approved Form I–130 on behalf of the potential principal and derivative beneficiaries. The decision whether to send the invitation is based on multiple discretionary factors. Such factors may include operational capacity considerations, the expected period of time until the beneficiary's immigrant visa becomes available, as well as other measures calibrated to best achieve the policy aims of this process as described in this Notice. Only after receiving an invitation may the petitioner be permitted to file a request and initiate consideration under this FRP process. The invitation will instruct the petitioner on next steps to initiate this process on behalf of the beneficiaries, including instructions on documentation to include in their Form I–134A. Each invitation will include an identifying number that the petitioner must include in the Form I–134A for each beneficiary on whose behalf they wish to request to be a supporter and to initiate consideration for advance authorization to travel to the United States to seek parole at an interior POE.

Step 2: Petitioner Files Form I–134a Online To Initiate This Process

After receiving an invitation, the U.S.C. or LPR petitioner who filed the approved Form I–130 on behalf of the beneficiaries may submit a Form I–134A for each beneficiary with USCIS through the USCIS online system to initiate this process. The Form I–134A identifies and collects information on both the petitioner and the beneficiary. The petitioner must submit a separate Form I–134A for each beneficiary, including derivatives of the principal beneficiary. The petitioner must submit evidence establishing their income and assets and commit to provide financial support to the beneficiary for the duration of parole. The petitioner must also submit evidence establishing the family relationships between the principal beneficiary and all derivative beneficiaries. USCIS will perform background checks on the petitioner and verify their financial information to ensure that the petitioner is able to financially support the beneficiary. If the petitioner's Form I–134A is confirmed, then the request proceeds to the next step.

Step 3: Beneficiary Electronically Provides Information To Support the Request

If a petitioner's Form I–134A is confirmed by USCIS, then the beneficiary named on the Form I–134A will receive an email from USCIS with instructions to create a USCIS online account and next steps for completing the request. The beneficiary will be required to confirm their biographic information in their online account and attest to meeting eligibility requirements.

As part of confirming eligibility in their USCIS online account, a beneficiary who seeks advance authorization to travel to the United States will need to confirm that they meet public health requirements, including certain vaccination requirements.

Step 4: Beneficiary Submits Request in CBP One Mobile Application

After confirming biographic information in their USCIS online account and completing required eligibility attestations, the beneficiary will receive instructions through USCIS for accessing the CBP One mobile application. The beneficiary must enter certain biographic and biometric information—including a ''live'' facial photograph—into CBP One.

Step 5: Approval To Travel to the United States

A beneficiary who establishes eligibility for this process, passes all the requisite vetting, and demonstrates that they otherwise warrant a favorable exercise of discretion, may receive an electronic advance authorization to travel from CBP, facilitating their ability to travel to the United States to seek a discretionary grant of parole, on a case-by-case basis, at an interior POE. The beneficiary will receive a notice in their USCIS online account confirming whether CBP has, in CBP's discretion, provided the beneficiary with advance authorization to travel to the United States. If approved, the beneficiary is responsible for securing their own travel via commercial air to an interior POE.[75] Approval of advance authorization to travel does not guarantee a beneficiary will be paroled into the United States upon inspection at the POE. Whether to parole the beneficiary is a discretionary, case-by-case determination made by CBP at the time the beneficiary arrives at the interior POE.

Step 6: Beneficiary Seeks Parole at the POE

CBP will inspect each beneficiary arriving at an interior POE under this process and consider each individual, on a case-by-case basis, for a grant of discretionary parole for a period of up to three years.

Upon arrival at the interior POE, the beneficiary will be required to submit additional biometrics to DHS, including another photograph and fingerprints. This biometric information will support additional vetting against available databases to inform an independent determination by CBP officers as to whether parole is warranted on a case-by-case basis and whether the beneficiary merits a favorable exercise of discretion.

A beneficiary who is determined to pose a national security or public safety threat will generally be denied parole under this process and will be processed consistent with established policy and procedure. A beneficiary who otherwise does not warrant parole pursuant to section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A), and as a matter of discretion upon inspection, will be processed under an appropriate

[74] For example, an applicant for adjustment of status who previously accrued more than one year of unlawful presence, departed, and thereafter reentered the United States without admission or parole is inadmissible and ineligible for adjustment unless they apply for and obtain consent to reapply for admission from outside the United States after waiting ten years after their last departure from the United States. *See* INA sec. 212(a)(9)(C)(i)(I), 8 U.S.C. 1182(a)(9)(C)(i)(I). In addition, an applicant for an immigrant visa who accrued more than 180 days of unlawful presence in the United States, departed (or is removed, as applicable), and again seeks admission (by filing an immigrant visa application) within 3 or 10 years of departure (or removal) is inadmissible and ineligible for an immigrant visa unless they apply for and obtain a waiver of inadmissibility. *See* INA sec. 212(a)(9)(B), 8 U.S.C. 1182(a)(9)(B). Additionally, an applicant for an immigrant visa who was ordered removed, departed, and again seeks admission within certain periods of time thereafter is inadmissible and therefore ineligible for an immigrant visa unless they apply for and obtain consent to reapply for admission. *See* INA sec. 212(a)(9)(A), 8 U.S.C. 1182(a)(9)(A).

[75] Air carriers can validate an approved and valid travel authorization submission using the same mechanisms that are currently in place to validate that a traveler has a valid visa or other documentation to facilitate issuance of a boarding pass for air travel.

disposition and may be referred to U.S. Immigration and Customs Enforcement (ICE) for detention.

Step 7: Parole

If granted parole at the POE, on a case-by-case basis in the exercise of discretion for urgent humanitarian reasons or significant public benefit, parole will generally be granted for a period of up to three years, subject to satisfying applicable health and vetting requirements, and the parolee will be eligible to apply for employment authorization for the duration of the parole period.[76]

All of the steps in this process, including the decision to confirm or non-confirm the Form I–134A, as well as the decision whether to issue advance authorization to travel and the parole decision at the interior POE, are entirely discretionary and not subject to appeal on any grounds. Parole may be terminated upon notice at DHS discretion, and the noncitizen may be placed into removal proceedings and/or detained if, for example, the parolee fails to maintain the conditions of parole or other derogatory information emerges during the parole period.

D. Termination and No Private Rights

As section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A), provides, parole decisions are made by the Secretary ''in his discretion.'' This process is being implemented as a matter of the Secretary's discretion, and the Secretary retains the sole discretion to terminate this FRP process at any point. It is not intended to, shall not be construed to, may not be relied upon to, and does not create any rights, privileges, benefits, substantive or procedural, enforceable by any party in any matter, civil or criminal, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

VI. Considerations in the Establishment of This FRP Process

DHS has considered the potential impact of this FRP process on individuals applying for benefits under other immigration programs or processes, given that USCIS and CBP may reassign employees and reallocate resources to administer this process. This reassignment or reallocation could potentially impact processing times for USCIS- or CBP-administered immigration programs and processes or forms such as parole-related employment authorization applications. Beneficiaries who are paroled into the United States under this FRP process may have to wait before being authorized to work in the United States, depending on the amount of time it takes USCIS to process beneficiaries' requests for employment authorization.[77] However, the impact of that waiting period is to some extent mitigated by the requirements of this process. Beneficiaries may not be paroled under this process unless their Form I–130 petitioner has filed on their behalf to initiate the FRP process, requesting to be a supporter and declaring their ability to financially support the beneficiary. As noted above, the petitioner must provide evidence to demonstrate their ability to support the beneficiary or must include similar evidence establishing that with the help of a co-supporter, they have the financial means to support the beneficiary.

Although personnel and resources may be diverted from other similar processes and programs or for the adjudication of forms such as parole-related employment authorization applications, participation in this process is by invitation only. DHS can adjust the number of invitations issued to alleviate pressure as resource limitations require. Therefore, for the processing of employment authorization applications, for example, the adjudication burden on USCIS can be controlled and limited as needed under this FRP process. As detailed above, each beneficiary of this process who is diverted away from irregular migration will also reduce the strain on border reception and processing capacity. Therefore, these costs are not significant enough to outweigh the benefits of the process.

DHS also considered the alternative approach of not establishing this process. As stated throughout this Notice, this process will provide many benefits and has few drawbacks. DHS has made an effort to identify and consider any reliance interests of the parties affected by establishment of this process. As explained in detail above, DHS has determined that there are significant public benefits of the case-by-case parole of noncitizens under this process. DHS also recognizes there are costs that may be incurred, such as for schools and social services (such as health care) in the period between their parole into the United States and the time when a beneficiary's immigrant visa already would have become available (at which point they soon thereafter would, in general, have been admitted as immigrants). Ultimately, DHS has determined that the significant public benefits of the case-by-case parole of noncitizens under this FRP process to the United States, and to other affected parties, including the reduction in irregular migration expected to be accomplished in connection with this process, justify the costs that may be incurred, while noting that this FRP process will not increase the total number of individuals eligible to enter the United States, as the potential beneficiaries already have a pathway to lawful permanent residence.[78]

Alternatively, as discussed below, a decision to forego establishing this process would adversely affect the United States' ability to negotiate for and request additional enforcement measures and increased cooperation from foreign partners with respect to removals and ensure continued collaboration on migration management. In addition, certain nationals of Ecuador still waiting for their immigrant visas to become available would remain separated from their family members for an extended period of time and could resort to irregular migration without this process. For any such Ecuadorian nationals, the USG would need to commit resources to respond to their arrival, processing, and removal pursuant to the INA. Those who manage to cross the border without being encountered by CBP would join the population of noncitizens living in the United States without authorization, unable to legally seek employment. The states in which they settle may be less likely to benefit from additional tax revenues and other positive economic contributions these noncitizens would have provided if they had a lawful pathway like this FRP process through which they may apply for employment authorization while they wait to apply to adjust to LPR status.

VII. Regulatory Requirements

A. Administrative Procedure Act

This process is exempt from notice-and-comment rulemaking and delayed effective date requirements on multiple grounds and is therefore amenable to immediate issuance and implementation.

[76] 8 CFR 274a.12(c)(11).

[77] USCIS, Check Case Processing Times, *https://egov.uscis.gov/processing-times/* (last visited Oct. 25, 2023). This website provides the approximate processing time a parolee can expect when filing Form I–765, Application for Employment Authorization.

[78] *See, e.g.,* National Academies of Sciences, Engineering, and Medicine, ''The Economic and Fiscal Consequences of Immigration'' (2017), *https://nap.nationalacademies.org/catalog/23550/the-economic-and-fiscal-consequences-of-immigration.*

First, DHS is merely adopting a general statement of policy,[79] *i.e.,* a ''statement issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.'' [80] As section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A), provides, parole decisions are made by the Secretary ''in his discretion.'' This policy creates a process for making discretionary, case-by-case parole decisions.

Second, even if this process were considered to be a legislative rule that would normally be subject to requirements for notice-and-comment rulemaking and a delayed effective date, the process would be exempt from such requirements because it involves a foreign affairs function of the United States.[81] Courts have held that this exemption applies when the rule in question ''is clearly and directly involved in a foreign affairs function.'' [82] In addition, although the text of the Administrative Procedure Act does not require an agency invoking this exemption to show that such procedures may result in ''definitely undesirable international consequences,'' some courts have required such a showing.[83]

This process satisfies both standards. Specifically, as discussed in the section above entitled, *Furthering Important Foreign Policy Objectives,* this FRP process is one part of the United States' ongoing efforts to engage hemispheric partners to increase their efforts to collaboratively manage irregular migration. As discussed in that section, and as further explained below, the expansion of lawful pathways for noncitizens to enter the United States is necessary to ensure our partners' continued collaboration on migration issues, including the ability of the United States to meet other immigration-management priorities such as the timely establishment of SMOs, which facilitate access to lawful pathways to the United States and other countries, family reunification, and access to temporary work visas.[84] Since the April 27, 2023 announcement,[85] the United States has engaged in ongoing negotiations to implement the announced initiatives in close coordination with regional partners including establishing SMOs in Colombia, Guatemala, and Costa Rica as part of its strategy to manage migration collaboratively in the Western Hemisphere.

As with the four recently implemented FRP processes and the modernization of the CFRP and HFRP processes, delaying issuance and implementation of this process to undertake rulemaking would complicate broader discussions and ongoing negotiations with key foreign partners about migration management. Ongoing negotiations with regional partners involve the implementation of a range of new measures, including establishing SMOs in key locations throughout the Western Hemisphere to manage and reduce irregular migration and improve qualified noncitizens' access to accelerated refugee processing, family reunification, and labor pathways in the United States. As a key part of these negotiations, the United States and its partners are providing meaningful alternatives to irregular migration, including through lawful pathways to the United States, Canada, and Spain, as well as integration in host countries closer to home. The success of SMOs and other new measures to reduce irregular migration to the SWB is therefore connected to the United States expanding access to lawful pathways, including FRP processes that will benefit nationals in countries identified to host SMOs.

Ecuador is committed to diminishing the flow of irregular migrants from Ecuador northward by imposing additional visa requirements for certain nationalities. To that end, Ecuador unilaterally has taken two very critical actions to prevent certain nationalities from abusing Ecuador's visa regime to irregularly travel to the Western Hemisphere. Ecuador passed new legislation imposing additional visa requirements on nationals arriving from Chad, Guinea-Bissau, Kyrgyzstan, Mauritania, Sierra Leone, Sudan, and South Sudan.[86] The new law went into effect on August 3, 2023, and since then, all new travelers from the seven countries must have visas prior to arrival in Ecuador. These additional nationalities follow Ecuador's late 2022 decision to add visa requirements for nationals arriving from Albania, Tajikistan, and Uzbekistan.[87] While Ecuador is taking this action unilaterally, representatives of the Government of Ecuador have emphasized the critical importance of availability of lawful pathways for Ecuadorian nationals, including labor pathways and processes for nationals of Ecuador to reunify with their family members in the United States.[88] Similarly, Foreign Minister Gustavo Manrique shared with local press that Ecuador is negotiating with the United States on hosting SMOs and noted their position on family reunification and labor pathways for Ecuadorians.[89] After months of negotiations, on October 19, the USG and the Government of Ecuador announced the establishment of SMOs in Ecuador.[90] In DHS's judgment, the delay associated with a public rulemaking process involving notice and comment and a delayed effective date would negatively impact ongoing efforts to operationalize SMOs in Ecuador to channel migrants to lawful pathways.

Such a delay would also be inconsistent with the dispatch with which DHS has appropriately implemented other FRP processes. Such processes support a series of efforts that the United States has been pursuing in the hemisphere to increase the availability of lawful pathways for migration and involve additional countries with destination pathways and as host countries for certain processing initiatives. The ability to implement such processes rapidly is critical for supporting the Administration's overall goals as part of these efforts, which include multi-faceted negotiations with a range of regional partners.

For instance, on May 2, 2023, the United States and Mexico jointly announced a number of measures to address the humanitarian situation caused by unprecedented migration flows in the hemisphere by creating incentives for migrants to use lawful pathways, while announcing that

[79] 5 U.S.C. 553(b)(A).

[80] *See Lincoln* v. *Vigil,* 508 U.S. 182, 197 (1993) (quoting *Chrysler Corp.* v. *Brown,* 441 U.S. 281,302 n.31 (1979)).

[81] 5 U.S.C. 553(a)(1).

[82] *See, e.g., Mast Indus.* v. *Regan,* 596 F. Supp. 1567, 1582 (C.I.T. 1984) (cleaned up).

[83] *See, e.g., Rajah* v. *Mukasey,* 544 F.3d 427, 437 (2d Cir. 2008).

[84] *See* DHS, Fact Sheet: U.S. Government Announces Sweeping New Actions to Manage Regional Migration, Apr. 27, 2023, *https://www.dhs.gov/news/2023/04/27/fact-sheet-us-government-announces-sweeping-new-actions-manage-regional-migration.*

[85] *Id.*

[86] Ministry of Foreign Affairs of Ecuador, LISTA DE PAÍSES QUE DEBEN PRESENTAR VISA AL INGRESAR AL ECUADOR, *https://www.cancilleria.gob.ec/2020/06/30/lista-de-paises-que-deben-presentar-visa-al-ingresar-al-ecuador/* (last visited Sept. 21, 2023).

[87] *Id.*

[88] The Department of State, Quito PRM Regional Refugee Coordinator Report, 23 QUITO 648, July 21, 2023.

[89] Gustavo Manrique: ''Dialogamos con EE.UU. para que los migrantes puedan tener una reunificación familiar'' (Gustavo Manrique: ''We are in dialogue with the US so that migrants can have family reunification''), July 10, 2023, *https://www.ecuavisa.com/noticias/politica/gustavo-manrique-dialogamos-con-ee-uu-para-que-los-migrantes-puedan-tener-una-reunificacion-familiar-YK5509735.*

[90] The Department of State, Announcement of Safe Mobility Office in Ecuador, Oct. 19, 2023, *https://www.state.gov/announcement-of-safe-mobility-office-in-ecuador/.*

consequences for unlawful entry would continue once the Title 42 public health Order was lifted. The announcements emphasized the importance of strengthening and expanding access to lawful pathways, which will continue to remain a central topic of bilateral relations.[91] Specifically, the United States stated its intention to welcome as many as 100,000 noncitizens from El Salvador, Guatemala, and Honduras under the FRP processes, while the Government of Mexico recognized the value in SMOs and is considering how it can contribute to their success.[92] Mexico concurrently agreed to continue to implement the joint initiative whereby the United States provides a lawful pathway through parole for nationals of Cuba, Haiti, Nicaragua, and Venezuela, while Mexico would accept the return of certain third-country migrants on humanitarian grounds beyond the lifting of the Title 42 public health Order on May 11, 2023.[93]

Similarly, on July 28, 2023, building on a series of successful lawful pathway initiatives the United States and the Government of Mexico agreed to launch last year,[94] the United States announced additional steps to expand access to safe, orderly, and lawful pathways for migration.[95] On July 28, the United States noted its full support to the Government of Mexico of efforts to establish international multipurpose space in Mexico to offer protection and labor pathways, including accepting refugee resettlement referrals to the U.S. Refugee Admissions Program from qualified noncitizens from Cuba, Haiti, Nicaragua, and Venezuela.[96] The United States and the Government of Mexico are working to implement this new commitment to expand access to lawful pathways. As stated in the **Federal Register** Notices implementing family reunification processes for certain nationals of Colombia,[97] El Salvador,[98] Guatemala,[99] and Honduras,[100] a delay in implementation of the U.S. commitment on family reunification pathways risks undermining Mexico's commitments, which are critical to the U.S. foreign policy approach to migration management in the Western Hemisphere.

Additionally, after a series of negotiations, on June 1, 2023, the United States and Guatemala issued a joint statement to commit to take a series of critical steps to humanely reduce irregular migration and expand lawful pathways under the L.A. Declaration.[101] As the first step of a comprehensive program to manage irregular migration, both countries are implementing a six-month pilot phase of SMOs.[102] These offices began accepting appointments on the website movilidadsegura.org on June 12, 2023.[103] In the same announcement, the United States and Guatemala stated that they will also deepen cooperation on border security and will continue to address the root causes of irregular migration.[104]

In addition, on June 4, 2023, the United States and Colombia announced the impending establishment of SMOs that would identify, register, and categorize the reasons for irregular migration and channel those who qualify through lawful pathways from Colombia to the United States.[105] The Safe Mobility initiative launched in Colombia on June 28, 2023, with SMOs currently operational in three cities throughout the country. SMOs in Colombia serve to facilitate access to lawful pathways to the United States and other countries, including expedited refugee processing and other humanitarian pathways.[106] The U.S. government also reaffirmed its commitment to expand lawful pathways for Colombians with temporary work visas and expanded family reunification.[107]

Furthermore, on June 12, 2023, the USG and the Government of Costa Rica, in furtherance of bilateral partnership and addressing hemispheric challenge of irregular migration, launched an exploratory six-month implementation of SMOs.[108] SMOs in Costa Rica serve to facilitate access to lawful pathways to the United States and other countries, including expedited refugee processing and other humanitarian pathways.[109] In addition to starting the SMOs initiative, the USG and the Government of Costa Rica reaffirmed their commitment to work with all countries across the region to promote integration of refugees and migrants, expand lawful pathways, and promote humane border management.[110]

Overall, delaying issuance and implementation of this process to undertake rulemaking would complicate ongoing negotiations with the Government of Ecuador, specifically, and overall U.S. efforts to manage migration together with foreign partners. Because this FRP process is an example of the United States' shared commitment to managing migration consistent with the L.A. Declaration and has been a key point in ongoing negotiations and partnerships, such a delay would risk undermining partner countries' multilateral and unilateral efforts, and in the case of Ecuador, putting at risk multiple efforts, including the United States' ability to continue SMO operations in Ecuador and Ecuador's willingness to unilaterally impose certain visa restrictions, which are critical to the U.S. foreign policy approach to migration management in the Western Hemisphere.

Furthermore, the delay associated with implementing this process through notice-and-comment rulemaking would

[91] *See* Mexico and United States Strengthen Joint Humanitarian Plan on Migration, May 2, 2023, *https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/02/mexico-and-united-states-strengthen-joint-humanitarian-plan-on-migration/.*

[92] *Id.*

[93] *Id.*

[94] *See* The White House, Remarks by President Biden and President López Obrador of Mexico Before Bilateral Meeting, July 12, 2022, *https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/07/12/remarks-by-president-biden-and-president-lopez-obrador-of-mexico-before-bilateral-meeting-2/.*

[95] *See* The White House, Statement from National Security Advisor Jake Sullivan on Legal Pathways Initiative with Mexico, July 28, 2023, *https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/28/statement-from-national-security-advisor-jake-sullivan-on-legal-pathways-initiative-with-mexico/.*

[96] *Id.*

[97] *See* Implementation of a Family Reunification Parole Process for Colombians, 88 FR 43591 (July 10, 2023).

[98] *See* Implementation of a Family Reunification Parole Process for Salvadorans, 88 FR 43611 (July 10, 2023).

[99] *See* Implementation of a Family Reunification Parole Process for Guatemalans, 88 FR 43581 (July 10, 2023).

[100] *See* Implementation of a Family Reunification Parole Process for Hondurans, 88 FR 43601 (July 10, 2023).

[101] *See* The White House, Joint Statement from the United States and Guatemala on Migration (June 1, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/01/joint-statement-from-the-united-states-and-guatemala-on-migration/.*

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] *See* United States Department of State, U.S.-Colombia Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 4, 2023), *https://www.state.gov/u-s-colombia-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/. See* The White House, Readout of Principal Deputy National Security Advisor Jon Finer's Meeting with Colombian Foreign Minister Alvaro Leyva (June 11, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/11/readout-of-principal-deputy-national-security-advisor-jon-finers-meeting-with-colombian-foreign-minister-alvaro-leyva/.*

[106] *Id.*

[107] *Id.*

[108] *See* United States Department of State, U.S.-Costa Rica Joint Commitment to Address the Hemispheric Challenge of Irregular Migration (June 12, 2023), *https://www.state.gov/u-s-costa-rica-joint-commitment-to-address-the-hemispheric-challenge-of-irregular-migration/.*

[109] *Id.*

[110] *Id.*

adversely affect the United States' ability to negotiate for and request additional enforcement measures and increased cooperation with removals. In diplomatic engagements, regional partner countries have repeatedly requested additional lawful pathways in return for increased law enforcement measures throughout the migratory routes, imposing additional requirements on key nationalities using their countries as a gateway to make irregular journeys to the SWB, and accepting additional removal flights with significantly reduced manifest times. As encounters of Ecuadorians along the SWB have remained high compared to the same months last year, maintaining and expanding their cooperation on removals is necessary to effectively manage irregular migration. Demographics and dynamics are evolving and difficult to predict, requiring flexibility in the responses of all governments involved. A key means of delivering on these partnerships, in keeping with the U.S. strategy and approach on migration management overall, is to make available lawful pathways to provide safe and orderly alternatives to the danger and consequences of irregular migration.

The invocation of the foreign affairs exemption here is also consistent with DHS precedent. For example, in 2017, DHS published a notice eliminating an exception to expedited removal for certain Cuban nationals, which explained that the change in policy was consistent with the foreign affairs exemption because the change was central to ongoing negotiations between the two countries.[111] DHS similarly invoked the foreign affairs exemption more recently in connection with the CHNV parole processes [112] and family reunification parole processes for certain nationals of Colombia, El Salvador, Guatemala, and Honduras announced on July 10, 2023.[113]

B. Paperwork Reduction Act (PRA)

Under the Paperwork Reduction Act (PRA), 44 U.S.C. chapter 35, all Departments are required to submit to the Office of Management and Budget (OMB), for review and approval, any new reporting requirements they impose. The process announced by this notice requires changes to the collections of information on Form I–134A, Online Request to be a Supporter and Declaration of Financial Support (OMB control number 1615–0157), which will be used for the FRP process for Ecuadorians and is being revised in connection with this notice by increasing the burden estimate. This process also requires changes to the collection of information for Advance Travel Authorization (ATA) (OMB Control Number 1651–0143); the revision to the ATA collection will add Ecuador to the list of countries authorized to utilize ATA. USCIS and CBP have submitted, and OMB has approved, requests for emergency authorization for OMB approval of the required changes (under 5 CFR 1320.13) to Form I–134A and ATA for a period of 6 months. USCIS and CBP will issue respective **Federal Register** notices seeking comment on these changes.[114]

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2023–25313 Filed 11–15–23; 8:45 am]

BILLING CODE 9111–97–P; 9111–14–P

[111] *See* Eliminating Exception To Expedited Removal Authority for Cuban Nationals Encountered in the United States or Arriving by Sea, 82 FR 4902 (Jan. 17, 2017).

[112] *See* Implementation of a Parole Process for Cubans, 88 FR 1266 (Jan. 9, 2023); Implementation of a Parole Process for Haitians, 88 FR 1243 (Jan. 9, 2023); Implementation of a Parole Process for Nicaraguans, 88 FR 1255 (Jan. 9, 2023); Implementation of Changes to the Parole Process for Venezuelans, 88 FR 1282 (Jan. 9, 2023); Implementation of a Parole Process for Venezuelans, 87 FR 63507 (Oct. 19, 2022).

[113] *See* DHS Announces Family Reunification Parole Processes for Colombia, El Salvador, Guatemala, and Honduras, July 17, 2023, *https://www.dhs.gov/news/2023/07/07/dhs-announces-family-reunification-parole-processes-colombia-el-salvador-guatemala;* Implementation of a Family Reunification Parole Process for Colombians, 88 FR 43591 (July 10, 2023); Implementation of a Family Reunification Parole Process for Salvadorans, 88 FR 43611 (July 10, 2023); Implementation of a Family Reunification Parole Process for Guatemalans, 88 FR 43581 (July 10, 2023); and Implementation of a Family Reunification Parole Process for Hondurans, 88 FR 43601 (July 10, 2023).

[114] Per the normal clearance procedures at 5 CFR 1320.10(e).

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7075–N–14]

60-Day Notice of Proposed Information Collection: Evaluation of Cohort 1 of the Moving to Work Demonstration Program Expansion OMB Control No.: 2528–0328

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Evaluation of Cohort 1 of the Moving to Work Demonstration Program Expansion.

OMB Approval Number: 2528–0328.

Type of Request: Extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Office of Policy Development and Research (PD&R), at the U.S. Department of Housing and Urban Development (HUD), is proposing this collection of information for the

Evaluation of Cohort 1 of the Moving to Work Demonstration Program Expansion.

Moving to Work (MTW) is a demonstration program that encourages public housing agencies (PHAs) to test ways to achieve three specific objectives: (1) increase the cost effectiveness of federal housing programs, (2) increase housing choice for low-income families, and/or (3) encourage greater self-sufficiency of households receiving housing assistance. MTW designation gives PHAs relief from many of the regulations and statutory provisions that apply to the public housing and Housing Choice Voucher (HCV) programs. MTW agencies can also merge their public housing and HCV funds into a single block grant and use these funds (if desired) for local activities outside of the typical public housing and HCV programs, such as providing supportive services or developing housing for populations with special needs. In 2016, Congress authorized HUD to expand the MTW program by 100 high performing PHAs.

The MTW expansion statute emphasizes evaluating the MTW program, directing HUD to expand the program in cohorts that would allow for ''one specific policy change to be implemented . . . .'' and rigorously evaluated. The first cohort of the expansion is testing the impact of MTW designation on small PHAs, defined for these purposes as PHAs administering no more than 1,000 housing units across their HCV and public housing programs. In Cohort 1, PHAs are free to implement any program and policy changes permissible under the MTW program. Under contract with HUD's Office of Policy Development and Research, Abt Associates Inc. is conducting an evaluation of Cohort 1 that includes a study of how PHAs use their MTW flexibility to meet the MTW program's goals and a study of the impact of MTW designation on cost effectiveness, self-sufficiency, and housing choice.

The Evaluation of Cohort 1 of the Moving to Work Demonstration Program Expansion is being implemented as a randomized control trial. To carry out the study, HUD randomly assigned the 43 eligible PHAs that submitted a Letter of Interest to HUD for Cohort 1 into one of two groups: a treatment group (33 PHAs) that was invited to complete the application for MTW designation and a control group (10 PHAs) that was not invited to complete the application for MTW designation and therefore was not permitted to receive MTW designation under Cohort 1. The evaluation will compare the outcomes of the treatment group PHAs to the outcomes of the control group PHAs over a five-year period. To the extent possible, this evaluation is relying on analysis of secondary data that PHAs already prepare and submit to HUD, however, some primary data collection is required to carry out the evaluation.

This **Federal Register** Notice provides an opportunity to comment on the information collection for the evaluation. The evaluation will use the data described in this information collection request to clarify and expand on information provided in the existing data sources and to capture qualitative information about the experiences of study PHAs implementing activities related to cost effectiveness, self-sufficiency, or housing choice without MTW flexibility. The proposed information collection consists of: (1) interviews with MTW (treatment group) PHAs; (2) online surveys to non-MTW (control group) PHAs; and (3) interviews with non-MTW (control group) PHAs.

Respondents: PHA Executive Directors and staff.

Estimated Number of Respondents: This information collection will affect approximately 129 PHA Executive Directors and Staff annually. HUD expects to collect data from approximately three staff at each of the 33 treatment group PHAs each year, and approximately two staff at each of the ten control group PHAs every other year.

ANNUALIZED BURDEN TABLE

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Interviews: Treatment PHAs	99	1	1	2	198	$52.14	$10,232.72
Online Surveys: Control PHAs	10	1	1	0.5	5	52.14	260.70
Interviews: Control PHAs	20	1	1	1.5	30	52.14	1,564.20
Total	129				233		12,148.62

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2023–25306 Filed 11–15–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7075–N–13]

60-Day Notice of Proposed Information Collection: Eviction Protection Grant Program; OMB Control No.: 2528–0331

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone 202–402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Eviction Protection Grant Program.

OMB Approval Number: 2528–0331.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Office of Policy Development and Research (PD&R), at the U.S. Department of Housing and Urban Development (HUD), is proposing the collection of additional information for the Eviction Protection Grant Program (EPGP).

The goal of this effort is to facilitate required management functions and analyses of the outcomes of HUD's Eviction Protection Grant Program. This research is expected to help the Federal government, states, and communities throughout the United States improve housing stability for households at risk of eviction or subject to eviction. In addition, this program can benefit municipalities and landlords per avoidance of evictions, improved timelines for evictions, reducing unpaid unit vacancies, and reducing the costs of litigation. This research will be used to assess the overall program, to include grantee and client outcomes. It will also assess variations in regional and local implementation of EPGP grants. The findings will support HUD in identifying opportunities for changes to legislation, policy, and program implementation for eviction support services.

This **Federal Register** Notice provides an opportunity to comment on the information collection for this effort entitled Updating Eviction Protection Grant Program Documents. This information collection is designed to support the study of households at risk of or subject to eviction, specifically to identify effective processes and corresponding outcomes for eviction support programs and translate this research into actionable programmatic recommendations with appropriate timelines, policy making and implementation changes to improve these outcomes. The project includes data collection among HUD EPGP grantees and clients who receive eviction support services.

Respondents: EPGP grantee representatives and administrators, and EPGP grantee clients.

Estimated Number of Respondents: This information collection will affect 21 EPGP grantee organizations and tens of thousands of households who interact with the grantee organizations. Grantees will collect data on all households served, to include racial, age, income and other demographics, the eviction-related services provided, and case outcomes. Grantees will further provide additional details about grant execution to meet the needs and obligations of the EPGP.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Cost
Pre award							
NOFO application narrative	100	1	100	40	4,000	$52.36	$209,440
Application for Federal Assistance (SF–424)	0	0	0	0	0	0.00	0.00
Disclosure of Lobbying Activities (SF–LLL)	0	0	0	0	0	0.00	0.00
Detailed Budget Worksheet, 424 CBW	100	1	100	3.12	312	52.36	16,336.32
Disclosure/Update Report (Form HUD–2880)	100	1	100	2	200	52.36	10,472
Total Pre award	100	1	100	45.12	4,512	52.36	236,248.32

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Cost
Post award							
Grant work plan	21	1	21	2	42	56.50	2,373.00
Detailed Budget Worksheet, 424 CBW	21	1	21	3.12	65.5	56.50	3,700.75
Client Services and Outcomes Report, 52698	21	*1,000	21,000	0.25	5,250	56.50	296,625.00
Extended Outcomes Report 52698(a) †	21	4	84	0.03	630	56.50	35,595
Benchmarks Plan and Report, 52699	21	4	84	0.5	42	56.50	2,373.00
Grant Detailed Voucher Worksheet, 52700	21	4	84	1	84	56.50	4,746.00
Grant reporting (narratives, existing process)	21	4	84	2	168	56.50	9,492.00
Total Post award	21	18	21,378	8.9	6,281.5	56.50	354,904.75
Totals	268	19	21,478	54.02	10,793.5	‡56.50	591,153.07

*Anticipated average number of annual responses per respondent (grantee), to be reported to HUD quarterly with grant activity report.
†The 52698a combines individual 52698 form data into a comprehensive database document. Completion might occur simultaneously with the 52698 if using integrated software (21,000 responses), or data entry may require 2 additional minutes per form.
‡The ''Avg. Hourly Wage Rate'' for each respondent reflects a wage of $35.87 pre-award (2021) and $38.70 post-award (2023) for professional and business services and a 1.46 multiplier to reflect a fully loaded wage rate.

Estimated Time per Response: Please see the tables below.

Frequency of Response: Please see the tables below.

Estimated Total Annual Cost: The pre-award period is complete, and unchanged for the initial 2021 EPGP notice. Active post-award costs are estimated to be $354,904.75. To collect sufficient information to meaningfully rate and rank applicants, a significant amount of information is requested through the NOFO. However, the NOFO has been designed to ask only for essential information and imposes strict page limits to reduce the burden. Two years of program execution resulted in the requirements and estimates shown below for the post award phase. The pre award portion of the table is unchanged from the initial submission. Note that the hourly and total costs were adjusted per wage inflation between 2021 and 2023.

Three federal staff members will review each eligible NOFO application. A single staff member will be responsible for all post award review. The number of hours and costs for staff to review are reflected in the following chart:

Information collection	Number of submissions	Frequency	Responses per year	Hrs. per review	Total hrs (per person)	Average pay per hr.	Total staff cost
Pre award review							
NOFO Narrative	100	1	100	2	200	$98.04	$19,608
Application for Federal Assistance (SF–424)	0	0	0	0	0	0	0
Disclosure of Lobbying Activities (SF–LLL)	0	0	0	0	0	0	0
Grant Application Detailed Budget Worksheet (424 CBW)	100	1	100	.5	50	98.04	4,902
Disclosure/Update Report (Form HUD–2880)	100	1	100	2	200	98.04	19,608
Total pre award	100	1	100	2.7	270	98.04	44,118
Post award review							
Assistance Award/Amendment (HUD–1044)	21	1	21	.3	6.3	105.30	663.39
Grant work plan	21	1	21	2	42	105.30	4,422.60
Detailed Budget Worksheet, 424 CBW	21	1	21	1	21	105.30	2,211.30
Client Services and Outcomes Report, 52698*	21	1,000	21,000	NA	NA	105.30	NA
Extended Outcomes Report 52698(a)	21	4	84	1	84	105.30	8,845.20

Information collection	Number of submissions	Frequency	Responses per year	Hrs. per review	Total hrs (per person)	Average pay per hr.	Total staff cost
Benchmarks Plan and Report, 52699	21	4	84	.5	42	105.30	4,422.60
Grant Detailed Voucher Worksheet, 52700	21	4	84	1	84	105.30	8,845.20
Grant reporting (narratives, existing process)	21	4	84	1	84	105.30	8,845.20
Total post award ...	168	18	399	6.8	363.3	105.30	38,255.49
Total	268	19	499	9.5	633.3	† 105.30	82,373.49

* Grantees submit individual 52698 forms online while the new 52698(a) data table report facilitates rapid aggregate analyses by federal staff.
† The ''Avg. Hourly Wage Rate'' for each respondent reflects a wage of $67.15 pre-award (2021) and $72.12 post-award (2023) and a 1.46 multiplier to reflect a fully loaded wage rate for GS 14, step 5 in the Washington, DC Locality Area (2023 OMB tables).

There are no additional costs for contractor, facilities, computer hardware and software, equipment maintenance, travel, printing, or postage.

Respondent's Obligation: Participation is voluntary.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2023–25301 Filed 11–15–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–OC–2023–N090; FXGO16600926000–245–FF09X60000]

Hunting and Wildlife Conservation Council Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Fish and Wildlife Service (Service) gives notice of a meeting of the Hunting and Wildlife Conservation Council (HWCC), in accordance with the Federal Advisory Committee Act.

DATES: *Meeting:* The HWCC will meet on Monday, December 4, 2023, from 9 a.m. to 4 p.m. (eastern time).

Registration: Registration to attend or participate in the meeting is required. The registration deadline is Monday, November 27, 2023. To register, please contact the Designated Federal Officer (DFO) (see **FOR FURTHER INFORMATION CONTACT**).

Public Comment: If you wish to provide oral public comment or provide a written comment for the HWCC to consider, contact the DFO (see **FOR FURTHER INFORMATION CONTACT**) no later than Monday, November 27, 2023.

Accessibility: The deadline for accessibility accommodation requests is Monday, November 27, 2023. For more information, please see *Accessibility Information* below.

ADDRESSES: The meeting will take place at the U.S. Department of the Interior, 1849 C Street NW, Washington, DC 20240. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the DFO (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Douglas Hobbs, Designated Federal Officer (DFO), by email at *doug_hobbs@fws.gov,* or by telephone at 703–358–2336. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Hunting and Wildlife Conservation Council (HWCC) was established to further the provisions of the Fish and Wildlife Act of 1956 (16 U.S.C. 742a *et seq.*), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701–1785), the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–ee), other statutes applicable to specific Department of the Interior bureaus, and Executive Order 13443 (August 16, 2007), ''Facilitation of Hunting Heritage and Wildlife Conservation.'' The HWCC's purpose is to provide recommendations to the Federal Government, through the Secretary of the Interior and the Secretary of Agriculture, regarding policies and endeavors that (a) benefit wildlife resources; (b) encourage partnership among the public; sporting conservation organizations; and Federal, State, Tribal, and territorial governments; and (c) benefit fair-chase recreational hunting and safe recreational shooting sports.

Meeting Agenda

The meeting will include discussion of and potential recommendations related to the future use or non-use of lead ammunition on National Wildlife Refuge System lands; briefings from Federal agency staff; reports by Council subcommittees; and other business. The HWCC will also hear public comment if

members of the public request to comment. The final agenda and other related meeting information will be posted on the HWCC website, *https://www.fws.gov/program/hwcc.*

Public Input

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the DFO, in writing (see **FOR FURTHER INFORMATION CONTACT**), for placement on the public speaker list for this meeting. Requests to address the HWCC during the meeting will be accommodated in the order the requests are received. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the DFO up to 30 days following the meeting.

Accessibility Information

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. Please contact the DFO (**FOR FURTHER INFORMATION CONTACT**) no later than Monday, November 27, 2023, to give the Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Ch. 10.

Matthew Huggler,

Acting Assistant Director—Office of Communications.

[FR Doc. 2023–25332 Filed 11–15–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX24EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National Geospatial Advisory Committee (NGAC) will take place and is open to members of the public.

DATES: The meeting will be held as a webinar/teleconference on Monday, December 4, 2023, from 11:00 a.m. to 5:00 p.m. Eastern Standard Time.

ADDRESSES: The meeting will be held online and via teleconference. Instructions for registration to attend the meeting will be posted at *www.fgdc.gov/ngac.* Comments can be sent by email to *gs-faca@usgs.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data Committee (FGDC), USGS, by mail at 909 First Avenue, Room 703, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 375–2565.

SUPPLEMENTARY INFORMATION: This meeting is being held consistent with the provisions of the FACA (5 U.S.C. Ch. 10), the Government in the Sunshine Act of 1976 (5 U.S.C. 552B, as amended), and 41 CFR part 102–3.

Purpose of the Meeting: The NGAC provides advice and recommendations related to management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure (NSDI), and the implementation of the Geospatial Data Act of 2018 (GDA) and Office of Management and Budget (OMB) Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC is available at: *www.fgdc.gov/ngac.*

Agenda Topics:

—FGDC Update
—Landsat Advisory Group
—3D Elevation Program (3DEP)
—GDA
—NSDI Strategic Planning
—Findable, Accessible, Interoperable, Reusable (FAIR) Data
—Public Comment

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Members of the public wishing to attend the meeting should visit *www.fgdc.gov/ngac or* contact Mr. John Mahoney (see **FOR FURTHER INFORMATION CONTACT**). Webinar/conference line instructions will be provided to registered attendees prior to the meeting.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

Public Disclosure of Comments: There will be an opportunity for public comment during the meeting. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. Written comments may also be sent to the NGAC for consideration. To allow for full consideration of information by NGAC members, written comments must be provided to John Mahoney (see **FOR FURTHER INFORMATION CONTACT**) at least three (3) business days prior to the meeting. Any written comments received will be provided to NGAC members before the meeting.

Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you may ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Ch. 10.

Kenneth Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2023–25246 Filed 11–15–23; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX23DJ56UFK1000]

Agency Information Collection Activities: Request for Comments on the USGS Water Use Data Acquisition

AGENCY: U. S. Geological Survey, Department of the Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 16, 2024.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Cheryl Dieter, USGS Maryland-Delaware-DC Water Science Center, 5522 Research Park Drive, Catonsville, MD 21228, or by email at *cadieter@usgs.gov.* Please reference 'OMB Information Collection 1028—NEW USGS Water Use Data Acquisition' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Cheryl Dieter by mail at Maryland-Delaware-DC Water Science Center, 5522 Research Park Drive, Catonsville, MD 21228; by email at *cadieter@usgs.gov,* or by telephone at 443–883–0761. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *https://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA, 44 U.S.C. 3501 *et seq.* and 5 CFR 1320.8(d)(1), all information collections require approval. We may not conduct or sponsor, nor are you required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency might minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: This notice identifies an information collection activity that the USGS Water Availability and Use Science Program has submitted to OMB for approval to collect information on the use of water resources in the United States. The information is used by USGS scientists to estimate water use in several categories including (but not limited to) public-supply, domestic, irrigation, thermoelectric-cooling, industrial, mining, aquaculture, and livestock applications. USGS national water-use estimates are disseminated to stakeholders and the general public on an ongoing basis and fulfill requirements of the SECURE Water Act. The information also supports regional and national water-availability studies in the United States. The USGS has produced estimates of annual water use by category aggregated at the county- and state level every five years since 1950. For 2020, models will be used to produce the estimates and they will be made at a higher temporal and spatial resolution than previous years' estimates. Model estimates are dependent on validation using the data collected nationally for specific water-use facilities. USGS water-use specialists will request reported water-use data annually from non-federal agencies. This collection also aims to request data from facilities on an ad hoc basis to acquire data for categories of use or locations where state-reported data are not sufficient for estimating water use. Respondents can provide relevant data in a variety of electronic formats, usually via websites, file sharing, or email. Information will also be gathered on the water-use data-delivery needs of USGS water-use stakeholders and other end users.

Title of Collection: USGS Water Use Data Acquisition.

OMB Control Number: 1028–NEW.

Form Number: DI–3680.

Type of Review: New collection.

Respondents/Affected Public: State and local government agencies, Individuals or households, businesses, Tribal governments.

Water-Resource Agencies

Total Estimated Number of Annual Respondents: 300.

Total Estimated Number of Annual Responses: 300.

Initial contact: 150 with completion time of 1 minute.

Data submission: 150 with completion time of 4 hours.

Total Estimated Number of Annual Burden Hours: 603 hours.

Water-Use Facilities

Estimated Number of Annual Respondents: 7,500.

Total Estimated Number of Annual Responses: 7,500.

Initial contact: 5,000 with completion time of 1 minute.

Data submission: 2,500 with completion time of 4 hours.

Total Estimated Number of Annual Burden Hours: 10,084 hours.

Individual Water Users

Total Estimated Number of Annual Respondents: 1,500.

Total Estimated Number of Annual Responses: 7,000.

Initial contact: 1,000 with completion time of 1 minute.

Data submission: 6,000 with completion time of 0.5 hours.

Total Estimated Number of Annual Burden Hours: 3,017 hours.

Data End-Users

Total Estimated Number of Annual Respondents: 300.

Total Estimated Number of Annual Responses: 300.

Initial contact: 150 with completion time of 1 minute.

Data submission: 150 with completion time of 15 minutes.

Total Estimated Number of Annual Burden Hours: 41 hours.

Totals Combining All Four Information-Collection Components

Total Estimated Number of Annual Respondents: 9,600.

Total Estimated Number of Annual Responses: 15,100.

Estimated Completion Time per Response: 1 minute–4 hours.

Total Estimated Number of Annual Burden Hours: 13,745 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once per year, except monthly for individual water-user reporting component.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA.

Donald W. Cline,

U.S. Geological Survey, Associate Director for Water.

[FR Doc. 2023–25249 Filed 11–15–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Fish and Wildlife Service

[BLM_FRN_MO4500175331]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement To Reconsider a Highway Right-of-Way Application and Associated Amendment of an Incidental Take Permit, Washington County, Utah

AGENCY: Bureau of Land Management, Fish and Wildlife Service, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and the Endangered Species Act of 1973, as amended (ESA), the Bureau of Land Management (BLM) and the Fish and Wildlife Service (FWS), as co-lead agencies, intend to prepare a Supplemental Environmental Impact Statement (SEIS) to further consider the effects of granting a right-of-way (ROW) to the Utah Department of Transportation (UDOT) for the Northern Corridor Project (a proposed highway) as well as a potential amendment to the Incidental Take Permit (ITP) issued to Washington County, Utah, under Section 10(a)(1)(B) of the ESA. This notice announces the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the SEIS. The BLM and FWS request the public submit comments concerning the scope of the analysis, potential alternatives, impacts of the proposed action and alternatives, and identification of relevant information and studies by December 18, 2023. To afford the BLM and FWS the opportunity to consider comments in the Draft SEIS, please ensure your comments are received prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later.

ADDRESSES: You may submit comments related to the highway ROW and associated amendment of an ITP by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2026562/510.*
- *Mail:* Bureau of Land Management, Attn: Northern Corridor SEIS, 345 East Riverside Drive, St. George, UT 84790.

Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2026562/570* and at the BLM St. George Field Office.

FOR FURTHER INFORMATION CONTACT: Dawna Ferris-Rowley, NCA Manager, Red Cliffs and Beaver Dam Wash NCAs, telephone (435) 688–3200; address 345 East Riverside Drive, St. George, UT 84790; email *BLM_UT_NorthernCorridor@blm.gov.* Contact Ms. Ferris-Rowley to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Ferris-Rowley. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The BLM and FWS are issuing this Notice of Intent pursuant to NEPA, 42 United States Code (U.S.C.) 4321 *et seq.;* the Council on Environmental Quality regulations for implementing NEPA, 43 Code of Federal Regulations (CFR) parts 1500–1508; and the Department of the Interior's NEPA regulations, 43 CFR part 46.

The SEIS is being prepared to supplement the analysis contained in the 2020 Final EIS (FEIS) by BLM and FWS (the entire FEIS can be found at: *https://eplanning.blm.gov/eplanning-ui/project/1502103/570*).

On September 4, 2018, UDOT submitted an application for a ROW grant for the Northern Corridor Project north of the City of St. George, Utah, on BLM-managed and non-Federal lands within the Red Cliffs National Conservation Area (NCA) and Red Cliffs Desert Reserve. To consider the application, the BLM needed to also consider amending the St. George Field Office and Red Cliffs NCA Resource Management Plans (RMPs). The Red Cliffs NCA was established through the passage of the Omnibus Public Land Management Act of 2009 (16 U.S.C. 460www), and the Red Cliffs Desert Reserve was established for the protection of the Mojave desert tortoise under the 1995 Washington County Habitat Conservation Plan. In 2015, pursuant to Section 10(a)(1)(B) of the ESA, Washington County applied to renew and amend the ITP. The restated and amended Habitat Conservation Plan associated with the ITP application described the Northern Corridor highway as a potential changed circumstance, which would be partially offset with the addition of a new sixth zone to the Red Cliffs Desert Reserve (Reserve Zone 6) as the primary conservation strategy.

In accordance with NEPA, the BLM and FWS prepared an EIS to analyze the environmental impacts associated with the proposed action and reasonable alternatives. The BLM also consulted with the FWS to meet the requirements in Section 7 of the ESA. The FWS issued a biological opinion to the BLM that determined the ROW and amendments to the RMPs were not likely to jeopardize the continued existence of the Mojave desert tortoise and that they were not likely to destroy or adversely modify designated critical habitat for the desert tortoise. The FWS issued an intra-agency biological opinion which determined that the ITP is not likely to jeopardize the continued existence of the Mojave desert tortoise, Holmgren milkvetch, Shivwits milkvetch, dwarf bear-poppy, Siler

pincushion cactus, Gierisch mallow, and Fickeisen plains cactus or result in the adverse modification of critical habitat for any of the above listed species.

On January 13, 2021, the Secretary of the Interior signed a Record of Decision that approved the Northern Corridor ROW application and approved the amendments to the RMPs. The decision approving the ROW was effective immediately. The BLM then signed and issued the ROW grant to UDOT on the same day. Also on January 13, 2021, the FWS Regional Director for Interior Regions 5 and 7 signed a Record of Decision approving the issuance of an ITP to Washington County. The FWS issued the ITP to Washington County on January 13, 2021.

On June 3, 2021, seven conservation organizations (collectively, Plaintiffs) filed an initial complaint in the United States District Court for the District of Columbia, Case No. 1:21–cv–01506. Among other claims, Plaintiffs alleged the BLM's ROW decision violated both NEPA and the National Historic Preservation Act (NHPA). The Plaintiffs stated, in part, that the FEIS did not fully address the changed circumstances of wildfire in the region and the impacts it may have on the Mojave desert tortoise, desert tortoise habitat, and the spread of invasive annual grasses. The Plaintiffs also alleged that the BLM failed to comply with the consultation requirements under Section 106 of the NHPA. On July 27, 2021, Plaintiffs amended their complaint to include the FWS and additional claims related to NEPA and the ESA.

As part of the ongoing litigation, the United States moved for the remand and partial vacatur of BLM's and FWS's 2021 decisions. In the motion, the United States acknowledged that the BLM did not comply with the NHPA as well as the BLM's and FWS's substantial and legitimate concerns that the FEIS may lack sufficient analysis of certain resource effects (see Summary of Expected Impacts). In addition to that pending motion, the United States and Plaintiffs have also reached a settlement agreement.

Purpose and Need for the Proposed Action

In 2018, UDOT applied for a ROW to construct a multi-lane, divided highway on BLM-administered lands within the Red Cliffs NCA and the overlapping Red Cliffs Desert Reserve. In January 2021, after completing the FEIS, the Secretary of the Interior approved the ROW application, and the BLM issued a FLPMA Title V ROW grant to UDOT. Per the motion and by the terms of the settlement agreement, the BLM's purpose and need for this action is to reconsider the 2018 ROW application to determine whether the BLM will approve, approve with modifications, or deny the application. The FWS's purpose and need for action is to consider an amendment of Washington County's ITP consistent with the BLM's reconsideration of UDOT's ROW application.

Preliminary Proposed Action and Alternatives

At this time, the BLM anticipates the range of alternatives analyzed in detail in the SEIS will be substantially similar to those analyzed in the FEIS completed in 2020 for the ROW alignments. The FWS anticipates the ITP-related alternatives will range between amending the ITP or not amending the ITP corresponding with the BLM's range of alternatives. The SEIS will not reconsider any amendments to the BLM's RMPs. The BLM and FWS welcome comments on all preliminary alternatives as well as suggestions for additional alternatives.

Summary of Expected Impacts

The impacts disclosed in the SEIS are expected to substantially align with the impacts that were analyzed in the 2020 FEIS with additional analysis of potential impacts, including further analysis of the effects of the construction and use of the Northern Corridor Project in the context of the following: (1) the trend in the increasing frequency and extent of wildfires in the Mojave Desert; (2) the rise of non-native/exotic and invasive vegetation in post-burn areas; and (3) the impacts increased fire and new non-native/exotic and invasive vegetation have on desert tortoise. The BLM is concerned that supplemental analysis may be needed to better inform its review of the potential impacts of UDOT's ROW application in light of impacts from wildfires to the desert tortoise and its habitat. The BLM also intends to complete the consultation requirements under the NHPA before issuing a new ROW decision.

Anticipated Permits and Authorizations

The BLM will reconsider UDOT's 2018 ROW application and decide whether to approve, approve with modifications, or deny UDOT's ROW application. The FWS will determine whether to amend Washington County's ITP for the Mojave desert tortoise.

Schedule for the Decision-Making Process

The BLM and FWS will provide additional opportunities for public participation consistent with the NEPA process, including a 45-day comment period on the Draft SEIS. The Draft SEIS is anticipated to be available for public review in spring 2024, and the Final SEIS is anticipated to be released in September 2024 with Records of Decision in November 2024.

Public Scoping Process

This Notice of Intent initiates the scoping period. The BLM and FWS will be holding one in-person public scoping meeting in St. George, Utah. The specific date and location of the scoping meeting will be announced in advance through local media, the ePlanning project page (see **ADDRESSES**), and the BLM website (see **ADDRESSES**).

Lead and Cooperating Agencies

Lead agencies are the BLM and the FWS. Based on who participated in the FEIS, cooperating agencies are likely to include the State of Utah—Public Lands Policy Coordinating Office, Washington City, Dixie Metropolitan Planning Organization, the City of St. George, the City of Ivins, Santa Clara City, and the City of Hurricane.

Responsible Officials

The responsible official for the BLM is the BLM Utah State Director. The scope of the State Director's decision is limited to the ROW. If the decision authorizes issuance of a new ROW grant, the St. George Field Manager will be the responsible official to issue the grant. The responsible official for the FWS is the Deputy Regional Director for the Mountain-Prairie Region. The scope of the Deputy Regional Director's decision is limited to the ITP for the Mojave desert tortoise.

Nature of Decision To Be Made

The Responsible Officials will determine whether to approve, approve with modifications, or deny the 2018 ROW application for the construction of a highway (BLM) and what amendments, if any, are needed to the ITP (FWS).

Additional Information

The BLM and FWS will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed action and all analyzed reasonable alternatives and, in accordance with 40 CFR 1502.14(e), include appropriate mitigation measures not already included in the proposed action or

alternatives. Mitigation may include avoidance, minimization, rectification, reduction or elimination over time, and compensation; and may be considered at multiple scales, including the landscape scale.

The BLM and FWS will utilize and coordinate the NEPA process to help support compliance with applicable procedural requirements under the ESA (16 U.S.C. 1536). BLM will also use the NEPA process to comply with Section 106 of the NHPA (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including the public involvement requirements of Section 106. Information about historic and cultural resources within the area potentially affected by the proposed project will assist the BLM in identifying and evaluating impacts to such resources. The BLM will also consult on cultural resources and create a Memorandum of Agreement with consulting parties.

The BLM and FWS will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM Manual Section 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that may be interested in or affected by the proposed action the BLM and the FWS are evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM and FWS to participate in the development of the environmental analysis as a cooperating agency.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can include in your comment a request to withhold your personal identifying information from public review, the agencies cannot guarantee that they will be able to do so.

(Authority: 40 CFR 1501.9)

Gregory Sheehan,

State Director.

Anna Munoz,

Deputy Regional Director.

[FR Doc. 2023–25252 Filed 11–15–23; 8:45 am]

BILLING CODE 4331–25–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NM_FRN_MO4500175760; NMNM 106216530, NMNM 109118]

Public Land Order No. 7934; Extension of Public Land Order No. 7591; Withdrawal for Federal Law Enforcement Training Center, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends the duration of the withdrawal created by Public Land Order (PLO) No. 7591 for an additional 20-year term. PLO No. 7591 withdrew 1,920.80 acres of public lands from location and entry under the United States mining laws, but not from leasing under the mineral leasing laws, and reserved the lands for the Department of Homeland Security (DHS) to protect, maintain, and operate its Federal Law Enforcement Training Center (FLETC) in Eddy County, New Mexico.

DATES: This PLO takes effect on November 19, 2023.

FOR FURTHER INFORMATION CONTACT: Tammie Hochstein, BLM Carlsbad Field Office Realty Specialist, by email at *thochste@blm.gov,* or (575) 234–5902. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or Tele Braille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The purpose of the withdrawal extended by this order is for the continued protection of the FLETC and to allow the DHS to continue operations without interference or any potential adverse impacts of mineral development.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, PLO No. 7591 (68 FR 65471, November 20, 2003), which withdrew 1,920.80 acres of public lands from location and entry under the United States mining laws for the Department of Homeland Security to protect, operate, and maintain its Federal Law Enforcement Training Center, is hereby extended for an additional 20-year period.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be further extended.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2023–25284 Filed 11–15–23; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–VRP–REGS–NPS0036654; PPWOVPADU0, POPFR2021.XZ0000 (222); OMB Control Number 1024–0026]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Special Park Use Applications

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995 we, the National Park Service (NPS) are proposing to renew an existing information collection with revisions.

DATES: Interested persons are invited to submit comments on or before December 18, 2023.

ADDRESSES: Written comments and suggestions on the information collection requirements should be submitted by the date specified above in **DATES** to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 13461 Sunrise Valley Drive, Mail Stop 244 Reston, VA 20192, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number 1024–0026 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Maggie Tyler, Special Park Uses Program Manager, 1849 C Street NW, Main Interior Building—Rm 2474, Washington D.C 20240; or at *Maggie_tyler@nps.gov*

(email); or 202–513–7092 (telephone). Please reference OMB Control Number 1024–0026 in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on October 28, 2022 (87 FR 65246). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Authorized by the National Park Service Act Organic Act, 54 U.S.C. 100101, we must preserve America's natural wonders unimpaired for future generations, while also making them available for the enjoyment of the visitor. Meeting this mandate requires that we balance preservation with use. Maintaining a good balance requires both information and use. In accordance with regulations at 36 CFR, we issue permits for special park uses. Special park uses cover a wide range of activities including, but not limited to special events, First Amendment activities, grazing and agricultural use, filming, still photography, construction, and vehicle access. Permits are issued for varying durations of time based on the requested use, but generally do not exceed 5 years. A new application must be submitted in order to request the renewal of an existing permit.

The information we collect in the special use applications allows park managers to determine if the requested use is consistent with the laws and NPS regulations referenced above and with the public interest. The park manager must also determine that the requested activity will not cause unacceptable impacts to park resources and values. The information is collected using the following NPS forms:

- 10–930—Application for Special Use Permit
- 10–930c—Application for Special Use Permit—Climbing
- 10–930s—Application for Special Use Permit (short form)
- 10–931—Application for Special Use Permit—Still Photography Permit (short)
- 10–932—Application for Special Use Permit—Still Photography Permit (long)
- 10–933—Application for Special Use Permit—Vehicle/Watercraft Use

With this renewal, we are requesting to introduce two new forms to this collection:

(1) Form 10–934 Application for Special Use Permit—Demonstrations and Distribution of Materials. This new form will be used to authorize First Amendment activities in system units.

(2) Form 10–930q—Special Park Use Application/Permit—Quarry Activities. Per 36 CFR 7.42, this new form will be used to authorize quarry activities specific to Pipestone National Monument.

Information collected on the forms is used to evaluate requests for Special Use Permits and facilitate the permitting process. If the requested use is consistent with park regulations, the information collected is used to issue a permit.

Title of Collection: Special Park Use Applications.

OMB Control Number: 1024–0026.

Form Number: NPS Forms 10–930, 10–930c, 10–930s, 10–930q *(new)* 10–931, 10–932, 10–933, 10–934 *(new).*

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals or households; businesses or other for-profit entities; and Federal, State, local and tribal governments.

Total Estimated Number of Annual Respondents: 80,542.

Total Estimated Number of Annual Responses: 80,542.

Estimated Completion Time per Response: Varies from 15 minutes to 30 minutes.

Total Estimated Number of Annual Burden Hours: 22,890.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $6,036,225 for application fees.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2023–25316 Filed 11–15–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–ACAD–36707; PPNEACADSO, PPMPSPDIZ.YM0000]

Notice of Public Meetings for the Acadia National Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Park Service

(NPS) is hereby giving notice that the Acadia National Park Advisory Commission (Commission) will meet as indicated below.

DATES: The Commission will meet: Monday, February 5, 2024; Monday, June 3, 2024; and Monday, September 9, 2024. All scheduled meetings will begin at 1 p.m. and will end by 4 p.m. (Eastern).

ADDRESSES: The February 5, 2024, and June 3, 2024, meetings will be held at the headquarters conference room, Acadia National Park, 20 McFarland Hill Drive, Bar Harbor, Maine 04609. The September 9, 2024, meeting will be held at the Schoodic Education and Research Center, Winter Harbor, Maine 04693. All three meetings will also be held virtually for those who are unable to attend in person and will be closed captioned.

FOR FURTHER INFORMATION CONTACT: Kathy Flanders, Superintendent's Secretary, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8702 or *kathy_flanders@nps.gov*. The format of the FY 2024 meetings and locations are subject to change, pending the COVID–19 pandemic and safety requirements. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Commission was established by section 103 of Public Law 99–420, as amended, (16 U.S.C. 341 note), and in accordance with the Federal Advisory Committee Act (5 U.S.C. Ch 10). The Commission advises the Secretary of the Interior and the NPS on matters relating to the management and development of Acadia National Park, including but not limited to, the acquisition of lands and interests in lands (including conservation easements on islands) and the termination of rights of use and occupancy.

The meetings are open to the public. Interested persons may make oral presentations to the Commission. Such requests should be made to the Superintendent at the beginning of the meeting. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Written comments can be sent to Kathy Flanders [see **FOR FURTHER INFORMATION CONTACT**]. All comments received will be provided to the Commission.

The Commission meeting locations may change based on inclement weather or exceptional circumstances. If a meeting location is changed, the Superintendent will issue a press release and use local newspapers to announce the change. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Purpose of the Meeting: The Commission meeting will consist of the following proposed agenda items:

1. Superintendent's Report
2. Committee Reports:
   - Land Conservation
   - Park Use
   - Science and Education
   - Historic
3. Old Business
4. New Business
5. Chairman's Report
6. Public Comments
7. Adjournment

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Ch 10.)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2023–25250 Filed 11–15–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83550000, 234R5065C6, RX.59389832.1009676]

Change in Discount Rate for Water Resources Planning

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of change in discount rate.

SUMMARY: The Bureau of Reclamation is announcing the interest rate to be used by Federal agencies in the formulation and evaluation of plans for water and related land resources is 2.75 percent for fiscal year 2024.

DATES: This discount rate is to be used for the period October 1, 2023, through and including September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Brandee Blumenthal, Bureau of Reclamation, Reclamation Law Administration Division, P.O. Box 25007, Denver, Colorado 80225; telephone (303) 445–2435; or email at *bblumenthal@usbr.gov*.

SUPPLEMENTARY INFORMATION: The Water Resources Planning Act of 1965 and the Water Resources Development Act of 1974 require an annual determination of a discount rate for Federal water resources planning. The discount rate for Federal water resources planning for fiscal year 2024 is 2.75 percent. The prior year's rate, as announced in the **Federal Register** on November 4, 2022 (87 FR 66745), was 2.50 percent for fiscal year 2023. Discounting is to be used to convert future monetary values to present values.

This rate has been computed in accordance with Section 80(a), Public Law 93–251 (88 Stat. 34), and 18 CFR 704.39, which: (1) specify that the rate will be based upon the average yield during the preceding fiscal year on interest-bearing marketable securities of the United States which, at the time the computation is made, have terms of 15 years or more remaining to maturity (average yield is rounded to nearest one-eighth percent); and (2) provide that the rate will not be raised or lowered more than one-quarter of 1 percent for any year. The U.S. Department of the Treasury calculated the specified average to be 4.0332 percent. In accordance with the Water Resource Council Rules and Regulations, the maximum adjustment allowed for the current fiscal year rate is one-quarter of one percentage point from the previous fiscal year rate, which was 2.50 percent. Therefore, the fiscal year 2024 rate is 2.75 percent.

The rate of 2.75 percent will be used by all Federal agencies in the formulation and evaluation of water and related land resources plans for the purpose of discounting future benefits and computing costs or otherwise converting benefits and costs to a common-time basis.

Christopher Beardsley,

Director, Policy and Programs.

[FR Doc. 2023–25310 Filed 11–15–23; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1332]

Certain Chocolate Milk Powder and Packaging Thereof; Notice of Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute a formal enforcement proceeding relating to the general exclusion order (''GEO'') issued on November 15, 2022, in the above-referenced investigation.

FOR FURTHER INFORMATION CONTACT: Paul Lall, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2043. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 1, 2020, based on a complaint filed on behalf of Meenaxi Enterprise Inc. (''Meenaxi'') of Edison, New Jersey. 85 FR 77237–8 (Dec. 1, 2020). The complaint alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain chocolate milk powder and packaging thereof by reason of infringement of U.S. Trademark Registration No. 4,206,026 (''the '026 mark''). The Commission's notice of investigation named as respondents Bharat Bazar Inc. of Union City, California; Madras Group Inc. d/b/a Madras Groceries of Sunnyvale, California; Organic Food d/b/a Namaste Plaza Indian Super Market (''Organic Food'') of Fremont, California; India Cash & Carry of Sunnyvale California; New India Bazar Inc. d/b/a New India Bazar of San Jose, California; Aapka Big Bazar of Jersey City, New Jersey; Siya Cash & Carry Inc. d/b/a Siya Cash & Carry of Newark, New Jersey; JFK Indian Grocery LLC d/b/a D-Mart Super Market of Jersey City, New Jersey; Trinethra Indian Super Markets of Newark, California; Apna Bazar Cash & Carry Inc. d/b/a Apna Bazar Cash & Carry of Edison, New Jersey; Subzi Mandi Cash & Carry Inc. d/b/a Mandi Cash & Carry of Piscataway, New Jersey; Patidar Cash & Carry Inc. d/b/a Patidar Cash & Carry of South Plainfield, New Jersey; Keemat Grocers of Sugarland, Texas; KGF World Food Warehouse Inc. d/b/a World Food Mart of Houston, Texas; Telfair Spices of Sugarland Texas; Indian Groceries and Spices Inc. d/b/a iShopIndia.com of Milwaukee, Wisconsin; Rani Foods LP d/b/a Rani's World Foods of Houston, Texas; Tathastu Trading LLC of South Plainfield, New Jersey; and Choice Trading LLC of Guttenberg, New Jersey. *Id.* The Office of Unfair Import Investigations (''OUII'') was also a party to the investigation.

All respondents were found in default. *See* Order No. 6 (Feb. 10, 2021), *unreviewed by* Comm'n Notice (Mar. 2, 2021); Order No. 23 (May 19, 2022), *unreviewed by* Comm'n Notice (Jun. 14, 2022).

On May 24, 2021, Meenaxi moved for summary determination of violation of section 337 by the respondents found in default by Order No. 6 and requested a GEO. On December 1, 2021, the former chief administrative law judge (''CALJ'') granted the motion as an initial determination (''ID'') (Order No. 15). No petitions for review of the ID were filed. The ID, however, noted discrepancies with respect to respondent Organic Food, calling into question whether that respondent was ever properly served with the complaint and notice of investigation and with the CALJ's order to show cause why the respondents should not be found in default, Order No. 5 (Jan. 13, 2021). *See* Order No. 15 at 1 n.1. The Commission determined *sua sponte* to review Order No. 15 and ordered reconsideration of Order No. 6 as to Organic Food and/or any other respondents who may not have been properly served with documents in the underlying investigation. Notice at 3 (Jan 18, 2022). The Commission remanded the investigation to an ALJ for further proceedings. *Id.*

On remand, the current CALJ issued Order No. 18, granting Meenaxi's unopposed motion for leave to amend the complaint and notice of investigation to (i) substitute Organic Food with proposed respondent Organic Ingredients Inc. d/b/a Namaste Plaza Indian Super Market (''Organic Ingredients'') of San Diego, California; (ii) correct the address of respondent New India Bazar Inc. d/b/a New India Bazar (''New India'') of San Jose, California; (iii) correct the address of respondent Bharat Bazar Inc. (''Bharat Bazar'') of Union City, California; and (iv) supplement the complaint with Exhibits 9–a, 9–b, and 9–c, concerning Organic Food and/or Organic Ingredients. Order No. 18 at 1–5 (Mar. 11, 2022), *unreviewed by* Comm'n Notice, 87 FR 22940 (Apr. 18, 2020). Meenaxi demonstrated that Bharat Bazar had been actually served with all of the documents in the investigation (prior to remand) despite incorrectly spelling Bharat Bazar's address as being on ''Niled Road'' instead of ''Niles Road.'' Order No. 18 at 4.

The current CALJ conducted remand proceedings as to Organic Ingredients and New India, first ordering them to respond to the amended complaint and notice of investigation, and then ordering them to respond to an order to show cause why they should not be found in default. *See* Order No. 27 at 3 (Aug. 3, 2022). On May 19, 2022, the CALJ issued an ID finding Organic Ingredients and New India in default (collectively with the respondents previously found in default, the ''Defaulting Respondents''). Order No. 23 (May 19, 2022), *unreviewed by* Comm'n Notice (June 14, 2022).

Subsequently, on June 15, 2022, following the remand determination of default, Meenaxi again moved for summary determination of violation by the Defaulting Respondents and requested a GEO. On July 6, 2022, OUII filed a response supporting the motion.

On August 3, 2022, the current CALJ issued a remand ID (''RID''), granting the second motion for summary determination and finding a violation of section 337 with respect to the '026 mark. The RID found that all Defaulting Respondents met the importation requirement and that Meenaxi satisfied the domestic industry requirement. *See* 19 U.S.C. 1337(a)(1)(B), (a)(2), and (a)(3). The RID also contained the CALJ's recommended determination (''RD'') on remedy and bonding. The RD recommended issuance of a GEO with

respect to the asserted '026 mark. No party petitioned for review of the ID.

On September 19, 2022, the Commission determined not to review the RID. 87 FR 58130–1 (Sept. 23, 2022). On November 15, 2022, the Commission issued a final determination finding a violation, issuing a GEO prohibiting the unlicensed importation of chocolate milk powder and packaging thereof that infringe the '026 mark, and terminating the investigation. 87 FR 70864–65. On the same day, the Commission issued an opinion explaining the basis for its final determination.

On October 9, 2023, Meenaxi filed a complaint requesting that the Commission institute an enforcement proceeding under Commission Rule 210.75 to investigate alleged violations of the General Exclusion Order by four proposed enforcement respondents: (1) Organic Ingredients; (2) New India; (3) Bharat Bazar; and (4) Coconut Hill Inc. of Sunnyvale, California. Meenaxi asserts that the four proposed enforcement respondents continue to import, sell for importation, advertise, market, distribute, offer to sell ''Bournvita'' products that infringe the '026 mark. Meenaxi also alleges that the four proposed enforcement respondents are in continuing violation of the GEO and as a result, it is sustaining ''immediate and irreparable harm.'' None of the respondents answered Meenaxi's enforcement complaint.

Having examined the enforcement complaint and the supporting documents, the Commission has determined to institute a formal enforcement proceeding, pursuant to Commission Rule 210.75(a) (19 CFR 210.75(a)), to determine whether violations of the GEO, issued on November 15, 2022 in the above-referenced investigation, have occurred and to determine what, if any, enforcement measures are appropriate. The named respondents are: (1) Organic Ingredients Inc. d/b/a Namaste Plaza Indian Super Market; (2) New India Bazar Inc.; (3) Bharat Bazar Inc.; and (4) Coconut Hill Inc. d/b/a Coconut Hill. OUII is also named as a party.

In the Order issued concurrently herewith, the Commission has delegated this enforcement proceeding to the CALJ for designation of a presiding Administrative Law Judge to conduct any necessary proceedings, issue an Enforcement Initial Determination, and make a recommendation on appropriate enforcement measures, if any.

The Commission's vote on this determination took place on November 9, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 9, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–25279 Filed 11–15–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–683 and 731–TA–1594–1596 (Final)]

Paper File Folders From China, India, and Vietnam

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of paper file folders from China, India, and Vietnam, provided for in subheading 4820.30.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the government of India.[2]

Background

The Commission instituted these investigations, effective October 12, 2022, following receipt of petitions filed with the Commission and Commerce by the Coalition of Domestic Folder Manufacturers, Hastings, Minnesota and Naperville, Illinois. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of paper file folders from India were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and imports of paper file folders from China, India, and Vietnam were sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 8, 2023 (88 FR 37579). The public hearing in connection with the investigations, originally scheduled for October 3, 2023, was cancelled.[3]

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 13, 2023. The views of the Commission are contained in USITC Publication 5472 (November 2023), entitled *Paper File Folders from China, India, and Vietnam: Investigation Nos. 701–TA–683 and 731–TA–1594–1596 (Final).*

By order of the Commission.

Issued: November 13, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–25331 Filed 11–15–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0023]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Import/Export Declaration for List I and List II Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 11, 2023, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section,

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 88 FR 69130, 88 FR 69134, 88 FR 69138, and 88 FR 69141, October 5, 2023.

[3] 88 FR 68670, October 4, 2023.

Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261, email: *scott.a.brinks@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0023. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Import/Export Declaration for List I and List II Chemicals.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* DEA Forms: 486, 486A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected public (Primary):* Business or other for-profit. Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: Section 1018 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 971) and Title 21 Code of Federal Regulations (21 CFR) Part 1313 require any persons who import, export, or conduct international transactions involving list I and list II chemicals are required to establish a system of recordkeeping and report certain information regarding those transactions to DEA. The chemicals subject to control are used in the clandestine manufacture of controlled substances. The reports of domestic, import, and export regulated transactions in listed chemicals are submitted electronically through the Diversion Control Division secure network application. Any person who desires to import non-narcotic substances in schedules III, IV, and V must electronically file their return information. Any person who desires to export non-narcotic substances in schedules III and IV and any other substance in schedule V is also required to electronically file a controlled substances import declaration/ controlled substance export invoice.

5. *Obligation to Respond:* Mandatory per 21 CFR 1313.

6. *Total Estimated Number of Respondents:* 631.

7. *Estimated Time per Respondent:* 11 minutes for DEA–486 Import, DEA–486 International, and DEA–486A Import, and 12 minutes for DEA–486 Export.

8. *Frequency:* 1 for DEA–486 Import and DEA–486A Import, 4 for DEA–486 International, and 77 for DEA–486 Export.

9. *Total Estimated Annual Time Burden:* Ex: 4,134 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 7, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25326 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0013]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Permit To Import Controlled Substances for Domestic and/or Scientific Purposes

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 11, 2023, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261, email: *scott.a.brinks@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0013. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Controlled Substances Import/Export Declaration.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes Pursuant to 21 U.S.C. 952.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected public (Primary):* Business or other for-profit.

Abstract: Section 1002 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 952) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.11, 1312.12 and 1312.13 requires any person who desires to import controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in section1312.30, or any nonnarcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, must have an import permit. To obtain the permit to import controlled substances for domestic and or scientific purposes, an application for the permit must be made to DEA on DEA Form 357.

5. *Obligation to Respond:* Mandatory per 21 CFR 1312.11

6. *Total Estimated Number of Respondents:* 124.

7. *Estimated Time per Respondent:* 0.26 minutes.

8. *Frequency:* 9.

9. *Total Estimated Annual Time Burden:* 264.35 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 8, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25325 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0004]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Permit To Export Controlled Substances, Application for Permit To Export Controlled Substances for Subsequent Reexport

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 11, 2023, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261, email: *scott.a.brinks@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:
—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0004. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR

cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Permit to Export Controlled Substances; Application for Permit to Export Controlled Substances for Subsequent Reexport.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* DEA Forms: 161, 161R, and 161R–EEA. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected public (Primary): Business or other for-profit. Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: Title 21, Code of Federal Regulations (21 CFR), Sections 1312.21 and 1312.22 require that any person who desires to export or reexport controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in § 1312.30, or any non-narcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, must have an export permit.

5. *Obligation to Respond:* Mandatory per 21 CFR 1312.

6. *Total Estimated Number of Respondents:* 162.

7. *Estimated Time per Respondent:* 30 minutes for DEA—161 (online) and 45 minutes for paper DEA–161, DEA–161R, and DEA–161REEA.

8. *Frequency:* DEA–161 (online) is 49.39506173 and paper DEA–161, DEA–161R, DEA–161REEA is 13.44444.

9. *Total Estimated Annual Time Burden:* 5,635 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 7, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25323 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0055]

Agency Information Collection Activities; Proposed eCollection eComments Requested; NICS Firearm Disposition Record

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on September 15, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jill A. Montgomery, NICS Business and Liaison Unit Chief, Federal Bureau of Investigation, Criminal Justice Information Services Division, National Instant Criminal Background Check System Section, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, *nicsliaison@fbi.gov* or (304) 625–2000.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1110–0055. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* NICS Firearm Disposition Record.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form number: None. Component: CJIS Division.

4. Affected public who will be asked or required to respond, as well as a brief abstract:

Affected Public: State, local and tribal governments, Federal Government.

Abstract: November 1993, the Brady Handgun Violence Prevention Act of 1993 (Brady Act) Public Law 103–159, was signed into law. The permanent provisions of the Brady Act, which went into effect on November 30, 1998, required the United States Attorney General to establish a NICS that FFLs may contact by telephone, or other

electronic means in addition to telephone for information to be supplied immediately on whether the receipt of a firearm by a prospective transferee would violate section 922 (g) or (n) of title 18, United States Code, or state law. There are additional authorized uses of NICS found at 28 CFR 25.6(j). The FBI authorized CJAs to initiate a NICS background check to assist their transfer of firearms to private individuals as a change to 28 CFR 25.6(j) in the **Federal Register**.

5. *Obligation to Respond:* Mandatory per 28 CFR 25.6(j).

6. *Total Estimated Number of Respondents:* 20,172.

7. *Estimated Time per Respondent:* Three minutes.

8. *Frequency:* 6.2 (6.24697601) times per year.

9. *Total Estimated Annual Time Burden:* 126,014 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 9, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25147 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Report of Theft or Loss of Controlled Substance and Report of Loss or Disappearance of Listed Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on September 20, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Courtney E. Mallon, Office of Diversion Control, Drug Enforcement Administration; Mailing address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812, email: *DPW@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0001. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Report of Theft or Loss of Controlled Substances and Report of Loss or Disappearance of Listed Chemical.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* DEA Form 106 and DEA Form 107. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected Public: (Primary):* Business or other for-profit. Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments. Abstract: In accordance with current 21 CFR 1301.74, a DEA registrant must notify the Field Division Office of the Administration in writing, of any theft or significant loss of any controlled substance within one business day of discovery of the theft or loss, and must complete and send to the DEA a DEA Form 106 upon determination of a theft or significant loss. The DEA Form 106 is designed to provide a uniform method of reporting and recording thefts and losses of controlled substances as required by 21 U.S.C. 827, 21 CFR 1301.74(c) and 1301.76(b). The form is entitled ''Report of Theft or Loss of Controlled Substances'' and it is used by the DEA to help determine the quantities and types of controlled substances that are stolen or lost. It may also serve as a record of the theft or loss for the registrant. DEA is modifying this collection to include DEA Form 107 as DEA Form 107 is more aligned with DEA Form 106. DEA Form 107 is used by regulated persons involved in reporting unusual or excessive loss or disappearance of a listed chemical. Each regulated person must report to the Special Agent in Charge of the DEA Diversional Office for the area in which the regulated person making the report is located any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person.

5. *Obligation to Respond:* Mandatory per 21 CFR 1301.74.

6. *Total Estimated Number of Respondents:* 10,547.

7. *Estimated Time per Respondent:* 20 minutes.

8. *Frequency:* Twice a year.

9. *Total Estimated Annual Time Burden:* 10,881 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 7, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25328 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0024]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Regulated Transactions in Tableting/ Encapsulating Machines

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 11, 2023, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261, email: *scott.a.brinks@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0024. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *Title of the Form/Collection:* Regulated Transactions in Tableting/ Encapsulating Machines.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* DEA Form 452. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected public (Primary): Business or other for-profit. Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: Each regulated person is required to report any unusual or excessive loss or disappearance of a listed chemical, and any regulated transaction in a tableting or encapsulating machine, to include any domestic regulated transaction in a tableting or encapsulating machine and any import or export of a tableting or encapsulating machine. 21 U.S.C. 830 (b)(1)(A), (C) and (D); 21 CFR 1310.05(a)(1), (3)–(4); 21 CFR 1310.05(c). Regulated persons include manufacturers, distributors, importers, and exporters of listed chemicals, tableting machines, or encapsulating machines, or persons who serve as brokers or traders for international transactions involving a listed chemical, tableting machine, or encapsulating machine. 21 CFR 1300.02(b). This report will be submitted electronically. DEA will be modifying this collection (1117–0024) and collection 1117–0001 by removing Form 107 from this collection and adding it to 1117–0001 because DEA Form 107 is more aligned with DEA Form 106 (which is approved under 1117–0001).

5. *Obligation to Respond:* Mandatory per 21 CFR 1310.

6. *Total Estimated Number of Respondents:* 274.

7. *Estimated Time per Respondent:* 33 minutes.

8. *Frequency:* 92.

9. *Total Estimated Annual Time Burden:* 8,367 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 8, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25327 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0009]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Controlled Substances Import/Export Declaration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Drug Enforcement Administration (DEA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 11, 2023, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 18, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261, email: *scott.a.brinks@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1117–0009. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Controlled Substances Import/Export Declaration.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* DEA Form 236. The Department of Justice component is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Affected public (Primary):* Business or other for-profit.

Abstract: DEA Form 236 enables DEA to monitor and control the importation and exportation of controlled substances. Analysis of these documents provides DEA with important intelligence regarding the international commerce in controlled substances and assists in the identification of suspected points of diversion.

5. *Obligation to Respond:* Mandatory.

6. *Total Estimated Number of Respondents:* 379.

7. *Estimated Time per Respondent:* 14.78424136 mins.

8. *Frequency:* 30.

9. *Total Estimated Annual Time Burden:* 2,818 hours.

10. *Total Estimated Annual Other Costs Burden:* $10,023.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: November 8, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25324 Filed 11–15–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Federal-State Unemployment Compensation Program: Certifications for 2023 Under the Federal Unemployment Tax Act.

AGENCY: Employment and Training Administration.

ACTION: Notice.

SUMMARY: The Secretary of Labor signed the annual certifications under the Federal Unemployment Tax Act, 26 U.S.C. 3301 *et seq.,* thereby enabling employers who make contributions to state unemployment funds to obtain certain credits against their liability for the federal unemployment tax. By letter, the certifications were transmitted to the Secretary of the Treasury. The letter and certifications are printed below.

Signed in Washington, DC, October 31, 2023.

Lenita Jacobs-Simmons,

Deputy Assistant Secretary, Employment and Training.

The Honorable Janet L. Yellen
Secretary of the Treasury
Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Dear Secretary Yellen:

Enclosed are an original and a copy of two separate certifications regarding unemployment compensation laws pursuant to the Federal Unemployment Tax Act, for the 12-month period ending on October 31, 2023. One certification is with respect to the federal unemployment tax credit under Section 3304 of the Internal Revenue Code of 1986 (IRC), and the other certification is with respect to the ''additional'' tax credit under Section 3303 of the IRC. Both certifications list all 53 states.

Sincerely,

Julie A. Su,
Acting Secretary of Labor.

Enclosures

CERTIFICATION OF STATES TO THE SECRETARY OF THE TREASURY PURSUANT TO SECTION 3304(c) OF THE INTERNAL REVENUE CODE OF 1986

In accordance with the provisions of Section 3304(c) of the Internal Revenue Code of 1986 (26 U.S.C. 3304(c)), I hereby certify the following named states to the Secretary of the Treasury for the 12-month period ending on October 31, 2023, in regard to the unemployment compensation laws of those states, which heretofore have been approved under the Federal Unemployment Tax Act:

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Virgin Islands
Washington
West Virginia
Wisconsin
Wyoming

This certification is for the maximum credit allowable under Section 3302(a) of the Code.

Signed at Washington, DC, on October 31, 2023.

Julie A. Su,
Acting Secretary of Labor.

CERTIFICATION OF STATE UNEMPLOYMENT COMPENSATION LAWS TO THE SECRETARY OF THE TREASURY PURSUANT TO SECTION 3303(b)(1) OF THE INTERNAL REVENUE CODE OF 1986

In accordance with the provisions of paragraph (1) of Section 3303(b) of the Internal Revenue Code of 1986 (26 U.S.C. 3303(b)(1)), I hereby certify the unemployment compensation laws of the following named states, which heretofore have been certified pursuant to paragraph (3) of Section 3303(b) of the Code, to the Secretary of the Treasury for the 12-month period ending on October 31, 2023:

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Virgin Islands
Washington
West Virginia
Wisconsin
Wyoming

This certification is for the maximum additional credit allowable under Section 3302(b) of the Code, subject to the limitations of Section 3302(c) of the Code.

Signed at Washington, DC, on October 31, 2023.

Julie A. Su,
Acting Secretary of Labor.

[FR Doc. 2023–25243 Filed 11–15–23; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Rigging Equipment for Material Handling

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 18, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of

the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The collection of information provisions of the standard specify affixing identification tags or markings on rigging equipment, developing and maintaining inspection records, and retaining proof-testing certificates. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 28, 2023 (88 FR 58620).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Rigging Equipment for Material Handling.

OMB Control Number: 1218–0233.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 115,829.

Total Estimated Number of Responses: 263,953.

Total Estimated Annual Time Burden: 49,160 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2023–25244 Filed 11–15–23; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (23–116); Document Number NASA–23–XXX; Docket Number–NASA–2022–0002]

National Environmental Policy Act; Mars Sample Return Campaign

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of availability of the Mars Sample Return (MSR) Campaign Record of Decision (ROD) for the Final Programmatic Environmental Impact Statement (PEIS).

SUMMARY: NASA announces its decision to implement the flight elements of the MSR Campaign. NASA's decision is supported by the detailed analysis found in the Final PEIS, as summarized in the agency's ROD, the availability of which is located under **ADDRESSES**.

Cooperating agencies for the MSR Campaign effort include the Department of the Air Force (DAF) for Hill Air Force Base, Utah, and Cape Canaveral Space Force Station, Florida; the Department of the Army for Dugway Proving Ground; the U.S. Department of Agriculture; and the U.S. Department of Health and Human Services—Centers for Disease Control and Prevention.

ADDRESSES: The complete text of the Tier 1 ROD for the MSR Campaign, as well as the Draft and Final PEIS, along with other supporting informational materials, are available at *https://www.nasa.gov/feature/nepa-mars-sample-return-campaign.* All comments received on the Draft PEIS are available in their entirety on the MSR Campaign Docket at *https://www.regulations.gov/docket/NASA-2022-0002.*

FOR FURTHER INFORMATION CONTACT: Mr. Steve Slaten, NASA Jet Propulsion Laboratory, by electronic mail at *Mars-sample-return-nepa@lists.nasa.gov* or by telephone at 202–358–0016. For questions regarding viewing the Docket, please call the *Regulations.gov* Help Desk at telephone: 1–877–378–5457 (toll free) or 703–454–9859.

SUPPLEMENTARY INFORMATION: The MSR Campaign includes a series of flight elements to Mars and ground operations on Earth, including spacecraft launches from Earth to Mars, retrieving the samples on Mars, and delivering them to Earth for study. The Preferred Alternative consists of the sum of the following: (1) launch of the Sample Retrieval Lander (SRL) element from Cape Canaveral Space Force Station or Kennedy Space Center and launch of the Earth Return Orbiter (ERO), which includes the Earth Entry System (EES), from the European Space Agency's launch facility in French Guiana; (2) landing of the EES (containing the retrieved Martian samples) back on Earth at the DAF-managed Utah Test and Training Range (UTTR); (3) recovery of the EES at UTTR, with supporting activities proposed at the U.S. Army-managed Dugway Proving Ground (DPG) in preparation for transfer of the EES with enclosed samples to a Sample Receiving Facility (SRF); (4) a programmatic review of representative modes of transportation of the EES from DPG to an SRF; and (5) a programmatic review of development and operation of representative types of an SRF. These last two ground elements of the MSR Campaign will be addressed under a forthcoming, tiered NEPA analysis and a separate ROD (*i.e.,* Tier 2 ROD).

The Final PEIS found that no significant adverse impacts are anticipated from implementing the MSR Campaign flight elements. NASA, in coordination with the DAF, will prepare a collaborative mitigation and monitoring plan to identify and track all short-term and long-term site preparation and EES recovery activities, non-discretionary requirements (*e.g.,* permit requirements), and Best Management Practices to ensure all actions to minimize potential environmental impacts associated with activities at DAF installations are accomplished in a timely and environmentally protective fashion.

Joel R. Carney,

Assistant Administrator, Office of Strategic Infrastructure.

[FR Doc. 2023–25242 Filed 11–15–23; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Social, Behavioral & Economic Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Social, Behavioral & Economic Sciences (#1171).

Date and Time: December 14, 2023—10 a.m.–4 p.m. (Eastern); December 15, 2023—10 a.m.–3 p.m. (Eastern).

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314, NSF Room W 2210/W 2220 (In-Person). The meeting will be held in a hybrid format, with some Advisory Committee members participating in person and others

participating virtually. For members of NSF and the external community, livestreaming and registration links will be available through the following page: *https://www.nsf.gov/sbe/advisory.jsp.*

Type of Meeting: Open.

Contact Persons: Garneski, John, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: (703) 292–4519.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to scientific programs and activities.

Agenda: Welcome, Introductions, Approval of Previous Advisory Committee (AC) Meeting Summary, and Preview of Agenda

Directorate for Social, Behavioral, and Economic Sciences (SBE) Update

Discussion on SBE and Artificial Intelligence-related research

Technology, Innovation, and Partnerships and SBE

SBE activities aligned with NSF's ''Creating Opportunities Everywhere'' portfolio

Dated: November 9, 2023.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2023–25278 Filed 11–15–23; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Alan T. Waterman Award Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Alan T. Waterman Award Committee (#1172).

Date and Time: January 29, 2024—12:30 p.m.–5:30 p.m. (Eastern).

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Type of Meeting: Closed.

Contact Persons: Gayle Pugh Lev, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–7589.

Purpose of Meeting: Virtual meeting to provide advice and recommendations in the selection of the Alan T. Waterman Award recipient(s).

Agenda: To review and evaluate nominations as part of the selection process for awards to be granted for the Alan T. Waterman Award program.

Reason for Closing: The nominations being reviewed include information of a personal nature where disclosure would constitute unwarranted invasions of personal privacy. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 9, 2023.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2023–25277 Filed 11–15–23; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Request for Information (RFI) on NSF Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research

AGENCY: National Science Foundation (NSF).

ACTION: Request for information.

SUMMARY: The National Science Foundation (NSF) is seeking public input from the science and engineering research and education community on implementing NSF Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research. This plan, described in **SUPPLEMENTARY INFORMATION**, represents an update to NSF current public access requirements in response to recent White House Office of Science and Technology Policy guidance. A primary consideration during the development of NSF's plan has been potential equity impacts of public access requirements. NSF's goal is to improve equity throughout the research life cycle, making data and opportunities available to all researchers, including those from marginalized communities and historically under-resourced institutions of higher education in the U.S. NSF is committed to considering the needs of the diverse US research community, including identifying possible unintended consequences that the plan and its implementation could produce.

DATES: Interested persons or organizations are invited to submit comments on or before 11:59 p.m. (EST) on January 2, 2024.

ADDRESSES: The preferred method of response is to complete as much of the online RFI as you wish. However, if you cannot or do not wish to access this tool, comments submitted in response to this notice may also be submitted by the following methods:

Email: PublicAccess2-RFI@nsf.gov. Email submissions should be machine-readable and not be copy-protected. Submissions should include ''RFI Response: NSF Public Access 2.0'' in the subject line of the message.

Mail: Attn. Martin Halbert, 2415 Eisenhower Ave., Alexandria, VA 22314.

Responses may address one or as many topics as desired from the enumerated list provided in this RFI, noting the corresponding number of the topic(s) to which the response pertains. Submissions must not exceed 3 pages (exclusive of cover page) in 11-point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) filing the comment, as well as the respondent type (*e.g.,* academic institution, advocacy group, professional society, community-based organization, industry, member of the public, government, other). Respondent's role in the organization may also be provided (*e.g.,* researcher, administrator, student, program manager, journalist) on a voluntary basis.

No business proprietary information, copyrighted information, or personally identifiable information (aside from that requested above) should be submitted in response to this RFI. Comments submitted in response to this RFI will be used internally at NSF and may be shared with other Federal agencies. Any online or public release of data will only be in aggregate form to protect the identity of submitters. Please note that all questions are optional.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Martin Halbert at *PublicAccess2-RFI@nsf.gov,* (703) 292–5111.

SUPPLEMENTARY INFORMATION: The U.S. National Science Foundation Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research has been prepared in response to the memorandum dated August 25, 2022, from the White House Office of Science and Technology Policy, or OSTP, titled Ensuring Free, Immediate, and Equitable Access to Federally Funded Research, and signed by Alondra Nelson. It updates NSF's original public access plan, Today's Data, Tomorrow's Discoveries: Increasing Access to the Results of Research Funded by the National Science Foundation, dated March 18, 2015.

Broadly, Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research describes how:

- all peer-reviewed scholarly publications resulting from NSF-funded research will be made freely available

and publicly accessible by default in the NSF Public Access Repository, or NSF–PAR, without embargo;

- such publications will be accessible for assistive technologies;
- scientific data associated with peer-reviewed publications resulting from NSF awards will be made available in disciplinary repositories;
- exceptions to the data-sharing requirements will be made based on legal, privacy, ethical, intellectual property and national security considerations; and
- persistent identifiers, or PIDs, and other critical information associated with peer-reviewed publications and data resulting from NSF-funded research will be collected and made publicly available in NSF–PAR.

NSF is committed to ensuring that its approach to public access enhances equity in the science and engineering ecosystem and wants to understand any potential barriers that may be faced by researchers in complying with new public access requirements. Responses may suggest areas of particular interest to the research community that inspire future NSF funding opportunities and development plans for NSF–PAR.

NSF seeks responses from all interested individuals and communities including—but not limited to—individual researchers, research institutions, libraries, scholarly societies, scholarly publishers, early career researchers, and students/educators. NSF is particularly interested in hearing from researchers new to public access at NSF, new to open science practices more generally, or working in fields or institutions with unique challenges in complying with public access requirements, to ensure that NSF is well-positioned to fully consider potential equity impacts as the plan is implemented.

Comments are welcome on all elements of NSF Public Access Plan 2.0 but would be particularly welcome for the issues/questions identified below. Please note that all questions are optional.

1. Overall, do you view public access requirements as having more positive or more negative effects on equity and inclusion in science (indicate one)?

- mostly positive
- somewhat positive
- neither positive nor negative
- somewhat negative
- mostly negative

2. Do you currently have access to data repositories that will enable you to comply with public access requirements? (indicate one)?

- Yes, I have access
- Yes, I have access, but it is limited
- No, I don't have access
- I don't know

3. What opportunities or benefits do you anticipate you and/or your institution would realize from the requirement that NSF-funded peer-reviewed publications be made available in the NSF Public Access Repository (NSF–PAR)? (Please limit response to 500 characters.)

4. What challenges or barriers do you anticipate personally facing while complying with the requirement that NSF-funded peer reviewed publications be made available in NSF–PAR? (Please limit response to 500 characters) What opportunities or benefits do you anticipate you and/or your institution would realize from the requirement that the data underlying your NSF-funded peer-reviewed publications be made publicly available? (Please limit response to 500 characters.)

5. What challenges or barriers do you anticipate personally facing while complying with the requirement that the data underlying your NSF-funded peer-reviewed publications be made publicly available? (Please limit response to 500 characters.)

6. How can NSF best engage affected communities regarding public access issues, in particular marginalized or underrepresented groups? (Please limit response to 500 characters.)

7. If you have any additional comments about NSF's Public Access Plan, please share them here. (Please limit response to 2,000 characters.)

8. What is your primary field of research, employment, or study (indicate one)?

- Astronomy and astrophysics
- Biological, agricultural, environmental life sciences
- Computer and information sciences
- Engineering
- Humanities or liberal arts
- Learning sciences/education research
- Library or communication sciences
- Mathematics and statistics
- Medical and health sciences
- Physical and geosciences (including atmospheric and ocean sciences)
- Social sciences
- Publisher (for profit)
- Publisher (society or non-profit)
- Other (please specify)

9. What type of institution(s) best describes where you work? (Note: if you hold a dual appointment, please indicate all that apply.)

- U.S. 4-year university; Doctoral-granting, high or very high research activity
- U.S. 4-year university; Doctoral-granting, other
- U.S. 4-year university or college; Masters-granting (*i.e.,* no Doctoral programs offered)
- U.S. 4-year college or university; Baccalaureate-granting (*i.e.,* no Doctoral or Masters programs offered)
- U.S. community or 2-year college
- U.S. university-affiliated research institute
- Government agency (Federal, State or local)
- Non-governmental, non-university affiliated research organization
- Non-profit organization (including tax-exempt, charitable organization and private foundation)
- For-profit company or organization
- Other (please specify)

10. If you work at a university, please indicate all categories that represent your university (indicate all that apply):

- Asian American and Native American Pacific Islander-Serving Institution (AANAPI)
- Hispanic Serving Institution (HSI)
- Historically Black College or University (HBCU)
- Minority serving Institution (MSI)
- Tribal College or University (TCU)
- Women's College or University
- Other
- None of the above

11. If you are engaged in academic research, in what stage of your career are you (indicate one)?

- undergraduate student
- graduate student
- early career researcher (<10 years post-Ph.D.)
- mid-career researcher (10–25 years post-Ph.D.)
- late-career researcher (<25 years post-Ph.D.)
- not applicable

12. What communities do you work with in your research (*i.e.,* about whom or from whom data is collected)? Please indicate all that apply.

- American Indian or Alaska Native communities
- Asian communities
- Black or African American communities
- Latine/x/o/a communities
- LGBTIQA+ communities
- Native Hawaiian or Other Pacific Islander communities
- Persons with disabilities
- non-US-based communities
- communities with limited socioeconomic status
- not applicable
- Other (please specify)

13. Are you Hispanic or Latino?

- No, I am not Hispanic or Latino
- Yes, I am Mexican or Chicano
- Yes, I am Puerto Rican

- Yes, I am Cuban
- Yes, I am other Hispanic or Latino (please specify):

14. What is your racial background (indicate all that apply)?

- American Indian or Alaska Native—specify Tribal affiliations(s)
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

15. Do you identify as a disabled person with respect to any of the following specific functions (indicate all that apply)?

- SEEING words or letters in ordinary newsprint (with glasses/contact lenses, if you usually wear them)
- HEARING in conversation with another person (with hearing aid or other assistive device, if you usually wear one)
- WALKING without human or mechanical assistance or using stairs
- LIFTING or carrying something as heavy as 10 pounds, such as a bag of groceries
- CONCENTRATING, REMEMBERING, or MAKING DECISIONS because of a physical, mental or emotional condition
- Other disability (please specify)

16. Is there anything else you would like to tell us about your identity that impacts the way you are perceived or your access to the scholarly ecosystem (*e.g.,* age, gender identity, sexual orientation etc.) (Please limit response to 2,000 characters.).

Authority: 42 U.S.C. 1861, *et al.*

Dated: November 8, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–25267 Filed 11–15–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–0398; NRC–2023–0184]

U.S. Department of Commerce; National Institute of Standards and Technology

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal application; opportunity to request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application from the U.S. Department of Commerce, National Institute of Standards and Technology (NIST or the applicant), to renew Special Nuclear Material (SNM) License Number 362 (SNM–362). The renewed license would authorize the applicant to continue to use SNM and other radiation sources for research and development, calibration and testing, and training activities at its campus in Gaithersburg, Maryland. If the license renewal application is approved, the license would authorize NIST to continue to possess and use SNM under NRC regulations for 10 years beyond its current license.

DATES: A request for a hearing or petition for leave to intervene must be filed by January 16, 2024.

ADDRESSES: Please refer to Docket ID NRC–2023–0184 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0184. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Osiris Siurano-Pérez, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7827, email: *Osiris.Siurano-Perez@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC received, by letter dated August 8, 2023 (ADAMS Package Accession No. ML23221A162), an application from NIST to renew its license, SNM–362. NIST is authorized to use SNM under part 70 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Special Nuclear Material,'' at its campus in Gaithersburg for research and development, calibration and testing, and training activities. More specifically, NIST uses SNM for activities associated with the development and maintenance of radiation measurement standards, radioactivity assessment, the provision of radiation measurement services, and the study of radiation interactions and processes in materials.

The renewed license would allow NIST to continue licensed activities for 10 years. NIST's current license would have expired on September 9, 2023; however, NIST timely filed a license renewal application. In accordance with 10 CFR 70.38(a), when a licensee files an application for renewal not less than 30 days before the expiration date of the existing license, the license will not expire until the Commission makes a final determination regarding the license renewal application. As such, NIST's current license is still in effect.

An NRC acceptance review of the revised application, dated October 6, 2023 (ADAMS Accession No. ML23271A220), found the application acceptable for a technical review. During the technical review, the NRC will evaluate the application for radiation safety, nuclear criticality safety, chemical safety, fire safety, security, decommissioning, decommissioning financial assurance, and material control/accountability. The NRC will document its findings in a safety evaluation report.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the renewal of the special nuclear materials license. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed within 60 days, the presiding officer will rule on the

petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local governmental body, federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h), no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC website at *https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate.*

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as discussed below, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system timestamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

Dated: November 6, 2023.

For the Nuclear Regulatory Commission.

Samantha C. Lav,

Chief, Fuel Facility Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–24804 Filed 11–15–23; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service

Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 8, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 102 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–48, CP2024–48.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–25258 Filed 11–15–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 9, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 104 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–50, CP2024–50.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–25262 Filed 11–15–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 8, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 103 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–49, CP2024–49.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–25261 Filed 11–15–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 16, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 8, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 101 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–47, CP2024–47.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–25263 Filed 11–15–23; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–325, OMB Control No. 3235–0385]

Submission for OMB Review; Comment Request; Extension: Rule 15g–9

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Section 15(c)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (the ''Exchange Act'') authorizes the Commission to promulgate rules that prescribe means reasonably designed to prevent fraudulent, deceptive, or manipulative practices in connection with over-the-counter (''OTC'') securities transactions. Pursuant to this authority, the Commission in 1989 adopted Rule 15c2–6, which was subsequently redesignated as Rule 15g–9 (17 CFR 240.15g–9) (the ''Rule''). The Rule requires broker-dealers to produce a written suitability determination for, and to obtain a written customer agreement to, certain recommended transactions in penny stocks that are not registered on a national securities exchange, and whose issuers do not meet certain minimum financial standards. The Rule is intended to prevent the indiscriminate use by broker-dealers of fraudulent, high pressure telephone sales campaigns to sell penny stocks to unsophisticated customers.

The Commission staff estimates that approximately five percent of registered broker-dealers, or 175 broker-dealers,[1] are subject to the Rule (5% × approximately 3,497 registered broker-dealers = 175 broker-dealers). As indicated above, the burden of the Rule on a respondent varies widely depending on the frequency with which new customers are solicited. On average, for all respondents, the staff has estimated that respondents process three new customers per week, or approximately 156 new customers

[1] As of July 1, 2023, there are 3,497 registered broker-dealers. 5% of 3,497 is 174.85, rounded up to 175.

requiring suitability determinations per year. We also estimate that a broker-dealer would take approximately one-half hour per new customer in obtaining, reviewing, and processing (including transmitting to the customer) the information required by Rule 15g–9, and each respondent would consequently spend 78 hours annually (156 new customers × .5 hours) obtaining the information required in the Rule. This would result in 27,300 annual responses per year for all respondents (175 respondents × 156 new customer suitability determinations per year). We determined, based on the estimate of 175 broker-dealer respondents, that the annual hour burden of Rule 15g–9 is 13,650 hours (175 respondents × 78 hours).

The broker-dealer must keep the written suitability determination and customer agreement required by the Rule for at least three years. Completing the suitability determination and obtaining the customer agreement in writing is mandatory for broker-dealers who effect transactions in penny stocks and do not qualify for an exemption, but does not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by December 18, 2023 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 13, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25355 Filed 11–15–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–096, OMB Control No. 3235–0151]

Submission for OMB Review; Comment Request; Extension: Rule 17Ac3–1(a) and Form TA–W

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17Ac3–1(a) (17 CFR 240.17Ac3–1(a)) and Form TA–W (17 CFR 249b.101), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Section 17A(c)(4)(B) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(34)(B) authorizes transfer agents registered with an appropriate regulatory agency (''ARA'') to withdraw from registration by filing with the ARA a written notice of withdrawal and by agreeing to such terms and conditions as the ARA deems necessary or appropriate in the public interest, for the protection of investors, or in the furtherance of the purposes of Section 17A.

In order to implement Section 17A(c)(4)(B) of the Exchange Act, the Commission promulgated Rule 17Ac3–1(a) and accompanying Form TA–W on September 1, 1977. Rule 17Ac3–1(a) provides that notice of withdrawal of registration as a transfer agent with the Commission shall be filed on Form TA–W. Form TA–W requires the withdrawing transfer agent to provide the Commission with certain information, including: (1) the locations where transfer agent activities are or were performed; (2) the reasons for ceasing the performance of such activities; (3) disclosure of unsatisfied judgments or liens; and (4) information regarding successor transfer agents.

The Commission uses the information disclosed on Form TA–W to determine whether the registered transfer agent applying for withdrawal from registration as a transfer agent should be allowed to deregister and, if so, whether the Commission should attach to the granting of the application any terms or conditions necessary or appropriate in the public interest, for the protection of investors, or in furtherance of the purposes of Section 17A of the Exchange Act. Without Rule 17Ac3–1(a) and Form TA–W, transfer agents registered with the Commission would not have a means to voluntarily deregister it is necessary or appropriate to do so.

On average, respondents have filed approximately 50 Form TA–Ws with the Commission annually from 2020 to 2023. A Form TA–W filing occurs only once, when a transfer agent is seeking deregistration. In view of the readily available information requested by Form TA–W, its short and simple presentation, and the Commission's experience with the filers, we estimate that approximately 30 minutes is required to complete and file Form TA–W. Thus, the total annual time burden to the transfer agent industry is approximately 25 hours (50 filings × 0.5 hours). We estimate that the internal labor cost of compliance per filing $39 (0.5 hours × $78 average hourly rate for clerical staff time).[1] Thus, the total internal compliance cost per year is thus approximately $975 (25 hours × $39 = $975).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by December 18, 2023 to

(i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 13, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25362 Filed 11–15–23; 8:45 am]

BILLING CODE 8011–01–P

[1] The $78 per hour figure for clerical staff time is from SIFMA's *Office Salaries in the Securities Industry 2013,* modified by Commission staff to account for an 1,800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–236, OMB Control No. 3235–0222]

Proposed Collection; Comment Request; Extension: Rule 17f–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for extension and approval.

Rule 17f–1 (17 CFR 270.17f–1) under the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a) is entitled: ''Custody of Securities with Members of National Securities Exchanges.'' Rule 17f–1 provides that any registered management investment company (''fund'') that wishes to place its assets in the custody of a national securities exchange member may do so only under a written contract that must be ratified initially and approved annually by a majority of the fund's board of directors. The written contract also must contain certain specified provisions. In addition, the rule requires an independent public accountant to examine the fund's assets in the custody of the exchange member at least three times during the fund's fiscal year. The rule requires the written contract and the certificate of each examination to be transmitted to the Commission. The purpose of the rule is to ensure the safekeeping of fund assets.

Commission staff estimates that each fund makes 1 response and spends an average of 3.5 hours annually in complying with the rule's requirements. Commission staff estimates that on an annual basis it takes: (i) 0.5 hours for the board of directors [1] to review and ratify the custodial contracts; and (ii) 3 hours for the fund's controller to assist the fund's independent public auditors in verifying the fund's assets. Approximately 8 funds rely on the rule annually, with a total of 8 responses.[2] Thus, the total annual hour burden for rule 17f–1 is approximately 28 hours.[3]

Funds that rely on rule 17f–1 generally use outside counsel to prepare the custodial contract for the board's review and to transmit the contract to the Commission. Commission staff estimates the cost of outside counsel to perform these tasks for a fund each year is $1,130.[4] Funds also must have an independent public accountant verify the fund's assets three times each year and prepare the certificate of examination. Commission staff estimates the annual cost for an independent public accountant to perform this service is $10,412.[5] Therefore, the total annual cost burden for a fund that relies on rule 17f–1 would be approximately $11,542.[6] As noted above, the staff estimates that 8 funds rely on rule 17f–1 each year, for an estimated total annualized cost burden of $92,336.[7]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Compliance with the collections of information required by rule 17f–1 is mandatory for funds that place their assets in the custody of a national securities exchange member. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by January 16, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 13, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25361 Filed 11–15–23; 8:45 am]

BILLING CODE 8011–01–P

[1] Estimates of the number of hours are based on conversations with representatives of mutual funds that comply with the rule. The actual number of hours may vary significantly depending on individual fund assets. The hour burden for rule 17f–1 does not include preparing the custody contract because that would be part of customary and usual business practice.

[2] Based on a review of Form N-17f–1 filings over the last three years the Commission staff estimates that an average of 8 funds rely on rule 17f–1 each year.

[3] This estimate is based on the following calculation: (8 respondents × 3.5 hours = 28 hours). The annual burden for rule 17f–1 does not include time spent preparing Form N-17f–1. The burden for Form N-17f–1 is included in a separate collection of information.

[4] This estimate is based on the following calculation: (2 hours of outside counsel time × $565 = $1,130). The staff has estimated the average cost of outside counsel at $565 per hour, based on information received from funds and their counsel.

[5] This estimate is based on information received from fund representatives estimating the aggregate annual cost of an independent public accountant's periodic verification of assets and preparation of the certificate of examination.

[6] This estimate is based on the following calculation: $1,130 + $10,412 = $11,542.

[7] This estimate is based on the following calculation: 8 funds × $11,542 = $92,336.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–578, OMB Control No. 3235–0639]

Proposed Collection; Comment Request; Extension: Rule 12d1–4

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 12d1–4 (17 CFR 270.12d1–4)under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act'') permits certain registered funds and business development companies (''BDC'') (''acquiring fund') that satisfy certain conditions to acquire shares of other certain registered funds and BDCs (''acquired fund'') in excess of the limits of section 12(d)(1) of the Act without obtaining an exemptive order from the Commission.[1] This collection of information is voluntary because rule

[1] *See* 17 CFR 270.12d1–4.

12d1–4 is an exemptive rule and, therefore, funds may choose not to rely on the proposed rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The purpose of the information collection requirement in rule 12d1–4 is to ensure both that the concerns that led Congress to adopt section 12(d)(1) are mitigated and that funds relying upon the rule as an exemption from that section comply with the rule's requirements. The following estimates of average internal burden hours are made solely for purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and are not derived from a comprehensive or even representative survey or study of the cost of Commission rules and forms.

Voting Provisions. With respect to voting provisions, Commission staff estimates that 446 acquiring funds will be subject to the requirements in rule 12d1–4(b)(ii), 436 of which will be utilizing mirror voting and 10 of which will be utilizing pass-through voting.[2] With respect to mirror voting, Commission staff estimates that, on average, internal counsel for such funds will spend 3 hours updating proxy voting policies and disclosures for such funds and 3 hours conducting voting procedures. Thus, the staff estimates that the annual hour burden of the collection of information imposed by the mirror voting provisions to be 6 hours per fund, resulting in a total burden of 2,616 hours.[3]

In addition to the mirror voting provisions of the rule, there are some circumstances in which the acquiring funds are the only shareholders of an acquired fund, and in such cases, pass-through voting may be used. Staff estimates that 10 funds will use pass-through voting. Staff estimates that internal counsel for such funds will spend 3 hours updating proxy voting policies and disclosures and 30 hours communicating with shareholders and voting accordingly. Thus, the staff estimates that the annual hour burden of the collection of information imposed by the pass-through provisions to be 33 hours per fund, resulting in a total burden of 330 hours.[4]

Combining the estimates for the mirror voting and pass-through voting calculations, staff estimates that 446 funds will spend a total of 2,946 hours complying with the voting provisions of the rule.[5]

Fund of Funds Investment Agreements. With respect to the fund of funds investment agreement provisions, Commission staff estimates that 12,900 funds that do not have the same investment adviser are subject to the requirement to enter into an agreement prior to the purchase of acquired fund shares in excess of section 12(d)(1)'s limits.[6] Commission staff estimates, however, that the majority of affected funds have already complied with this requirement and staff assumes that, absent structured data to further calculate, 645 funds (5% of affected funds) would be newly subject to the rule on an annual basis.[7] Commission staff estimates that such newly affected funds will spend 20 hours negotiating and memorializing the necessary agreements. Commission staff further estimates that newly affected funds will spend 6 hours establishing recordkeeping and policies and procedures. Accordingly, staff estimates that the annual burden solely for newly affected funds will be 26 hours.[8] Commission staff further estimates that all affected funds will spend 12 hours on ongoing recordkeeping, resulting in a total annual hour burden of 171,570 hours.[9]

Management Companies—Fund Filings. With respect to the management company fund finding provisions, Commission staff estimates that 2,974 acquired management companies will be subject to rule 12d1–4.[10] Commission staff further estimates that 4,965 acquiring management companies will be subject to rule 12d1–4.[11] This results in 7,939 management companies being subject to rule 12d1–4.[12] Commission staff estimates that such management companies will spend 18 hours conducting evaluations and creating, reviewing, and maintaining written materials pursuant to the rule, resulting in a total annual hour burden of 142,902 hours.[13]

UITs—Principal Underwriter or Depositor Evaluations. With respect to

[2] 446 acquiring funds that will invest in open-end funds or UITs in reliance on rule 12d1–4 and beyond the 25% voting threshold = 4,061 series of management companies relying upon rule 12d1–4 or statutory exemption per Form N–CEN items C.7.l and C.7.m (based on data as of December 2022, as derived from N–CEN filings through July 14, 2023) plus 37 acquiring BDCs (consistent with the prior renewal) and multiplied by 11% of acquiring funds that invest in at least one open-end fund or UIT beyond the 25% voting threshold of the rule (as estimated in the prior renewal). This estimate assumes that acquiring funds with current investments in other funds beyond the limits of section 12(d)(1) are subject to rule 12d1–4 at the same rate as the acquiring funds with current investments in other funds within the limits of section 12(d)(1). We lack structured data that would allow us to estimate the percentage of acquiring funds that are within the same group of investment companies as the acquired fund or the acquiring fund's investment sub-adviser or any person controlling, controlled by, or under common control with such investment sub-adviser acts as the acquired fund's investment adviser or depositor, and thus will be subject to the rule's voting condition. To avoid underestimating the costs associated with this aspect of rule 12d1–4, we assume that all the 446 acquiring funds will be subject to the rule's conditions. We estimate that of 10 funds will utilize pass-through voting in limited circumstances. In circumstances where all holders of the outstanding voting securities of the acquired fund are required by rule 12d1–4 or otherwise under section 12(d)(1) to mirror vote the securities of the acquired fund, the acquiring fund may use pass-through instead of mirror voting. It is estimated that (consistent with the prior renewal) 2.2% of acquiring funds that will invest in open-end funds or UITs in reliance on rule 12d1–4 and beyond the 25% voting threshold will use pass-through voting (*i.e.,* 2.2% of 446 acquiring funds equals 10 funds using pass-through voting).

[3] This estimate is based on the following calculations: 2,616 = 6 hours × 436 funds.

[4] This estimate is based on the following calculations: 330 hours (33 hours × 10 funds).

[5] This estimate is based on the following calculations: 446 (436 + 10; combined total of funds using mirror voting and funds using pass-through voting); 2,946 (2,616 hours plus 330 hours).

[6] This estimate is based on the number of acquiring-acquired fund pairs that do not share the same adviser as indicated in form N–PORT data between December 2022 and July 14, 2023 (18,695) and, consistent with the prior renewal, assumes that 69% of such acquiring-acquired fund pairs will be subject to rule 12d1–4 (*i.e.,* 12,900 = 18,695 × 0.69).

[7] This estimate is based on the following calculation: 645 = 12,900 × 0.05.

[8] This estimate is based on the following calculations: 26 hours = 20 + 6.

[9] This estimate is based on the following calculations: 171,570 hours = (26 hours × 645 newly affected funds) + (12 hours × 12,900 affected funds).

[10] 2,974 acquired management companies that will be subject to rule 12d1–4 = 4,310 acquired management companies × 69% of acquired management companies that will be subject to rule 12d1–4 (as estimated in the prior renewal). Our calculation assumes that the estimate of acquiring funds that will be subject to rule 12d1–4 is also applicable to acquired funds. 4,310 acquired management companies = 3,170 acquired registered investment companies (based on data as of December 2022, as derived from N–PORT filings through July 14, 2023) × 17,546 registered investment companies (based on data as of December 2022, as derived from N–PORT filings through July 14, 2023)/12,906 management companies (based on data as of December 2022, as derived from N–CEN filings through July 14, 2023). This estimate assumes that acquired management companies with investments from acquiring funds beyond the limits of section 12(d)(1) will be subject to rule 12d1–4 at the same rate as the acquired management companies with investments from acquiring funds within the limits of section 12(d)(1).

[11] 4,965 acquiring management companies that will be subject to rule 12d1–4 = 7,195 acquiring management companies (based on data as of December 2022, as derived from N–PORT filings through July 14, 2023) × 69% of acquiring management companies that will be subject to rule 12d1–4 (consistent with the prior renewal). This estimate assumes that acquiring management companies with current investments in other funds beyond the limits of section 12(d)(1) will be subject to rule 12d1–4 at the same rate as the acquiring management companies with current investments in other funds within the limits of section 12(d)(1) following the rule adoption.

[12] 7,939 = 2,974 + 4,965.

[13] This estimate is based on the following calculations: 142,902 = 18 hours × 7,939 funds.

the UIT principal underwriter or depositor evaluations, Commission staff estimates that 541 acquiring UITs will be subject to rule 12d1–4.[14] Commission staff estimates that such UITs will spend 5 hours annually conducting evaluations and creating, reviewing, and maintaining written materials.[15] This results in a total annual hour burden of 2,705 hours.[16]

Separate Accounts Funding Variable Insurance Contracts. With respect to the separate account funding variable insurance contracts, Commission staff estimates that 186 acquiring separate accounts will be subject to rule 12d1–4.[17] Commission staff estimates that separate accounts will spend 4 hours annually obtaining certificates and maintaining records, resulting in a total annual hour burden of 744 hours.[18]

The following estimates of external costs are made solely for purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and are not derived from a comprehensive or even representative survey or study of the cost of Commission rules and forms.

Voting Provisions. The staff estimates that, on average, outside counsel will spend 1 hour per vote conducting voting procedures with respect to mirror voting at a cost of $565 per hour. Staff therefore estimates an annual external cost burden of $246,340 with respect to mirror voting.[19] Staff further estimates that, with respect to pass-through voting, outside counsel will spend 1 hour to assist funds in communicating with shareholders and voting accordingly at a rate of $565 per hour. Staff therefore estimates an annual external cost burden of $5,650 with respect to pass-through voting.[20] Accordingly, staff estimates a total annual external cost of $251,990 for compliance with the voting provisions of the rule.[21]

Fund of Funds Investment Agreement. Staff estimates that, on average, for funds newly subject to the rule, outside counsel will spend 2 hours negotiating and memorializing the necessary agreements under the rule at a cost of $565 per hour. Staff further estimates that, on average, for funds newly subject to the rule, outside counsel will spend 4 hours establishing recordkeeping policies and procedures. Accordingly, staff estimates a total annual external costs of $2,186,550 for compliance with the fund of funds investment agreement provisions of the rule.[22]

Management Companies—Fund Filings. It is estimated that there is no external cost burden with respect to the management company findings provisions of the rule.

UITs—Principal Underwriter or Depositor Evaluations. It is estimated that there is no external cost burden with respect to the UIT evaluation provisions of the rule.

Separate Accounts Funding Variable Insurance Contracts. It is estimated that there is no external cost burden with respect to the separate account certification provisions of the rule.

As outlined above, we estimate the total external cost burden to comply with rule 12d1–4 to be $2,438,540.[23]

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by January 16, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 13, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25360 Filed 11–15–23; 8:45 am]

BILLING CODE 8011–01–P

[14] This estimate assumes that there are 1,353 series of UITs and that 40% of such UITS are acquiring UITs (as estimated in the prior renewal). The estimate of 1,353 series of UITs is based on data as of December 2022, as derived from N–CEN filings (items F.18 and F.19) through July 14, 2023.

[15] This estimate assumes 2.5 hours of general clerk time and 2.5 hours of senior computer operator time 5 hours = 2.5 + 2.5.

[16] This estimate is based on the following calculations: 2,705 = 5 hours × 541 funds.

[17] 186 acquiring separate accounts that will be subject to rule 12d1–4 = [418 variable annuity separate accounts registered as UITs + 240 variable life insurance separate accounts registered as UITs + 15 management company separate accounts (these figures are based on data as of December 2022, as derived from N–CEN filings through July 14, 2023)] × 40% of funds that are acquiring funds (as estimated in the prior renewal) × 69% of acquiring separate accounts that will be subject to rule 12d1–4 as estimated by a commenter (as estimated in the prior renewal).

[18] This estimate is based on the following calculations: 744 = 4 hours × 186 funds.

[19] $246,340 = ($565 × 1 hour) × 436.

[20] $5,650 = ($565 × 1 hour) × 10 funds subject to pass through voting.

[21] $251,990 = $246,340 + $5,650.

[22] $2,186,550 = [($565 × 2) + ($565 × 4)] × 645 funds newly subject to the fund of funds investment agreement provisions of the rule. *See* footnote 7 for the calculation of funds newly subject to the rule.

[23] $2,438,540 = $251,990 + $2,186,550.

SMALL BUSINESS ADMINISTRATION

National Small Business Development Center Advisory Board

AGENCY: Small Business Administration.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time and agenda for a meeting of the National Small Business Development Center Advisory Board. The meeting will be open to the public; however, advance notice of attendance is required.

DATES: Tuesday, December 5, 2023, at 2:00 p.m. EST.

ADDRESSES: Meeting will be held via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: Rachel Karton, Office of Small Business Development Centers, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416; *Rachel.newman-karton@sba.gov;* 202–619–1816.

If anyone wishes to be a listening participant or would like to request accommodations, please contact Rachel Karton at the information above.

SUPPLEMENTARY INFORMATION: Pursuant to section l0(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), the SBA announces the meetings of the National SBDC Advisory Board. This Board provides advice and counsel to the SBA Administrator and Associate Administrator for Small Business Development Centers.

Purpose

The purpose of the meeting is to discuss the following pertaining to the SBDC Program:

- Annual Plan
- Outreach and Engagement with SBDC State Directors

Additionally, SBA will be seeking three volunteers from the Advisory Board to participate as judges for the National Small Business Week Small

Business Development Centers Excellence and Innovation Award.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2023–25296 Filed 11–15–23; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36735]

3i RR Holdings GP LLC, 3i RR Holdings Partnership L.P., 3i RR Intermediate Holdings LLC, 3i RR LLC, Regional Rail Holdings, LLC, Regional Rail Sub Holdings LLC, and Regional Rail, LLC—Control Exemption—Indiana Eastern Railroad, LLC

3i RR Holdings GP LLC, 3i RR Holdings Partnership L.P., 3i RR Intermediate Holdings LLC, 3i RR LLC, Regional Rail Holdings, LLC, and Regional Rail Sub Holdings LLC (collectively, 3i RR) and Regional Rail, LLC (Regional Rail), each a noncarrier, have filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Indiana Eastern Railroad, LLC (IERR). IERR is a Class III rail carrier that operates a rail line in Indiana and Ohio and, doing business as Ohio South Central Railroad, operates on a separate, noncontiguous line in Ohio.

According to the verified notice, Regional Rail is directly controlled by Regional Rail Sub Holdings LLC, which is controlled by Regional Rail Holdings, LLC, which is controlled by 3i RR LLC, which is controlled by 3i RR Intermediate Holdings LLC, which is controlled by 3i RR Holdings Partnership L.P., which is controlled by 3i RR Holdings GP LLC. The verified notice states that Regional Rail is a noncarrier holding company that directly controls 11 Class III rail carriers in the eastern United States.[1]

According to the verified notice, pursuant to a membership interest purchase agreement to be entered into by Regional Rail, IERR, and IERR's current owners, Regional Rail proposes to acquire all the existing equity interest of IERR and assume direct control of that carrier.[2] 3i RR would assume indirect control of IERR. The verified notice further states that no significant changes in the rail services currently provided by IERR are anticipated as a result of the proposed transaction and that the agreement does not include any provision that would limit the future interchange of traffic with a third-party connecting carrier.

3i RR and Regional Rail represent that: (1) the rail lines of IERR do not connect with the lines of the rail carriers currently controlled by 3i RR and Regional Rail; (2) this control transaction is not part of a series of anticipated transactions that would result in such a connection; and (3) the transaction does not involve a Class I rail carrier. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2).

This transaction may be consummated on or after November 30, 2023, the effective date of the exemption (30 days after the verified notice was filed).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 22, 2023.

All pleadings, referring to Docket No. FD 36735, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on 3i RR's and Regional Rail's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to 3i RR and Regional Rail, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 8, 2023.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023–25298 Filed 11–15–23; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2020–0532; Summary Notice No. –2023–43]

Petition for Exemption; Summary of Petition Received; Causey Aviation Unmanned, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2023.

ADDRESSES: Send comments identified by docket number FAA–2020–0532 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m.,

[1] Those carriers, and the states in which they operate, are: (1) Carolina Coastal Railway, Inc. (North Carolina and South Carolina); (2) East Penn Railroad, LLC (Delaware and Pennsylvania); (3) Florida Central Railroad Company, Inc. (Florida); (4) Florida Midland Railroad Company, Inc. (Florida); (5) Florida Northern Railroad Company, Inc. (Florida); (6) Middletown & New Jersey Railroad, LLC (New York); (7) Port Manatee Railroad LLC (Florida); (8) Tyburn Railroad LLC (Pennsylvania); (9) Effingham Railroad Company (Illinois); (10) Illinois Western Railroad Company (Illinois); and (11) South Point & Ohio Railroad, Inc. (Ohio).

[2] Public and confidential versions of the agreement were filed with the verified notice. The confidential version was submitted under seal concurrent with a motion for protective order, which is addressed in a separate decision.

Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 9, 2023.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0532.

Petitioner: Causey Aviation Unmanned, Inc.

Section(s) of 14 CFR Affected: §§ 61.133, 91.7(a), 91.119(b) and (c), 91.121, 91.151(b), 91.203(a)(1), 135.25(a), 135.63(c) and (d), 135.79(a)(1) through (3), 135.149(a), 135.161(a)(1), (a)(3) and (b)(1), 135.203(b), 135.209(b), 135.243(b)(1) and (b)(2), 135.267(a)(1) through (3) and (c)(1) through (3), 135.293(h), and 135.415(b)

Description of Relief Sought: Causey Aviation Unmanned, Inc. requests an amendment to Exemption No. 19508 to allow commercial package delivery under Part 135 air carrier operations outside of the United States using the Rigitech Eiger unmanned aircraft system.

[FR Doc. 2023–25294 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2022–0268; Summary Notice No. 2023–42]

Petition for Exemption; Summary of Petition Received; American Aerospace Technologies Incorporated

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2023.

ADDRESSES: Send comments identified by docket number FAA–2022–0268 using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.

• *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sean O'Tormey at 202–267–4044, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 9, 2023.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2022–0268.

Petitioner: American Aerospace Technologies Incorporated.

Section(s) of 14 CFR Affected: §§ 61.133(a), 91.7(a), 91.9(b)(2), 91.105(a)(1), 91.105(a)(2), 91.107, 91.109, 91.121, 91.203(a), 91.203(b), 91.405(a), 91.407(a)(1), 91.409(a)(1), 91.409(a)(2), and Part 21, Subpart H, of Title 14, Code of Federal Regulations.

Description of Relief Sought: Petitioner is seeking to operate a fixed wing unmanned aircraft systems (UAS) weighing over 55 pounds, in order to conduct: critical infrastructure inspection of pipeline and oil field surveillance; emergency response (*e.g.,* wildland fire surveillance); research and development; and training, all beyond visual line of site (BVLOS) of the pilot in command (PIC) using Detect and Avoid systems, in the San Joaquin Valley of California.

[FR Doc. 2023–25291 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2023–1782; Summary Notice No.–2023–45]

Petition for Exemption; Summary of Petition Received; SkyWest Charter

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the

FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–1782 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jimeca Callaham, (202) 267–0312, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 9, 2023.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2023–1782.

Petitioner: SkyWest Charter.

Section(s) of 14 CFR Affected: § 135.324(a).

Description of Relief Sought: SkyWest Charter (SWC), a part 135 air carrier certificate holder, requests relief from the requirements of Section 135.324(a) to the extent necessary to allow personnel from SkyWest Airlines, a part 121 air carrier certificate holder, to conduct training, testing and checking of SWC's pilots using SkyWest Airlines' training programs.

[FR Doc. 2023–25293 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration Aviation Rulemaking Advisory Committee Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: This notice announces a meeting of ARAC.

DATES: FAA will hold the meeting on Thursday, December 14, 2023, from 1:00 p.m. to 4:00 p.m. Eastern Time.

FAA must receive requests to attend the meeting by Tuesday, November 28, 2023.

FAA must receive requests for accommodations to a disability by Tuesday, November 28, 2023.

FAA must receive any written materials for review during the meeting by Tuesday, November 28, 2023.

ADDRESSES: The meeting will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, and virtually on Zoom. However, if FAA is unable to hold the meeting in person due to circumstances outside of its control, FAA will hold a virtual meeting, notifying registrants with the meeting details and posting any updates on FAA Committee website. Members of the public who wish to observe the meeting must RSVP by emailing *9-awa-arac@faa.gov.* General committee information, including copies of the meeting minutes, will be available on FAA Committee website at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/.*

FOR FURTHER INFORMATION CONTACT: Aliah Duckett, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–7489; email *9-awa-arac@faa.gov.* Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

ARAC was created under the Federal Advisory Committee Act, in accordance with Title 5 of the United States Code (5 U.S.C. Ch.10) to provide advice and recommendations to FAA concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Status Updates
  - Active Working Groups
  - Transport Airplane and Engine (TAE) Subcommittee
- Recommendation Reports
- Any Other Business

Detailed agenda information will be posted on FAA Committee website address listed in the **ADDRESSES** section at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public for virtual or in person attendance on a first-come, first-served basis, as there is limited space. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section and provide the following information: full legal name, country of citizenship, and name of your industry association or applicable affiliation. Please indicate if you plan to observe the meeting in person or virtually. FAA will email registrants the meeting access information in a timely manner prior to the start of the meeting.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

FAA is not accepting oral presentations at this meeting due to time constraints. Any member of the public may present a written statement

to the committee at any time. The public may present written statements to ARAC by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on November 13, 2023.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2023–25334 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2022–0077; Summary Notice No. –2023–44]

Petition for Exemption; Summary of Petition Received; Kiwi Technologies, Inc. d/b/a Guardian Agriculture

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2023.

ADDRESSES: Send comments identified by docket number FAA–2022–0077 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, 202–683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 9, 2023.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2022–0077.

Petitioner: Kiwi Technologies, Inc. d/b/a Guardian Agriculture.

Section(s) of 14 CFR Affected: §§ 61.3(a)(1)(i), 91.7(a), 91.119(c), 91.121, 91.151(b), 91.403(b), 91.405(a), 91.407(a)(1), 91.409(a)(1), 91.409(a)(2), 91.417(a), 91.417(b), 137.19(c), 137.19(d), 137.19(e)(2)(ii), 137.19(iii), 137.19(v), 137.31, 137.33, 137.41(c), 137.42.

Description of Relief Sought: Guardian Agriculture seeks to amend their existing grant of exemption, Exemption No. 18866, which provides relief necessary to operate an electric vertical take-off and landing (eVTOL) multi-rotor aircraft designed to conduct Part 137 agricultural spraying operations in rural low-risk operating environments in Class G airspace. The proposed amendments, if granted, would allow the petitioner to: (1) increase the maximum takeoff weight (MTOW) of its SC1 uncrewed aircraft (UA) from 494 pounds (lbs.) to 645 lbs.; (2) reduce the required standoff distance to operate closer than 500 feet from vessels, vehicles, and structures; (3) allow for UA night operations; (4) increase the maximum UA airspeed from 25 knots (kts) to 45 kts; (5) eliminate the requirement that a visual observer (VO) be used for all operations, and; (6) allow the pilot in command to hold a third-class medical certificate in lieu of a second-class medical certificate.

[FR Doc. 2023–25292 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0195]

Hours of Service of Drivers: Reiman Corp.; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces a request from Reiman Corp. for an exemption from certain hours-of-service (HOS) regulations. Reiman Corp.'s drivers transport latex embedded cement for use at highway construction sites. Reiman Corp. requests that it be allowed to operate under the same hours-of-service exception provided for ''specially trained drivers of commercial motor vehicles that are specially constructed to service oil wells.'' FMCSA requests public comment on the applicant's request for exemption.

DATES: Comments must be received on or before December 18, 2023.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number (FDMS) FMCSA–2023–0195 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2023–0195) for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL–14 FDMS, which can be reviewed under the ''Department Wide System of Records Notices'' at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; 202–366–4225 or *pearlie.robinson@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2023–0195), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number ''FMCSA–2023–0195'' in the ''Keyword'' box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Applicant's Request

Reiman Corp. indicated that it is involved in the construction of highway roads and bridges. Reiman Corp. requests an exemption from certain HOS regulations because it considers its operations similar to oilfield operations exempted in 49 CFR 391.5(d)(2), including that its drivers are specially trained to operate vehicles that are specially designed to transport specific products with vehicle-mounted equipment. The requested exemption would allow Reiman Corp.'s drivers to record waiting time at construction sites as ''off-duty'' for purposes of §§ 395.8 and 395.15. Further, waiting time would not be included in calculating the 14-hour period in § 395.3(a)(2). However, Reiman Corp.'s specially trained drivers would not be eligible to use the short-haul operation provisions of § 395.1(e)(1) if the company were granted this exemption.

A copy of Reiman Corp.'s application for exemption is included in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Reiman Corp.'s application for an exemption from certain HOS regulations in 49 CFR part 395. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–25304 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0201]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Safe Fleet Bus and Rail

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA requests public comment on an application for exemption from Safe Fleet Bus and Rail (Safe Fleet) to allow motor carriers to operate commercial motor vehicles (CMV) equipped with Safe Fleet's ''MirrorLESS'' camera monitor system (CMS) installed as an alternative to the two rear-vision mirrors required by the Federal Motor Carrier Safety Regulations (FMCSRs).

DATES: Comments must be received on or before December 18, 2023.

ADDRESSES: You may submit comments identified by docket number FMCSA–2023–0201 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2023-0201/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–5541, *MCPSV@dot.gov.* If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2023–0201), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2023-0201/document,* click on this notice, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

FMCSA will consider all comments and material received during the comment period. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2023-0201/document* and choose the document to review. To view comments, click this notice, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the FMCSRs. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely maintain a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (§ 381.305(a)). The Agency must publish its decision in the **Federal Register** (§ 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (§ 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (§ 381.315(c)(2)). The exemption may be renewed (§ 381.300(b)).

III. Safe Fleet's Application for Exemption

Section 393.80(a) of the FMCSRs requires that each bus, truck, and truck tractor be equipped with two rear-vision mirrors, one at each side. The mirrors must be positioned to reflect to the driver a view of the highway to the rear and the area along both sides of the CMV. Section 393.80(a) cross-references the National Highway Traffic Safety Administration's standard for mirrors on motor vehicles (*i.e.,* 49 CFR 571.111, Federal Motor Vehicle Safety Standard (FMVSS) No. 111). Paragraph S7.1 of FMVSS No. 111 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a gross vehicle weight rating (GVWR) greater than 4,536 kg and less than 11,340 kg and each bus, other than a school bus, with a GVWR of more than 4,536 kg. Paragraph S8.1 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a GVWR of 11,340 kg or more. Safe Fleet has applied for an exemption from 393.80(a) to allow motor carriers to operate CMVs equipped with the company's

MirrorLESS CMS installed as an alternative to the two rear-vision mirrors required by the FMCSRs. A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b)(6), FMCSA requests public comment from all interested persons on Safe Fleet's application for an exemption from the requirement for two rear-vision mirrors in § 393.80(a). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–25303 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0061]

Request for Comment: NHTSA's Nondiscrimination Compliance Program

AGENCY: National Highway Traffic Safety Administration, Department of Transportation.

ACTION: Request for comment on NHTSA's Nondiscrimination Compliance Program.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) is issuing Nondiscrimination Compliance Guidelines for NHTSA Financial Assistance Recipients (Nondiscrimination Guidelines). Federal financial assistance recipients (recipients) must comply with applicable Federal civil rights statutes and regulations, including Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Title IX of the Education Amendments Act of 1972, and their implementing regulations. Collectively, these laws prohibit discrimination based on race, color, national origin (including limited English proficiency), disability, age, and sex in federally funded programs or activities. NHTSA's Nondiscrimination Guidelines will provide guidance for recipients on how to comply with their Federal civil rights obligations. NHTSA is seeking input and comments from all traffic safety stakeholders and the public to inform the development of NHTSA's Nondiscrimination Guidelines, including methods for collecting civil rights data.

DATES: Comments should be submitted no later than January 16, 2024.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail: Docket Management Facility:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: All submissions must include the agency name and Docket No. NHTSA–2023–0061. All comments received will be posted without change, including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and search for Docket No. NHTSA–2023–0061.

Privacy Act: Anyone is able to search the electronic form for all comments received into USDOT's dockets by entering the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an organization, association, business, or other entity). You may review the U.S. Department of Transportation's (USDOT) complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For more information, contact Heather Moss, Division Chief, Title VI Compliance, Office of Civil Rights, National Highway Traffic Safety Administration, Telephone number: (202) 366–0972. You may also contact NHTSA's Office of Civil Rights at *NHTSACivilRights@dot.gov.*

SUPPLEMENTARY INFORMATION: We continue to face an urgent and preventable traffic fatality crisis on our Nation's roadways. The National Highway Traffic Safety Administration (NHTSA) and our partners are working to deliver accountable, efficient, and data-driven highway safety programs to save lives and reverse this deadly national trend. NHTSA's grants and cooperative agreements are key to achieving our collective long-term goal of zero roadway fatalities nationwide.

As a condition of receiving Federal financial assistance (FFA), recipients must comply with applicable provisions of laws and policies prohibiting discrimination, including: [1]

- Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.,* which prohibits discrimination based on race, color, or national origin (including limited English proficiency); [2]
- Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 *et seq.,* which prohibits discrimination based on disability; [3]
- Age Discrimination Act of 1975 (Age Discrimination Act), 42 U.S.C. 6101 *et seq.,* which prohibits discrimination based on age; and
- Title IX of the Education Amendments Act of 1972 (Title IX), 20 U.S.C. 1681 *et seq.,* which prohibits discrimination based on sex in education programs or activities.

FFA includes grants and loans of Federal funds; the grant or donation of Federal property and interests in property; the detail of Federal personnel; the sale and lease of, and the

[1] NHTSA has also incorporated public participation and engagement requirements into its Uniform Procedures for State Highway Safety Grant Programs. 23 CFR part 1300. Pursuant to the Infrastructure Investment and Jobs Act, NHTSA requires that NHTSA-funded State highway safety programs result from meaningful public participation and engagement from affected communities, particularly those most significantly impacted by traffic crashes resulting in injuries and fatalities. *See* 23 U.S.C. 402(b)(1)(B); *see also id.*

[2] DOT 1000.12C (effective June 11, 2021) also provides policy guidance to USDOT Departmental Offices and Operating Administrations for establishing and maintaining Title VI compliance programs.

[3] States must also comply with the Americans with Disabilities Act of 1990 (ADA) in all services, programs, and activities regardless of whether they receive Federal funds. 42 U.S.C 12131 *et seq.*

permission to use (on other than a casual or transient basis), Federal property; and any Federal agreement, arrangement, or other contract that has as one of its purposes the provision of assistance. *See e.g.,* 49 CFR 21.3.

NHTSA's Office of Civil Rights (NCR) ensures that NHTSA and its recipients comply with these Federal civil rights laws that prohibit discrimination in federally funded programs or activities. NCR's administrative enforcement authority includes Title VI, Section 504, Age Discrimination Act, and Title IX. To fulfil its mandate, NCR conducts external complaint investigations and compliance reviews, provides technical assistance to internal and external stakeholders, conducts nationwide trainings, and represents NHTSA on internal and external workgroups and initiatives to advance Federal civil rights policy priorities.

Through this request for comment (RFC), NHTSA seeks input to inform the development of Nondiscrimination Compliance Guidelines for NHTSA Financial Assistance Recipients (Nondiscrimination Guidelines). NHTSA's Nondiscrimination Guidelines will provide guidance for recipients on how to comply with their Federal civil rights obligations. NHTSA is publishing this RFC to engage a broad cross-section of stakeholders and the public. After considering and incorporating comments and information received from this solicitation, NHTSA intends to publish draft Nondiscrimination Guidelines for comment before publishing final guidance.

NHTSA requests responsive comments and feedback from all interested parties. When responding, please specify if you are responding on behalf of an applicant, recipient, traffic safety organization, or other stakeholder, and identify the type of applicable funding (*e.g.,* highway safety program grant, research-based cooperative agreement), if known.

I. Pre-Award Data Collection Requirements for Primary and Direct Recipients

The U.S. Department of Justice's (USDOJ) Title VI Coordination regulations apply to all FFA-awarding agencies. 28 CFR 42. These regulations direct Federal agencies to publish guidelines describing the nature of Title VI coverage, methods of enforcement, examples of prohibited practices, and requirements for data collection. *See* 28 CFR 42.404(a). These regulations also require that, ''[p]rior to approval of [FFA], the [F]ederal agency shall make written determination as to whether the applicant is in compliance with [T]itle VI . . . . The basis for such a determination . . . , shall be submission of an assurance of compliance and a review of the data submitted by the applicant.'' *Id.* § 42.407.

Section 42.406(d) of USDOJ's Title VI Coordination regulations lists the types of data that, ''to the extent necessary and appropriate for determining compliance with [T]itle VI,'' applicants should submit to and be reviewed by Federal agencies prior to granting funds. In addition to submitting an assurance that it will compile and maintain records as required, an applicant should provide: (1) notice of civil rights lawsuits and complaints filed against it; (2) a description of FFA applications that it has pending in other agencies and of other FFA being provided; (3) a description of recent civil rights compliance reviews; and (4) a statement as to whether the applicant has been found in noncompliance with any relevant civil rights requirements. *See id.* USDOT's Title VI implementing regulations also require recipients to ''keep such records and submit to the Secretary timely, complete, and accurate compliance reports at such times, and in such form and containing such information, as the Secretary may determine to be necessary to enable [the Secretary] to ascertain whether the recipient has complied or is complying with this [rule].'' 49 CFR 21.9(b). NHTSA's Nondiscrimination Guidelines will facilitate NHTSA's pre-award data collection in accordance with these requirements.[4]

NHTSA will require recipients to provide pre-award Federal civil rights compliance data once every three years. If a recipient's FFA term does not run a full three years, such a recipient will be obligated to provide pre-award compliance data again if they receive a subsequent award more than three years after the prior award.

NHTSA requests comments and responses to the following specific categories of information that NHTSA will collect prior to awarding FFA. In providing comments and responses, please address the following for each category of information to be collected: (i) the processes and procedures required of staff who are preparing applications to obtain the information; (ii) the anticipated staffing, burden hours, and timeline required to obtain, analyze, and provide the information; (iii) best methods for relaying the information (*e.g.,* fillable form, report template); and (iv) ways for NHTSA to enhance the quality, usefulness, and clarity of the information collected.

1. List of all pending civil rights lawsuits and administrative complaints (including basis and status) filed under Federal law against the applicant/recipient that allege discrimination based on race, color, national origin (including limited English proficiency), disability, age, or sex during the last three years;

2. List of all civil rights lawsuits and administrative complaint investigations decided against the applicant/recipient within the last three years that alleged discrimination under Federal law based on race, color, national origin (including limited English proficiency), disability, age, or sex and provide a copy or copies of applicable decision(s) and describe all corrective action(s) taken;

3. List of all Federal civil rights compliance reviews of the applicant/recipient conducted by any Federal agency within the last three years, enclose copy or copies of the review(s) and any decision(s), order(s), or agreement(s) based on the review(s), and describe any corrective action(s) taken.

4. Description of FFA applications pending in other Federal agencies and of other current FFA provided;

5. Demographic information on the population served by the federally funded program or activity;

6. Description of the applicant's/recipient's discrimination complaint process;

7. Statement affirming that staff has been designated to coordinate and carry out the responsibilities for compliance with Federal civil rights laws, and the name, title (*e.g.,* Title VI Coordinator, ADA Coordinator), description of responsibilities, and contact information for such staff;

8. Whether the applicant/recipient provides initial and continuing public notice of its nondiscrimination policy statement and, if so, whether (a) the methods of notice accommodate individuals with visual and/or hearing disabilities, (b) the notice is posted in a prominent place on the applicant's/recipient's website, in the offices or facilities or, for educational programs and activities, in appropriate periodicals and other written communications; and (c) the notice identifies a designated civil rights coordinator;

9. Whether the applicant/recipient has a written policy/procedure for individuals with disabilities to request reasonable accommodations to access benefits and services;

10. Whether the applicant/recipient has a written policy/procedure for providing meaningful access to benefits

[4] *See id.; see also* 49 CFR 25.605; 49 CFR 27.121(b); 45 CFR 90.42(a).

and services for persons with limited English proficiency; and

11. Whether applicant/recipient has a plan to ensure Federal civil rights compliance in subrecipient programs, if any, including subrecipient compliance reviews.

II. Compliance Reviews

NHTSA must also conduct periodic compliance reviews of its recipients. *See* 49 CFR 21.11(a); 49 CFR 25.605; 49 CFR 27.123(a); *see also* 45 CFR 90.42(a). Post-award reviews are conducted as desk audits and/or on-site visits. Because the review may cover all or a portion of the recipient's compliance with specific Federal civil rights laws, the scope of a review is defined on a case-by-case basis. NHTSA may summarize the results of the review in a draft compliance report, which will include findings of no deficiency (no corrective action necessary), findings of deficiency (corrective action required), and advisory comments, as appropriate. If findings of deficiency remain in the final compliance report, the recipient will be required to take corrective action, develop a timeline for compliance, and report its progress.

NHTSA requests comments and responses to the following questions:

1. What factors should NHTSA consider in developing a compliance timeline for a finding of deficiency?

2. Is there a minimum time period for which NHTSA should monitor a recipient after a finding of deficiency?

3. How frequently should NHTSA require progress reports from a recipient who is undertaking corrective action following a finding of deficiency.

III. Implementation and Additional Considerations

1. What promising practices are NHTSA recipients—larger and smaller recipients, and national organizations—using to:

a. Engage traditionally underserved communities, and how is the effectiveness assessed?

b. Review policies and practices to ensure that programs and activities do not result in disparate impacts based on race, color, national origin (including limited English proficiency), disability, age, or sex?

c. Ensure that individuals and communities with limited English proficiency have meaningful access to the recipient's programs and activities?

d. Ensure effective communication with individuals with communication-related disabilities (*e.g.,* visual, auditory)?

e. Ensure that facilities are free from physical barriers to access for individuals with disabilities?

f. Ensure that subrecipients comply with Federal civil rights laws?

2. What factors should NHTSA consider when tailoring compliance information, requirements, and guidelines to each recipient type (*e.g.,* type of funding, award size)?

3. Should NHTSA require and collect any additional pre-award Federal civil rights compliance information not discussed above or included in applicable funding notices prior to awarding FFA? If so, what is that information and how should NHTSA collect it?

4. What considerations and benchmarks (*e.g.,* formula grant application deadlines, budgetary phases) should NHTSA incorporate into the implementation timeline for its Nondiscrimination Guidelines?

5. What specific subject matter technical assistance and trainings would help to ensure that recipients fulfill their Federal civil rights obligations?

6. What additional supports (*e.g.,* webinars, internet-accessible information on NHTSA's web page, subject-specific resource lists, factsheets, checklists, templates, sample notices and forms, illustrative analysis) will assist applicants and recipients in fulfilling the requirements of NHTSA's proposed Nondiscrimination Guidelines?

The information collection described in this RFC is necessary to successfully maintain a robust and meaningful civil rights compliance program. NHTSA welcomes any additional feedback related to Federal civil rights compliance and NHTSA's forthcoming Nondiscrimination Guidelines, including topics not specifically referenced above. NHTSA invites comments regarding the time burden and costs of proposed data collections.

All interested parties are encouraged to respond to this RFC. Submissions are strictly voluntary. Individuals or entities responding to this RFC should state their role as well as knowledge of and experience with Federal civil rights compliance and community engagement. NHTSA may request additional clarifying information from any or all respondents. If a respondent does not wish to be contacted by NHTSA for additional information, it should include a corresponding statement to that effect in the response. All information submitted should be unclassified and should not contain proprietary information. Although NHTSA will review and consider all responses to this RFC, NHTSA will not officially respond to the information received.

Comments may be submitted and viewed at Docket No. NHTSA–2023–0061 at *https://www.regulations.gov.*

Issued in Washington, DC.

Regina Morgan,

Director, NHTSA Office of Civil Rights.

[FR Doc. 2023–25266 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2015–0271]

Agency Request for Renewal of a Previously Approved Information Collection: Prioritization and Allocation Authority Exercised by the Secretary of Transportation Under the Defense Production Act

AGENCY: Office of the Secretary of Transportation, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves information required in an application to request Special Priorities Assistance. The information to be collected is necessary to facilitate the supply of civil transportation resources to promote the national defense. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995, Public Law 104–13.

DATES: Written comments should be submitted by December 18, 2023.

ADDRESSES: Your comments should be identified by Docket No. DOT–OST–2015–0271 and may be submitted through one of the following methods:

- *Office of Management and Budget, Attention:* Desk Officer for U.S. Department of Transportation, Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.
- *Email: oira_submission@omb.eop.gov.*
- *Fax:* (202) 395–5806. Attention: DOT/OST Desk Officer.

FOR FURTHER INFORMATION CONTACT: Anita Womack, 202–366–2250, Office of Intelligence, Security and Emergency Response, Office of the Secretary of Transportation, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105–0567.

Title: Prioritization and Allocation Authority Exercised by the Secretary of Transportation Under the Defense Production Act.

Form Numbers: OST F 1254.

Type of Review: Renewal of a previously approved information collection.

Background: The Defense Production Act Reauthorization of 2009 requires each Federal agency with delegated authority under section 101 of the Defense Production Act of 1950, as amended (50 U.S.C. App. Sec. 4501 *et seq.*) to issue final rules establishing standards and procedures by which the priorities and allocations authority is used to promote the national defense. The Secretary of Transportation has the delegated authority for all forms of civil transportation. DOT's final rule, Transportation Priorities and Allocation System (TPAS), published October 2012, requires this information collection. Form OST F 1254, Request for Special Priorities Assistance, would be filled out by private sector applicants, such as transportation companies or organizations. The private sector applicant must submit company information, the services or items for which the assistance is requested, and specific information about those services or items.

Respondents: Private sector applicants, such as transportation companies or organizations.

Number of Respondents: We estimate 6 respondents.

Total Annual Burden: We estimate an average burden of 30 minutes per respondent for an estimated total annual burden of 3 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:48.

Issued in Washington, DC, on November 13, 2023.

Donna O'Berry,

Acting Director, Office of Intelligence, Security and Emergency Response.

[FR Doc. 2023–25337 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT–OST–2023–0137]

Advisory Committee on Transportation Equity (ACTE); Notice of Public Meeting; Correction

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of public meeting; correction

SUMMARY: DOT OST published a document in the **Federal Register** on November 1, 2023, announcing a meeting of ACTE, which will take place in person at the Hilton Durham, North Carolina. The document did not include the link for members of the public to provide recommendations to members of the ACTE.

FOR FURTHER INFORMATION CONTACT: Sandra Norman, Senior Advisor and Designated Federal Officer, Departmental Office of Civil Rights, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (804) 836–2893, *ACTE@dot.gov.* Any ACTE-related request or submissions should be sent via email to the point of contact listed above.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 1, 2023, in FR Doc. 2023–24099, on page 75093, update the **SUPPLEMENTARY INFORMATION** caption to read, in addition to the previously posted content:

Members of the ACTE are requesting members of the public complete the following survey (*https://www.surveymonkey.com/r/GZDGXZQ*) in order to capture stories, feedback, questions, and concerns that, upon review, will be incorporated into the ACTE Recommendations Report due to the Secretary in June 2024. The deadline to complete the survey is close of business on Friday, November 17, 2023.

Dated: November 9, 2023.

Irene Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2023–25364 Filed 11–15–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Correction to Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice; Correction.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) published a document in the **Federal Register** of Tuesday, April 20, 2021, concerning the publishing of names on OFAC's Specially Designated Nationals and Blocked Persons List. The document contained incorrect bases for designation that are being corrected here.

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Correction

In the **Federal Register** of Tuesday, April 20, 2021, 86 FR 20595, on page 20596, under STEPANOV, Artem Nikolaevich, delete ''Linked To: PRIGOZHIN, Yevgeniy, Viktorovich'' and replace with ''Linked To: OOO YUNIDZHET'' and correct the basis for designation to:

''Designated pursuant to section 2(a)(iii) of Executive Order (E.O.) 13848 for having acted or purported to act for or on behalf of, directly or indirectly, OOO YUNIDZHET, a person whose property and interests in property are blocked pursuant to E.O. 13848.

Also designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, OOO YUNIDZHET, a person whose property and interests in property are blocked pursuant to E.O. 13661.

Also designated pursuant to section 1(a)(ii)(C) of E.O. 13694, as amended by E.O. 13757, for having acted or purported to act for or on behalf of, directly or indirectly, OOO

YUNIDZHET, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended by E.O. 13757.''

It was incorrectly listed previously as, ''Designated pursuant to section 2(a)(ii) of E.O. 13848 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

Also designated pursuant to section 1(a)(iii)(B) E.O. 13694, as amended for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661, as amended for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.''

Dated: November 9, 2023.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2023–25299 Filed 11–15–23; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Proposed Collections; Comment Requests

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on an information collection that is due for extension approval by the Office of Management and Budget. The Office of International Affairs of the Department of the Treasury is soliciting comments concerning extension without change of the following three related forms: Foreign Currency Form FC–1 (OMB No. 1505–0010), Weekly Consolidated Foreign Currency Report of Major Market Participants; Form FC–2 (OMB No. 1505–0010); Monthly Consolidated Foreign Currency Report of Major Market Participants; Form FC–3 (OMB No. 1505–0010), Quarterly Consolidated Foreign Currency Report. The reports are mandatory.

DATES: Written comments should be received on or before January 16, 2024 to be assured of consideration.

ADDRESSES: Copies of the proposed forms and instructions are available on the Federal Reserve Bank of New York's website. They are in the section for Banking Reporting Forms and Instructions, on the web pages for the TFC–1, TFC–2 and TFC–3 forms, for example at: *https://www.newyorkfed.org/banking/reportingforms/TFC_1.html; https://www.newyorkfed.org/banking/reportingforms/TFC_2.html;* and *https://www.newyorkfed.org/banking/reportingforms/TFC_3.html.* Requests for additional information should be directed to Mr. Foehl.

FOR FURTHER INFORMATION CONTACT: Direct all written comments to Brady Foehl, Markets Room, Department of the Treasury, Room 1328, 1500 Pennsylvania Avenue NW, Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Foehl by email (*Brady.Foehl@treasury.gov*) or telephone (202–622–2423).

SUPPLEMENTARY INFORMATION:

Title: Weekly Consolidated Foreign Currency Report of Major Market Participants, Foreign Currency Form FC–1.

OMB Control Number: 1505–0010.

Title: Monthly Consolidated Foreign Currency Report of Major Market Participants, Foreign Currency Form FC–2.

OMB Control Number: 1505–0010.

Title: Quarterly Consolidated Foreign Currency Report, Foreign Currency Form FC–3.

OMB Control Number: 1505–0010.

Abstract: The filing of Foreign Currency Forms FC–1, FC–2, and FC–3 is pursuant to (31 U.S.C. 5315, which directs the Secretary of the Treasury to prescribe regulations (31 CFR 128, subpart C), requiring reports on foreign currency transactions conducted by a United States person or a foreign person controlled by a United States person. The forms collect data on the foreign exchange spot, forward, futures, and options markets from all significant market participants.

Current Actions: No changes in the forms will be made.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents:

Foreign Currency Form FC–1: 29 respondents.

Foreign Currency Form FC–2: 29 respondents.

Foreign Currency Form FC–3: 47 respondents.

Estimated Average Time Per Response:

Foreign Currency Form FC–1: 48 minutes (0.8 hours) per response.

Foreign Currency Form FC–2: Three hours 36 minutes (3.6 hours) per response.

Foreign Currency Form FC–3: Eight (8) hours per response.

Estimated Total Annual Burden Hours:

Foreign Currency Form FC–1: 1,206 hours, based on 52 reporting periods per year.

Foreign Currency Form FC–2: 1,253 hours, based on 12 reporting periods per year.

Foreign Currency Form FC–3: 1,504 hours, based on 4 reporting periods per year.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) whether Foreign Currency Forms FC–1, FC–2, and FC–3 are necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimates of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Brady L. Foehl,

Financial Analyst, Markets Room, U.S. Department of the Treasury.

[FR Doc. 2023–25353 Filed 11–15–23; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Family, Caregiver and Survivor Advisory Committee, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (FACA), 5 U.S.C. Ch. 10, that the Veterans' Family, Caregiver and Survivor Advisory

Committee will meet virtually on November 30 and December 1, 2023. The meeting sessions will begin and end as follows:

Date(s)	Time(s)
November 30, 2023.	12:00 p.m. to 3:00 p.m. Eastern Standard Time (EST).
December 1, 2023.	12:00 p.m. to 3:00 p.m. EST.

The meeting is open to the public and will be conducted via the WebEx conference platform.

The purpose of the Committee is to provide advice to the Secretary of Veterans Affairs (SECVA) with respect to the administration of benefits by the Department of Veterans Affairs (VA) for services to Veterans' families, caregivers and survivors.

On Thursday, November 30 and Friday, December 1, 2023, the agenda will include opening remarks from the Executive Director, Caregiver Support Program, Veterans Health Administration (VHA) and the Committee Chair. There will be briefings by the VA Office of Geriatrics and Extended Care, Care Management and Social Work Services, and Readjustment Counseling Service.

Time will be allocated for receiving public comments on December 1, 2023, 1:30 p.m. to 2:30 p.m. EST. Individuals wishing to make public comments should contact Dr. Betty Moseley Brown, Designated Federal Officer at (210) 392–2505 or *VHA12CSPFAC@va.gov* and are requested to submit a 1 to 2-page summary of their comments for inclusion in the official meeting record. In the interest of time, each speaker will be held to a 5-minute time limit. The Committee will accept written comments from interested parties on relevant issues until Monday, November 27, 2023, at 5:00 p.m. EST. Each public speaker will receive a confirmed time for speaking via email from the Designated Federal Officer.

All attending should register at the following link: *https://veteransaffairs.webex.com/webappng/sites/veteransaffairs/webinar/webinarSeries/register/aaa9fdda9fdc463e8acbea9444a71ede.* Anyone seeking additional information should contact Dr. Betty Moseley Brown, at (210) 392–2505 or *Betty.MoseleyBrown@va.gov*.

Dated: November 13, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–25335 Filed 11–15–23; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

VA National Academic Affiliations Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. Ch. 10, that the VA National Academic Affiliations Council will meet via conference call on December 11, 2023, from 1:00 p.m. to 3:00 p.m. EST. The meeting is open to the public.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On December 11, 2023, the Council will receive project updates and have discussions on actions affecting the educational mission of VA. The Council will receive public comments from 2:25 p.m. to 2:55 p.m. EST.

Interested persons may attend and/or present oral statements to the Council.

The dial in number to attend the conference call is: 669–254–5252. At the prompt, enter meeting ID 161 511 8883, then press #. The meeting passcode is 079818 then press #. Individuals seeking to present oral statements are invited to submit a 1–2-page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting or at any time, by email to *nellie.mitchell@va.gov,* or by mail to Nellie Mitchell, MS, RHIA, Designated Federal Officer, Office of Academic Affiliations (14AA), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Ms. Mitchell via email or by phone at (608) 358–9902.

Dated: November 9, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–25285 Filed 11–15–23; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

Vol. 88 Thursday,
No. 220 November 16, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.
Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, and 600

[CMS–1784–F]

RIN 0938–AV07

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; payment for dental services inextricably linked to specific covered medical services; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider and supplier enrollment policies, electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); updates to the Ambulance Fee Schedule regulations and the Medicare Ground Ambulance Data Collection System; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; expansion of the diabetes screening and diabetes definitions; pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners; appropriate use criteria for advanced diagnostic imaging; early release of Medicare Advantage risk adjustment data; a social determinants of health risk assessment in the annual wellness visit and Basic Health Program.

DATES: These regulations are effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for the following issues: practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts; the comment solicitation on strategies for updates to practice expense data collection and methodology, caregiver training services, community health integration services, social determinants of health risk assessment, and principal illness navigation services; potentially misvalued services under the PFS, direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology; teaching physician services, advancing access to behavioral health services, PFS payment for evaluation and management services, geographic practice cost indices (GPCIs), payment for skin substitutes, supervision of outpatient therapy services, KX modifier thresholds, diabetes self-management training (DSMT) services, and DSMT telehealth services, and dental services inextricably linked to specific covered services.

Laura Ashbaugh, (410) 786–1113, and Erick Carrera, (410) 786–8949, Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to dental services inextricably linked to specific covered medical services.

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, and Rachel Radzyner, (410) 786–8215, for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Laura Ashbaugh, (410) 786–1113, and Ariana Pitcher, (667) 290–8840, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov*, for issues related to FQHC payments.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, for issues related to RHC payments.

Kianna Banks, (410) 786–3498 and Cara Meyer, (667) 290–9856, for issues related to RHCs and FQHCs definitions of staff and Conditions for Certification or Coverage.

Sarah Fulton, (410) 786–2749, for issues related to pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners.

Lindsey Baldwin, (410) 786–1694, Ariana Pitcher, (667) 290–8840, or *OTP_Medicare@cms.hhs.gov*, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology.

Lucy Bertocci, (410) 786–3776, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program advance investment payments, and eligibility requirements.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to preventive vaccine administration services.

Mollie Howerton, (410) 786–5395, for issues related to Medicare Diabetes Prevention Program.

Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging.

Frank Whelan, (410) 786–1302, for issues related to Medicare and Medicaid provider and supplier enrollment regulation updates.

Daniel Feller, (410) 786–6913 for issues related to expanding diabetes screening and definitions.

Daniel Feller, (410) 786–6913 for issues related to a social determinants of health risk assessment in the annual wellness visit.

Mei Zhang, (410) 786–7837, and Kimberly Go, (410) 786–4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov*, for issues related to the Ambulance Fee Schedule (AFS) and the Medicare Ground Ambulance Data Collection System.

Mary Rossi-Coajou, (410) 786–6051, for issues related to hospice Conditions of Participation.

Cameron Ingram, (410) 409–8023 for issues related to Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA of 1988.

Meg Barry, (410) 786–1536, for issues related to the Basic Health Program (BHP) provisions.

Renee O'Neill, (410) 786–8821, or Sophia Sugumar, (410) 786–1648, for inquiries related to Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2024 PFS final rule, refer to item CMS–1784–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major final rule includes provisions regarding other Medicare payment policies described in sections III. and IV.

This rulemaking updates the Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Conditions for Certification and Conditions for Coverage (CfCs), respectively, to implement the provisions of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328, December 29, 2022), now allowing payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) or Mental Health Counselor (MHC).

This rulemaking also updates the Hospice Conditions of Participation (CoPs) to implement division FF, section 4121 of the CAA 2023 regarding the addition of marriage and family therapists (MFTs) or mental health counselors (MHCs) as part of the hospice interdisciplinary team and make changes to the hospice personnel requirements.

This rulemaking also seeks to further advance Medicare's overall value-based care strategy of growth, alignment, and equity through the Medicare Shared Savings Program (Shared Savings Program) and the Quality Payment Program (QPP). The structure of the programs enables us to develop a set of tools for measuring and encouraging improvements in care, which may support a shift to clinician payment over time into Advanced Alternative Payment Models (APMs) and accountable care arrangements which reduce care fragmentation and unnecessary costs for patients and the health system.

This rulemaking also updates the public reporting requirements of procedure volume data (Part B non-institutional claims) on clinician profile pages of the Compare Tool to include Medicare Advantage (MA) encounter data. This enables us to use and analyze MA encounter data as part of the aggregated information disclosed through the Care Compare website, more broadly fulfilling the public reporting requirements of section 104 of the MACRA and section 10331 of the ACA and providing beneficiaries with useful and appropriate information when selecting a provider. This rulemaking also amends § 422.310(f)(3) to permit the release of the MA encounter data on the timeframe(s) used for disclosure and release of the data on the Care Compare website.

This rulemaking also updates the Ambulance Fee Schedule regulations to implement division FF, section 4103 of the CAA 2023 regarding the ground ambulance extenders provisions and also provides further changes and clarifications to the Medicare Ground Ambulance Data Collection System.

This rulemaking also updates Medicare and Medicaid provider and supplier enrollment regulations.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that we establish each year by regulation the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2024 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare and Medicaid provider and supplier enrollment policies, and other policies regarding programs administered by CMS.

Specifically, this final rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the

Social Security Act (the Act) (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Payment for Skin Substitutes (section II.H.)
- Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)
- Advancing Access to Behavioral Health Services (section II.J.)
- Policies on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services (section II.K.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)
- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medicare Diabetes Prevention Program Expanded Model (section III.I.)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.J.)
- Medicare and Medicaid Provider and Supplier Enrollment (section III.K.)
- Expand Diabetes Screening and Diabetes Definitions (section III.L.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.M.)
- Changes to the Regulations Associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS) (section III.N.)
- Hospice: Changes to the Hospice Conditions of Participation (section III.O.)
- RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.)
- Changes to the Basic Health Program Regulations (section III.Q.)
- Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.)
- A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

C. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this final rule.

II. Provisions of the Final Rule for the PFS

A. Background

In accordance with section 1848 of the Act, CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the Relative Value Scale Update Committee (RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new

survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2024 PFS final rule PE/HR'' on the CMS website under downloads for the CY 2024 PFS final rule at*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for

calculating PE RVUs is the same for both the facility and nonfacility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2024 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for CY 2024. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the major adverse impact on MP RVUs that result from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of several dozen low volume HCPCS codes with recommended expected specialty assignments.

Response: After reviewing the information provided by the commenters to determine that the submitted specialty assignments were appropriate for the services in question, we are finalizing the additions to the list of expected specialty assignments for low volume services identified in Table 1. We agreed with the commenters that CPT code 33230 should be crosswalked to the Cardiac Electrophysiology specialty and that CPT code 96446 should be crosswalked to the Gynecological Oncology specialty. However, we do not have PE/HR data for these specialties as they were not part of the PPIS when it was conducted in 2007; therefore, we are crosswalking these CPT codes to the Cardiology and Obstetrics/Gynecology specialties, respectively, as listed on Table 1.

We disagreed with the commenters that CPT code 44384 should be

crosswalked to the Gastroenterology specialty and that CPT code 60505 should be crosswalked to the General Surgery specialty. In each case, there was another specialty which was reported more than twice as often in the claims data as the requested specialty. Therefore, we are crosswalking CPT code 44384 to the Urology specialty and CPT code 60505 to the Otolaryngology specialty as these were the dominant specialties in the claims data. These crosswalks are included in Table 1.

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TABLE 1: New Additions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Expected Specialty Assignment
11920	Correct skin color 6.0 cm/<	PLASTIC AND RECONSTRUCTIVE SURGERY
15934	Remove sacrum pressure sore	PLASTIC AND RECONSTRUCTIVE SURGERY
24201	Rmvl fb upper arm/elbw deep	ORTHOPEDIC SURGERY
25035	Treat forearm bone lesion	ORTHOPEDIC SURGERY
25077	Resect forearm/wrist tum<3cm	GENERAL SURGERY
26500	Hand tendon reconstruction	ORTHOPEDIC SURGERY
27049	Resect hip/pelv tum < 5 cm	ORTHOPEDIC SURGERY
27888	Amputation of foot at ankle	VASCULAR SURGERY
28406	Treatment of heel fracture	ORTHOPEDIC SURGERY
28455	Treat midfoot fracture each	PODIATRY
28496	Treat big toe fracture	ORTHOPEDIC SURGERY
28600	Treat foot dislocation	PODIATRY
29435	Apply short leg cast	ORTHOPEDIC SURGERY
31201	Removal of ethmoid sinus	OTOLARYNGOLOGY
31660	Bronch thermoplsty 1 lobe	PULMONARY DISEASE
31750	Repair of windpipe	OTOLARYNGOLOGY
32310	Removal of chest lining	THORACIC SURGERY
32815	Close bronchial fistula	THORACIC SURGERY
33141	Heart tmr w/other procedure	THORACIC SURGERY
33230*	Insrt pulse gen w/dual leads	CARDIOLOGY
34490	Removal of vein clot	VASCULAR SURGERY
35103	Repair artery rupture aorta	VASCULAR SURGERY
42305	Drainage of salivary gland	OTOLARYNGOLOGY
43205	Esophagus endoscopy/ligation	GASTROENTEROLOGY
43327	Esoph fundoplasty lap	GENERAL SURGERY
43635	Removal of stomach partial	GENERAL SURGERY
44384*	Small bowel endoscopy	UROLOGY
50225	Removal kidney open complex	UROLOGY
50236	Removal of kidney & ureter	UROLOGY
50800	Implant ureter in bowel	UROLOGY
51575	Removal of bladder & nodes	UROLOGY
52325	Cystoscopy stone removal	UROLOGY
57284	Repair paravag defect open	OBSTETRICS/GYNECOLOGY
58145	Myomectomy vag method	OBSTETRICS/GYNECOLOGY
58353	Endometr ablate thermal	OBSTETRICS/GYNECOLOGY
58559	Hysteroscopy lysis	OBSTETRICS/GYNECOLOGY
60505*	Explore parathyroid glands	OTOLARYNGOLOGY
61215	Insert brain-fluid device	NEUROSURGERY
62268	Drain spinal cord cyst	NEUROSURGERY
62287	Dcmprn px perq 1/mlt lumbar	INTERVENTIONAL PAIN MANAGEMENT
63185	Incise spine nrv half segmnt	NEUROSURGERY
64605	Injection treatment of nerve	NEUROSURGERY
65175	Removal of ocular implant	OPHTHALMOLOGY
65410	Biopsy of cornea	OPHTHALMOLOGY
67208	Treatment of retinal lesion	OPHTHALMOLOGY
67334	Revise eye muscle w/suture	OPHTHALMOLOGY
67405	Explore/drain eye socket	OPHTHALMOLOGY
67505	Inject/treat eye socket	OPHTHALMOLOGY
68328	Revise/graft eyelid lining	OPHTHALMOLOGY
72255	Myelography thoracic spine	DIAGNOSTIC RADIOLOGY
73085	Contrast x-ray of elbow	DIAGNOSTIC RADIOLOGY
76810	Ob us >= 14 wks addl fetus	OBSTETRICS/GYNECOLOGY
78740	Ureteral reflux study	UROLOGY
88355	Analysis skeletal muscle	CLINICAL LABORATORY

HCPCS	Short Descriptor	Expected Specialty Assignment
91020	Gastric motility studies	GASTROENTEROLOGY
92312	Contact lens fitting	OPTOMETRY
92325	Modification of contact lens	OPTOMETRY
92615	Laryngoscopic sensory i&r	OTOLARYNGOLOGY
96446*	Chemotx admn prtl cavity	OBSTETRICS/GYNECOLOGY

* Recommended specialty assignment crosswalked; see below.

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Comment: A commenter noted that the CMS expected specialty assignment list in the public use file that was part of the CY 2024 proposed rule also includes a column specifying if a service that previously had an anticipated specialty override continues to meet the criteria for the override to be applied for CY 2024. The commenter provided a list of approximately a dozen CPT codes and requested additional information as to why the expected specialty override was not being applied in these cases.

Response: We reviewed the CPT codes identified by the commenter and can provide the following information about their expected specialty override status for CY 2024. CMS did not apply the specialty override to CPT codes 33238, 33254, 33475, and 33507 as each code exceeded 100 allowed services in the Medicare claims data. CMS did not apply the specialty override to CPT codes 33602, 33619, 33778, and 43045 because they were unneeded, with the entirety of their very small number of allowed services already reported under their expected specialty. CPT codes 33600, 33710, and 43312 did have their respective specialty overrides applied; this was correctly detailed in the public use file for the CY 2024 proposed rule for CPT code 43312 but was missing from CPT codes 33600 and 33710, due to a technical error in the generation of the public use file.

We also note for commenters that each HCPCS code that appears on the list of expected specialty assignments for low volume services remains on the list from year to year, even if the code in question is not a low volume service for a certain calendar year because the volume rises to over 100 services. The HCPCS codes and expected specialty assignment remain on the list, and will be applied should the code fall below the low volume threshold (below 100 services) in any calendar year; as a result, there is no need to ''reactivate'' individual codes as some commenters have suggested in past submissions.

After consideration of the public comments, we are finalizing the updates to the list of expected specialty assignments for low volume services as detailed Table 1.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

Comment: Several commenters referenced the CY 2018 PFS finalized policy for the adjustment to allocation of indirect PE for some office-based services, generally services associated with behavioral health (82 FR 52999 through 53000). Commenters stated that for each of the services that qualify for the indirect PE allocation adjustment, CMS first establishes an indirect PE floor using the work RVU for the qualifying service and the ratio between the indirect PE RVUs and the work RVUs for the marker code (currently CPT code 99213). Commenters stated that CMS then identifies the difference between the indirect PE RVU for the qualifying service produced under standard methodology and the indirect PE floor; the modified methodology then increases the allocation of indirect PE RVUs to one quarter of that difference. Commenters stated that they supported the current policy, since they believe that the current PFS reimbursement rate methodology undervalues behavioral health services and recommended that CMS expand the indirect PE floor methodology by increasing the minimum value for non-facility indirect PE RVUs by adding the *full* difference between the indirect PE floor RVUs and indirect PE RVUs calculated for the eligible codes under the standard methodology (instead of one quarter of the distance). Commenters stated that this expansion of the current indirect PE floor policy would assure that a more appropriate number of indirect PE RVUs are allocated to these services and would provide greater resources to behavioral health practitioners providing services to Medicare beneficiaries with behavioral and mental health needs.

Response: We appreciate the support from the commenters for our previously finalized policy for the adjustment to allocation of indirect PE for some office-based services. While we share the concern of the commenters in ensuring that behavioral health practitioners have the proper resources that they need to provide services to Medicare beneficiaries, we note that we did not propose to make any adjustments to this indirect PE policy for CY 2024 and we are not finalizing any adjustments to this indirect PE policy for CY 2024. We will consider the recommendations from the commenters for potential use in future rulemaking.

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

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TABLE 2: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)− life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.

usage = variable, see discussion below in this final rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different

types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we referred readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2024.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'' of the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time has elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the

implementation of the finalized CY 2023 rebased and revised MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comment in the CY 2023 PFS proposed rule on when and how to best incorporate the CY 2023 rebased and revised MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comment on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation and many commenters expressed concerns with the redistributive impacts of the implementation of the rebased and revised MEI in PFS ratesetting. Many commenters also noted that the AMA has stated it intends to collect practice cost data from physician practices in the near future which could be used to derive cost share weights for the MEI and RVU shares.

In light of the AMA's intended data collection efforts in the near future and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, we continue to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Therefore, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2024.

As discussed above, in the CY 2023 PFS rulemaking, we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services. The final 2017-based MEI relies on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership, not limited to only self-employed physicians. The 2006-based MEI relied on the 2006 AMA PPIS survey data; as of this CY 2024 rulemaking, this survey had not been updated. Given the changes in the physician and supplier industry and the time since the last update to the base year, we finalized a methodology that would allow us to update the MEI on a consistent basis in the future. The 2017-based MEI cost share weights are derived predominantly from the annual expense data from the U.S. Census Bureau's Services Annual Survey (SAS, *https://www.census.gov/programs-surveys/sas.html*). We supplement the 2017 SAS expense data by using several data sources to further disaggregate compensation costs and all other residual costs (87 FR 69688 through 69708).

We continue to review more recently available data from the Census Bureau Services Annual Survey, the main data source for the major components of the 2017-based MEI cost share weights. Data is currently available through 2021. Given that the impact of the PHE may influence the 2020 and 2021 data, we continue to evaluate whether the recent trends are reflective of sustained shifts in cost structures or were temporary as a result of the COVID–19 PHE. The 2022 data from the Services Annual Survey will be available later this year. We will monitor that data and any other data that may become available related to physician services' input expenses and will propose any changes to the MEI, if appropriate, in future rulemaking.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our continued delayed implementation of the rebased and revised MEI in PFS ratesetting. Most of these commenters urged CMS to pause consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices have concluded. A few commenters urged CMS to implement the MEI for PFS ratesetting as soon as possible.

Response: We appreciate commenters' feedback, specifically as it relates to updating PFS ratesetting, and will consider the commenters' feedback in future rulemaking.

Comment: One commenter stated that the methodology for deriving the 2017-based MEI cost share weights is flawed because the use of the SAS data as the primary data source for expenses omits facility-based physicians which, according to BLS Occupational Employment and Wage Statistics (OEWS) data, accounts for 36 percent of physicians who are employed in the health sector. The commenter states that correcting for the omission would result in an increase to the physician work cost share weight and a much smaller reduction to the professional liability insurance (PLI) cost share weight in the MEI.

The commenter noted that in response to a similar comment in the CY 2023 PFS final rule, CMS responded that ''for physicians who are employed in other healthcare settings directly, such as hospitals, we do not believe that including costs for physicians that do not incur any operating expenses associated with running a practice would be technically appropriate.'' However, the commenter stated that this fails to consider that the MEI cost share weights also cover physician compensation and professional liability insurance. The commenter stated that by excluding NAICS 6221 General Medical and Surgical Hospitals in the CMS MEI cost share weights analysis, CMS inadvertently omitted over $30 billion in physician compensation and over $7 billion in professional liability insurance compensation. Also, the commenter noted that physician practices do still have some indirect PE costs even for providers who are solely facility-based (coding, billing, scheduling, etc.). The commenter claimed that the CMS analysis of the US Census SAS data captured a large majority of PE covered by the PFS but only a subset of the physician compensation and professional liability insurance premiums.

The commenter requested that CMS make changes to the methodology for deriving the MEI cost share weights to correct for the omission of costs for facility-based physicians.

Response: We appreciate the commenter's concern regarding the methodology for the 2017-based MEI. As explained in the 2023 PFS final rule (87 FR 69688 through 69710), the development of the MEI cost share weights (which would reflect all costs including work, PE and PLI) is intended to be consistent with costs associated with providing physician services as paid for by the PFS. Thus, we are using a data source that reflects the nature of those costs, which we have determined to be the U.S. Census Bureau's Services Annual Survey. This data source shows all ownership types of physicians' offices as determined by the North American Industrial Classification System (NAICS). Unfortunately, there is currently no data source available that would provide a comprehensive

collection of physician expense data for physicians that directly contract with hospitals or other healthcare settings. While there are compensation costs for employed physicians working in an alternative setting such as a hospital or SNF and other associated expenses, including those for PLI, those costs would be captured in reporting for those other settings—such as hospitals, home health agencies, or skilled nursing facilities. For example, if a physician is directly employed by a hospital, that is, not just a hospital-owned physician practice, then those costs would be captured in the reported SAS expenses for NAICS 622 (Hospitals) and on the Medicare cost report submitted by the hospital. Unfortunately, there is currently no mechanism for identifying those specific expenses distinct to providing physician services separately from the provider's other expenses. Therefore, we have used a data source that we believe reflects the most up-to-date, comprehensive, and regularly published data on physician expenses for the majority of physicians (which would be captured in NAICS 621111—Offices of Physicians). We welcome the public to provide any other data source that could be considered, in concert with the SAS data, to address the commenters concerns. Additionally, we understand that the AMA is currently collecting data on physician expenses and we will analyze the data if made available to CMS. We note that CMS did not propose changes to the methodology for deriving the MEI cost share weights for CY 2024.or.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2024 direct PE input public use files, which are available on the CMS website under downloads for the CY 2024 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the

CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2024, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2024 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2024, we proposed to update the price of 16 supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2023 PFS final rule. The 16 supply and equipment items with proposed updated prices were listed in the valuation of specific codes section of the preamble under Table 15, CY 2024 Invoices Received for Existing Direct PE Inputs (88 FR 52348).

We did not propose to update the price of another eleven supplies which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- *Extended external ECG patch, medical magnetic tape recorder (SD339):* We received additional invoices for the SD339 supply from an interested party. Upon review of the invoices, we determined that they contained the identical price point that we previously incorporated into last year's rule when we finalized a price of $260.35 for the supply item (87 FR 69514 through 69516). Since these invoices did not contain any new information, we stated in the proposed rule that we are maintaining the previously finalized price of $260.35 for the SD339 supply.

- *Permanent marking pen (SL477), Liquid coverslip (Ventana 650–010) (SL479), EZ Prep (10X) (Ventana 950–102) (SL481), Cell Conditioning 1 (Ventana 950–124) (SL482), and Hematoxylin II (Ventana 790–2208) (SL483):* We received invoices from interested parties for use in updating the price of these laboratory supplies. In each case, however, we were able to find the same supply item available for sale online at the current price or cheaper. Therefore, we do not believe that the submitted invoices represent typical market pricing for these supplies and we did not propose to update their prices.

- *Mask, surgical (SB033), scalpel with blade, surgical (#10–20) (SF033), eye shield, non-fog (SG049), gauze, non-sterile 4in x 4in (SG051), and towel, paper (Bounty) (per sheet) (SK082):* We received invoices from interested parties for use in updating the price of these common supply items. In each case, we received a single invoice and once again we were able to find the same supply items available for sale online at the current price or cheaper. Generally speaking, we avoid updating the price for common supply items like the SB033 surgical mask (included in approximately 380 HCPCS codes) based on the submission of a single invoice, as an invoice unrepresentative of current market pricing will have far-reaching effects across the PFS. We did not find that the typical price for a surgical mask had increased by more than 60 percent since the supply and equipment pricing update concluded in CY 2022, and as such we stated in the proposed rule that we are maintaining the current price for these supply items.

We received the following comments on our proposed updates to supply and equipment pricing:

Comment: Several commenters stated that they supported the proposed pricing updates of the following supplies and equipment items: SC084, SC085, SM008, SL491, EP034, EP111, SA110, SL077, SL495, SL475, SL488, SL474, and SL486. The commenters urged CMS to finalize the updates as proposed.

Response: We appreciate the support for our proposed pricing from the commenters.

Comment: A commenter stated that they had submitted invoices during the pre-rulemaking period, in February 2023, to support CMS with identifying the appropriate direct PE inputs for equipment and supplies used in physician pathology services. The commenter listed ten supply and equipment items with updated pricing in the proposed rule (EP034, EP111, SA110, SL077, SL474, SL475, SL486, SL488, SL491, SL495) and stated that they supported the proposed pricing changes for these items and urged CMS to finalize them as proposed in the final rule.

Response: We appreciate the support for our proposed pricing from the commenter.

Comment: Several commenters stated that they appreciated CMS' conclusion that the current price of $260.35 should be maintained for supply item SD339 (extended external ECG patch, medical magnetic tape recorder) for CY 2024. The commenters stated that the proposed pricing represented much-needed payment stability for providers of the long term electrocardiographic (LT–ECG) monitoring service and it was in the best interest of Medicare beneficiaries for CMS to support continued patient access to these services through the maintenance of fair and stable provider reimbursement.

Response: We appreciate the support for our proposed pricing from the commenters.

Comment: A commenter submitted approximately 50 invoices with the intention of persuading CMS to update the pricing for the Tubing set, blood warmer (SC084) and Tubing set, plasma exchange (SC085) supplies. The commenter stated that these invoices were based on sales to U.S. customers in June and July 2023 and requested that CMS update their prices to reflect the data contained on the invoices.

Response: We appreciate the large quantity of pricing data provided by the commenter for use in updating the pricing of the SC084 and SC085 supplies. After reviewing the invoices, we agree with the commenter that the Tubing set, blood warmer (SC084) supply is more accurately priced at $16.27 and the Tubing set, plasma exchange (SC085) supply is more accurately priced at $277.20. We are finalizing these updated prices based on the market-based pricing contained in this large sample of submitted invoices.

The following are additional comments that we received associated with supply and equipment pricing:

Comment: A commenter stated that the non-facility reimbursement is significantly undervalued for CPT code 36836 (*Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation*). The commenter stated that an angiography room (EL011) should be included in the equipment item inputs for CPT code 36836, since it is included in CPT code 36837, instead of the current vascular ultrasound room (EL016). The commenter also stated that CMS should update the pricing for the Ellipsys Vascular Access Catheter (SD351) supply item as the price of $6,000 is not representative of the current cost of the device. The commenter submitted approximately 70 invoices with the intention of persuading CMS to update the pricing for the SD351 supply to $7,378.75.

Response: We disagree with the commenter that the use of an angiography room would be more typical than the use of a vascular ultrasound room for CPT code 36837; the vascular ultrasound room was recommended by the RUC and finalized by CMS in CY 2023 rulemaking (87 FR 69485 through 69489). However, we appreciate the submission of a large quantity of pricing data provided by the commenter for use in updating the pricing of the SD351 supply. We previously wrote in CY 2023 rulemaking that we were concerned that the submission of a single invoice would represent an increase from $6,000 to $8,950 for the SD351 supply, an extraordinary increase in the span of 6 months since the service was reviewed at the January 2022 RUC meeting, and that we would consider supply pricing in future updates to this service.

With the much larger batch of invoice data supplied by the commenter, it is clear that the Ellipsys Vascular Access Catheter (SD351) supply item has a bimodal pricing structure, with almost exactly half of the submitted invoices listed at the current price of $6,000 while the other half were priced at $8,950. Based on this updated pricing data, we therefore agree that the commenter's suggested price change to $7,378.75 is an appropriate update to the price of the SD351 supply as it falls between the two poles of the pricing distribution. We are finalizing this update to the price of the SD351 supply to more accurately reflect the typical market price.

Comment: A commenter submitted a series of approximately 100 invoices for use in pricing a new supply item known as the WatchPAT One device. The commenter stated that this was a separate supply from the WatchPAT pneumo-opt slp probes (SD263) item currently listed in the CMS supply database priced at $73.32. The commenter detailed the clinical benefits associated with the WatchPAT One device and provided to CMS copies of purchase invoices reflecting sales of approximately 3,000 units across all geographic regions of the country to support the commenter's requested value of $98.20 for the supply item.

Response: We appreciate the submission of this large quantity of pricing data associated with the WatchPAT One device. Although there are no HCPCS codes that currently include the WatchPAT One device as a supply item, we will add the WatchPAT One device to our supply database with its own supply code (SD362) at the requested price of $98.20 so that it can be used in future reviews of services that typically make use of this product.

Comment: A commenter stated that there are numerous discrepancies between the aggregated cost of some of the supply packs and the individual item components contained within. The commenter stated that these mathematical errors should be rectified as soon as possible by CMS to ensure that the sum correctly matches the totals from the individual items, and the commenter recommended that CMS resolve these pricing discrepancies in the supply packs during CY 2024 rulemaking. The commenter submitted RUC workgroup recommendations to update pricing for a series of supply packs along with their comment letter.

Response: We appreciate the additional information and RUC workgroup recommendations provided by the commenter regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs, and because we did not propose to address supply pack pricing in the CY 2024 proposed

rule, we believe that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We believe that interested parties will be better served if CMS addresses this topic in a comprehensive manner during a potential future rulemaking in which commenters could provide feedback in response to proposed pricing updates.

Comment: A commenter reviewed the issue of skin adhesives and identified several generic alternatives to the use of the skin adhesive (Dermabond) (SG007) supply. The commenter stated that there are multiple skin adhesive products, at different price points, available that work similarly to Dermabond and requested that generic alternatives should be used overall in place of brand names in the CMS supply database. The commenter made a series of suggestions for CMS to create new medical supply item codes to encompass the generic formulations of cyanoacrylate skin adhesive in multidose form and single use sterile application.

Response: We note that these revisions to the skin adhesive supplies were incorporated into the recommendations from the April 2023 RUC meeting where several skin adhesive procedures were reviewed. As we stated with respect to the pricing of supply packs above, we believe that this issue would be better addressed in a potential future rulemaking, for example as part of the RUC review of these skin adhesive procedures for the upcoming CY 2025 cycle. This would allow CMS to make any potential revisions to the skin adhesive supplies while the HCPCS codes in question are also under formal review to minimize disruption to existing services.

Comment: Several commenters recommended that CMS separately identify and pay for high-cost disposable supplies. Commenters stated that this would address the outsized impact that high-cost disposable supplies have within the current PE RVU methodology; if high cost supplies were paid separately with appropriate HCPCS codes, their indirect expense would no longer be associated with that service. Commenters stated that the result would be that indirect PE RVUs would be redistributed throughout the specialty PE pool and the PE for all other services. Commenters recommended that CMS separately identify and pay for high-cost disposable supplies priced more than $500 using appropriate HCPCS codes.

Response: We have received a number of prior requests from interested parties, including the RUC, to implement separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. (For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251)).

After consideration of the comments, we are finalizing updates to the pricing of the supply and equipment items as listed in Table 17 and detailed above. These supply and equipment items with updated prices are listed in the valuation of specific codes section of the preamble under Table 17, CY 2024 Invoices Received for Existing Direct PE Inputs.

(1) Invoice Submission

We remind readers that we routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types, and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We

believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. (86 FR 65025) An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 5.

TABLE 5: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Updates

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64

rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032).

Based on comments received on the CY 2023 proposed rule, we finalized a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist''. We also finalized an update in the pricing of three clinical labor types: from $0.60 to $0.84 for the Vascular Interventional Technologist (L041A), from $0.63 to $0.79 for the Mammography Technologist (L043A), and from $0.76 to $0.78 for the CT Technologist (L046A) based on submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey (87 FR 69422 through 69425).

(2) CY 2024 Clinical Labor Pricing Update Proposals

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2024 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2024 was based on the clinical labor pricing that we finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 of the update:

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TABLE 6: Proposed CY 2024 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.268	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.335	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.420	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.410	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.495	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.375	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.534	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.423	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.573	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.663	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.498	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.460	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.485	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.545	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.488	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.555	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.579	62%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.731	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.575	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.575	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.578	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.585	52%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.702	84%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.683	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.780	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.638	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	0.703	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.688	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.688	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.643	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.643	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.761	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.793	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.793	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.698	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.705	51%
L051C	RN/CORF	L051A	0.51	0.76	0.698	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.738	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.725	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.818	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.753	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.805	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.779	50%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.840	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.409	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.986	41%

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 and CY 2023 PFS final rules in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

We received the following comments on our clinical labor pricing update proposals for CY 2024:

Comment: Several commenters stated that CMS created a rank order anomaly in the pricing of the cytotechnologist (L045A) clinical labor type when it increased the clinical labor rates for the vascular interventional technologist (L041A), mammography technologist (L043A), and CT technologist (L046A) in CY 2023. The commenters stated that the education requirements for a cytotechnologist were greater than the requirements for these clinical labor types and that the cytotechnologist should be valued 10 percent more than the CT technologist based on Salary Expert data. Commenters stated that cytotechnologists are responsible for more intensive clinical responsibilities than MRI technologists, such as preparing and evaluating human cellular samples from all body sites, to detect and highlight for the pathologist's attention cells with pre-cancerous changes, cancer cells, benign tumors, infectious agents, and inflammatory processes. Commenters requested that CMS crosswalk the cytotechnologist clinical labor type to the BLS 29–9092 category (genetic counselors) at a rate of $0.85 to correct this pricing anomaly and supported their request with data from the 2021 American Society of Clinical Pathologists (ASCP) Wage Survey of Medical Laboratories, in which the average cost per minute for cytotechnologists was $0.86.

Response: We appreciate the additional information surrounding the cytotechnologist (L045A) clinical labor type supplied by the commenters, especially the 2021 ASCP wage survey containing wage data on this clinical labor type. After reviewing the information submitted by the commenters, we concur that a crosswalk to the BLS 29–9092 category at a rate of $0.85 would be more accurate for the L045A clinical labor type, based on the wage data provided by Salary Expert and the 2021 ASCP wage survey. We are finalizing this update in the clinical labor pricing of the L045A clinical labor type from $0.76 to $0.85 based on this new information.

Comment: Several commenters expressed their disagreement with the ongoing clinical labor pricing update. Commenters stated that the pricing update continued to apply a huge and unfair burden on specialties that require expensive supplies and/or equipment to care for their patients, and that while the increase in clinical labor pricing was appropriate, it was not appropriate that some physicians were negatively impacted by the change. Commenters stated that these dramatic cuts will also further exacerbate disparities in access to care and health outcomes, among rural and minority populations, by constraining and in some cases preventing physicians in community-based office settings from providing critical patient care to underserved populations. Commenters asked CMS to hold harmless the specialties that were most affected by the clinical labor pricing update and not move forward with the third year of the phase-in. One commenter disagreed with the finalized BLS 2021 benefit multiplier of 1.296 and stated that CMS should use the originally proposed 1.366 benefits multiplier instead.

Response: We finalized the implementation of the clinical labor pricing update 2 years ago in the CY 2022 PFS final rule (86 FR 65020 through 65037) where we previously addressed these same comments. As we stated at that time, although we recognize that payment for some services will be reduced because of the pricing update, due to the budget neutrality requirements of the PFS, we do not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs over time. The PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs; continuing to use clinical labor cost data that are nearly 2 decades old would maintain distortions in relativity that undervalue many services which involve a higher proportion of clinical labor. As noted above, we also finalized the implementation of the pricing update through a 4-year transition to help address the concerns of the commenters about stabilizing RVUs and reducing large fluctuations in year-to-year payments.

For CY 2024, we solicited comments regarding new wage data or other additional information for use in clinical labor pricing from interested parties. The clinical labor pricing update itself, including its pricing methodology, was previously finalized through rulemaking and the first 2 years of the 4-year transition have already been implemented; as such, these comments are out of scope for CY 2024 rulemaking.

After consideration of the comments, we are finalizing the clinical labor prices as shown in Table 7; aside from the Cytotechnologist (L045A) clinical labor type detailed above, all other clinical labor pricing remains unchanged from the proposed rule.

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TABLE 7: Finalized CY 2024 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.268	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.335	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.420	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.410	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.495	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.375	18%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.534	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.423	19%
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L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.663	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.498	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.460	32%
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L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.805	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.779	50%
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L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.409	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.986	41%

* Updated for CY 2024

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the remaining course of the 4-year transition period. We welcome additional feedback on clinical labor pricing from commenters in next year's rulemaking cycle, especially any data that will continue to improve the accuracy of our finalized pricing.

d. Technical Corrections to Direct PE Input Database and Supporting Files

Following the publication of the CY 2023 PFS proposed rule, an interested party notified CMS that CPT code 86153 (*Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required*) appeared to be missing its work time in the Physician Work Time public use file. We reviewed the request from the interested party and determined that this was indeed an unintended technical error; we stated in the CY 2013 PFS final rule that we were finalizing 0 minutes pre-service time, 20 minutes intraservice time, and 0 minutes post-service time to CPT code 86153 (77 FR 69059); however, work time was inadvertently completely missing for this code. Therefore, we proposed to add the correct 20 minutes of intraservice work time to CPT code 86153 for CY 2024.

Comment: A commenter stated that they agreed with the correction of this error and urged CMS to finalize the update of 20 minutes of intra service work time for CPT code 86153.

Response: We appreciate the support for our proposal from the commenter. We received no other comments regarding this proposal, and we are finalizing the addition of the correct 20 minutes of intraservice work time to CPT code 86153 for CY 2024, as proposed.

We received the following comments on technical corrections to the direct PE input database and supporting files:

Comment: A commenter stated that transcatheter valve procedures are extremely technical in nature and require a highly functional multi-disciplinary surgical and operating room team, which was not reflected in the indicators currently assigned to certain Category III codes associated with this service. The commenter stated that these Category III codes should have their assistant surgeon, co-surgeon, and team surgeon indicators match CPT codes 33418 and 33419. Specifically, the commenter requested that CMS change the assistant surgeon payment policy indicator from ''0'' to ''2'' for the following transcatheter valve CPT codes: 0483T, 0544T, 0545T, 0569T, 0570T and 0646T; change the co-surgeon payment policy indicator from ''0'' to ''1'' for transcatheter valve CPT codes 0544T, 0545T, 0569T and 0570T, and to ''2'' for CPT code 0646T; and change the team surgeon payment policy indicator from ''0'' to ''1'' for CPT code 0646T.

Response: We appreciate the feedback from the commenter regarding the need for greater consistency in the indicators for these Category III transcatheter valve procedures. After reviewing the request from the commenter, we concur that these Category III codes should match the assistant surgeon, co-surgeon, and team surgeon indicators for CPT codes 33418 and 33419 which had a national coverage determination released to this effect in 2014 and 2015 (see *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM9002.pdf*). Therefore, we are finalizing the indicator changes requested by the commenter in the previous paragraph.

Comment: Several commenters raised the topic of indirect PE allocation for the home PT/INR monitoring services described by HCPCS codes G0248 and G0249. Commenters stated their appreciation that CMS acknowledged their concerns about the lack of a specialty designation that accurately reflects the indirect costs of home PT/INR monitoring suppliers in the CY 2021 PFS rulemaking cycle and agreed to update the indirect factors for home PT/INR monitoring by crosswalking to the General Practice Specialty (85 FR 84477 through 84478). Commenters stated that proposed policies in the CY 2023 PFS rule completely negated the limited benefit from this crosswalk to General Practice, and they again appreciated that CMS changed the crosswalk for PT/INR suppliers to the All Physician specialty which more closely reflected indirect-to-direct cost ratios for home PT/INR monitoring services (87 FR 69417 through 69419). Commenters noted that CMS did not propose any changes in the crosswalk for these services and requested that the crosswalk remain as previously finalized for CY 2024.

Response: As the commenters noted, we did not propose any changes to the specialty crosswalk for indirect PE allocation for home PT/INR monitoring services and we are not finalizing any changes to the crosswalk for PT/INR monitoring services. Nevertheless, we appreciate the support from the commenters for our previously finalized policies.

Comment: A commenter questioned the proposed PE RVU for CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) in the nonfacility setting. The commenter stated that the proposed reduction was an unfair decrease that was specific only to CPT code 97610 when other clinically similar CPT wound care codes were not similarly reduced. The commenter requested that the nonfacility PE RVU for CPT code 97610 be reviewed for accuracy and increased

to match its previous valuation for CY 2024.

Response: We reviewed CPT code 97610 in response to the commenter's concerns and we can confirm that there are no technical errors affecting the valuation of this code. We did not make any specific proposals regarding CPT code 97610 for CY 2024; however, the valuation for this code is being affected by the ongoing clinical labor pricing transition. Supply costs make up 94.5 percent of the direct PE inputs for CPT code 97610 and, as a result, the increased pricing for clinical labor across all services on the PFS translates into a lower valuation for CPT code 97610, after budget neutrality is applied to the PE. For additional information on this topic, we direct readers to the extended discussion of the clinical labor pricing update in the CY 2022 final rule (86 FR 65020 through 65037).

Comment: A commenter stated that StrategyGen's market-based supply and equipment research contained numerous flaws in how it arrived at the cost of the external counterpulsation (ECP) system (EQ012) used in HCPCS code G0166 (*External counterpulsation, per treatment session*) for CY 2021. The commenter stated that they appreciated CMS' assistance in recent years to correct some of these errors, but the continued phase-in of PE RVU decreases associated with equipment costs, as well as the clinical labor pricing updates adversely impacting services with high capital expenses, continued to place incredible stress on the reimbursement for ECP therapy. The commenter stated that the reimbursement for a full course of therapy has decreased from 2018 to 2023 by nearly the cost of the routinely purchased supplies necessary for delivering this service, and as a result it is no surprise that practices that do not specialize in ECP therapy would rather abandon the service than continue to pay the expensive system maintenance costs.

Response: We note for the commenter that we did not make any proposals specifically regarding HCPCS code G0166 or the EQ012 equipment for CY 2024 and the commenter did not supply invoices or other data to support a change in pricing. If the commenter has reason to believe that the EQ012 equipment is inaccurately priced, interested parties are encouraged to submit invoices containing pricing data with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*. If the commenter believes that HCPCS code G0166 may be potentially misvalued, we encourage them to consider nominating the code under our potentially misvalued process (detailed in section II.C. of this final rule) for additional review.

5. Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011 through 2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA PPIS data for certain specialties (76 FR

73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016 through 2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 through 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that might affect or factor into PE calculations. We reminded readers that we have worked with interested parties and CMS contractors for years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology.

As described in last year's rule, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology relies on AMA PPIS data, which may represent the best aggregated available source of information at this time. However, we acknowledge the limitations and challenges interested parties have raised about using the current data for indirect PE allocations, which we have also examined in related ongoing research. We noted in last year's rule that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

Many commenters last year asked that CMS wait for the AMA to complete a refresh of AMA survey data. We responded to these comments by explaining the tension that waiting creates in light of concerns raised by other interested parties. Waiting for refreshed survey data would result in CMS using data nearly 20 years old to form indirect PE inputs to set rates for services on the PFS. We reminded readers that many of the critical issues discussed in the background and history above are mainly unchanged and possibly would not be addressed by an updated survey alone but may also require revisions to the PFS ratesetting methodology.

b. Summary of the Comments and Responses for the Request for Information

In the CY 2024 PFS proposed rule, we continued to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. We stated that submissions should discuss the feasibility and burden of implementing any suggested adjustments and highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments. We stated that we were continuing to consider ways that we may engage in dialogue with interested parties to better understand how to address possible long-term policies and methods for PFS ratesetting. We believe some of those concerns may be alleviated by having ways to refresh data and make transparent how the information affects valuations for services payable under the PFS more accurately and precisely.

Considering our ratesetting methodology and prior experiences implementing new data, we issued a follow-up solicitation for general information. We solicited comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types.

We also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In light of the considerations discussed above, we requested feedback on the following:

(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over-allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable and accurate means to account for indirect PEs across various specialties or practice types?

(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?

(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

(5) Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

We received public comments on this RFI. The following is a summary of the comments we received and our responses.

Comment: Most commenters stated that CMS should defer significant changes until the AMA PPIS results become available. In responding to our RFI, the AMA RUC provided a set of responses, which many other commenters repeated in their separate, individual comments. In summary, the AMA RUC letter responds to all five prompts in the RFI with rationales that support the assertion that CMS should not consider further changes until PPIS data collection and analysis is complete.

Response: We thank the AMA RUC for commenting. In totality, the AMA comments generally do not support any change to the methodology and assert that CMS should wait to consider any further changes until PPIS updates become available. Further, we note that through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey.[1] We believe the AMA's approach may possibly mitigate nonresponse bias, which created challenges using previous PPIS data. However, we remain uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected.

Comment: Some commenters did not recommend that CMS defer significant changes until the AMA PPIS results become available. These commenters stated that reliance on the PPIS updates may not improve the accuracy and stability of the PE methodology because of the survey design, possible implementation challenges, and a possible lack of transparency or granularity in resulting datasets.

Response: We thank commenters for their feedback. We believe it remains important to reflect on the challenges with our current methodology, and to continue to consider alternatives that improve the stability and accuracy of our overall PE methodology. We reiterate our discussion summarizing the responses to last year's RFI in the CY 2023 final rule (refer to 87 FR 69429 through 69432). In last year's RFI, we signaled our intent to move to a standardized and routine approach to valuation of PE and we solicited feedback. We solicited comment on the appropriate instrument, methods, and timing for updating PE data, and requested information on any alternatives that would result in more predictable results, increased efficiencies, or reduced burdens, for subsequent updates in later years CMS continues to seek alternatives that use verifiable, more objective data sets in the future to supplement or augment survey data used to establish PE RVUs for PFS services.

Comment: Some commenters stated that regardless of whether one supports or does not support updating and using updated PPIS data, the duration between updates and the expense of fielding a survey instrument may promote further market consolidation. Additionally, other commenters stated that dependence on the PPIS or survey data in general, due to timing and frequency constraints, may continue to jeopardize independent practice and discourage fair competition among suppliers and providers of services paid under the PFS. These commenters assert that if current trends continue, it will result in far fewer independent practices and more consolidation before the availability of updated survey data, undermining the sampling methodology of any survey and the general goals of our PE methodology updates.

Response: We thank commenters for their feedback, and we encourage interested parties to continue to engage with us regarding the intersection of PE data and these important issues

Comment: We received a comment co-signed by a broad and varied set of interested parties (for example, professional membership organizations, vendors, practitioners, health systems) that requested a separate RFI. The authors asked that CMS address topics regarding machine learning, AI, and software and explore a means outside our annual rulemaking cycle, so that CMS may address changes in healthcare related to these topics and better account for such changes in payment moving forward. Commenters asserted that the rapid pace of innovation may require far more significant changes than would be practical to address in a given calendar year. The commenters also highlighted the AMA's efforts to develop Appendix S of the CPT Manual, which establishes a taxonomy for medical AI.

Response: We remain committed to fostering dialogue with interested parties on a variety of PE issues, including how to most appropriately incorporate new and evolving technologies in both collection of PE data and the PE methodology itself. Further, we acknowledge the efforts of the AMA to establish a taxonomy for AI, which was informed by engagement with HHS ONC and others (refer to *https://www.healthit.gov/sites/default/files/page/2020-02/GettingerModeratorSlidesAIPanelsforONCAnnualMeeting12720Final.pdf*). We encourage readers to review general resources that provide overviews of efforts across HHS that address these topics. Examples include ONC's AI Showcase, held in late 2022, available at *https://www.healthit.gov/news/events/onc-artificial-intelligence-showcase-seizing-opportunities-and-managing-risks-use-ai* and this year's issuance of a notice of proposed rulemaking for Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1), (88 FR 23746); as well as the FDA's Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan, available at *https://www.fda.gov/media/145022/download* and Good Machine Learning Practice for Medical Device Development: Guiding Principles, available at *https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles*.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this final rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and

[1] Refer to the AMA's summary of the PPIS, available at *https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf.*

specialty recommendations submitted to us by the RUC for our review. We also considered information provided by other interested parties such as from the general medical-related community and the public. We conducted a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed

discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes'' [2]). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2024 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative. For CY 2024, we received 10 nominations concerning various codes. The nominations are as follows:

(1) CPT Code 59200

In the CY 2022 PFS proposed rule, an interested party nominated CPT code 59200 (*Insertion cervical dilator (e.g., laminaria, prostaglandin*)) (000 zero day global code) as potentially misvalued, because the direct PE inputs for this code do not include the supply item, Dilapan-S. Previous parties had initially sought to establish a Level II HCPCS code for Dilapan-S, but CMS did not find sufficient evidence to support that request. The same interested party then submitted Dilapan-S to be considered as a practice expense (PE) supply input to a Level I CPT code 59200 (86 FR 65045). This year, a different interested party nominated CPT code 59200 again, and provided the same reasoning as to why this code is potentially misvalued.

Specifically, the current nominee recommended adding 4 rods of Dilapan-S at $80.00 per unit, for a total of $320.00 to this one PE supply inputs, as a replacement for the current PE supply item—laminaria tent (a small rod of dehydrated seaweed that rehydrates, absorbing the water from the surrounding tissue). The laminaria tent is currently listed at $4.0683 per unit, with a total of 3 units, for a total of $12.20. The current nominee stated that Dilapan-S is more consistent and reliable, and suggested that it had higher patient satisfaction than the laminaria tent, and that it was less likely to cause leukocytosis. CPT code 59200 is a relatively low volume code, with respect to Medicare claims and, as the nominator stated, this service is more typically billed for the Medicaid population, as evidenced by 1.3 million Medicaid claims for this service. Medicaid programs are able to set their own payment policies, which can be different from Medicare payment policies. The current Medicare payment for CPT code 59200 in CY 2023 is about $108.10 in the nonfacility/office setting, which is much less than the typical cost of the Dilapan-S supplies requested by the interested party. The requested 4 rods of Dilapan-S would increase the

[2] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

supply costs of CPT code 59200 by a factor of five and represent an enormous increase in the direct costs for the service.

We did not agree that CPT code 59200 was potentially misvalued, and we did not agree with interested parties that the use of the Dilapan-S supply would be typical for the service. By including the increased direct costs of the service ($320.00, the typical cost of four units of this supply item, Dilapan-S) in the valuation for this code, the cost of this service would expand both Medicare spending and cost sharing for any beneficiary who received this service. The cost of Dilapan-S is over 19 times higher than the cost of the current supply item (laminaria tent) for CPT code 59200. We agreed with the nominator that CPT code 59200 was more frequently reported in the Medicaid population, and therefore, we suggested that interested parties submit a request for new and separate Medicaid payments to Medicaid.

While we did not propose to consider CPT code 59200 as potentially misvalued for CY 2024, we solicited comments on this code. Specifically, we asked commenters whether the absence of supply item Dilapan-S makes the nonfacility/office Medicare payment for this code potentially misvalued.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters suggested replacing the laminaria tent supply item with Dilapan-S, both of which are used to dilate the cervix in preparation for the induction of labor. Commenters stated that the code and supply input pricing for CPT code 59200 are both outdated since the service has evolved and the prices for its PE and supply items have increased since the code was last reviewed in 2003. One commenter noted that the use of the laminaria tent instead of Dilapan-S is not typical of, and does not reflect the standard of care for, term induction of labor; and that there are now many methods of cervical dilation, including pharmacological, mechanical, and surgical.

Also, commenters noted that CPT code 59200 only describes the insertion of the cervical dilator using the laminaria and/or prostaglandins and it does not describe the insertion of the cervical dilator with other practice expense supply items. As a result, commenters suggested CPT code 59200 should be reviewed.

Response: We thank commenters for pointing out that CPT code 59200 is a specific procedure for cervical dilation and that other methods of cervical dilation (pharmacological, mechanical, and surgical) have come into practice that are not described by CPT code 59200. We also appreciate commenters' pointing out that the current market price of the laminaria tent has increased since the supply item price was established in 2003. Lastly, we acknowledge commenters' suggestion regarding the replacement of the supply item laminaria tent with Dilapan-S.

Comment: A number of commenters stated that CPT code 59200 performed in the office or in the outpatient setting is more efficient in many ways (including in overall costs) and helps in inducing labor, which in turn, helps promotes vaginal births rather than concluding as Cesarean sections when there is not enough dilation. The commenters noted that in comparison, vaginal births obviously shorten hospital stays and patient recoveries and improves patient satisfaction in the birthing method.

Commenters noted that alternate cervical dilation such as prostaglandins medication must be administered as inpatient, and mechanical dilation is performed in an outpatient setting, but CPT code 59200 can typically be performed in the office, which is more desirable. Physicians have noted that patient populations today tend to have higher incidences of obesity, hypertension, diabetes, and advancing maternal age complications and to ensure healthy births and maintain the highest standards of care, the induction of labor is necessary, which begins with CPT code 59200, cervical dilation. One commenter adds that the use of laminaria instead of Dilapan-S is not the standard of care for term induction of labor.

Response: After reviewing the comments concerning CPT code 59200, we are mainly concerned with whether the code currently represents how the medical procedure is performed today. We agree with commenters that CPT code 59200 is a potentially misvalued service since the code has not been reviewed in 20 years and the current typical practice of this code has likely evolved since then, warranting a comprehensive review. As such, we believe that CPT code 59200 could benefit from a review of its supply, equipment, and clinical labor items, plus physician work RVUs and physician work times. Therefore, based on the information provided by commenters regarding the outdated nature of the code and supply input pricing, we are finalizing CPT code 59200 as potentially misvalued for CY 2024.

(2) CPT Code 27279

CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) (090 day global code) was nominated as potentially misvalued due to the absence of separate direct PE inputs for this 090 day global code in the nonfacility office setting. Currently, the PFS only prices CPT code 27279 in the facility setting, at about $826.85 for the physician's professional services, but the nominators were seeking separate direct PE inputs for this service to better account for valuation when performed in the nonfacility/office setting.

The nominator claimed that CPT code 27279 could be safely and effectively furnished in the nonfacility setting and that this procedure has a low-risk profile, similar to kyphoplasty (CPT codes 22513, 22514, and 22515), which is currently furnished in the nonfacility setting. The nominator described Kyphoplasty as ''a percutaneous minimally invasive procedure depositing poly methyl methacrylate via a cannula into vertebral bodies near neural structures.'' The nominator stated that permitting payment for direct PE inputs for CPT code 27279 in the nonfacility/office setting would increase access to this service for Medicare patients. The nominator also submitted one sample invoice for $17,985.00 with three units of the itemized supply item IFuse-3D Implant 7.0 mm x 55mm, US ($5,995.00 per unit) to illustrate the high direct PE costs for CPT code 27279, should CMS value this code in the nonfacility/office setting.

We expressed concern about whether this 090-day surgical service could be safely and effectively furnished in the non-facility/office setting (for example, in an office-based surgical suite). We welcomed comments on the nomination of CPT code 27279 for consideration as potentially misvalued.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported establishing a nonfacility/office payment for CPT code 27279. Commenters stated that while the procedure is currently performed in ASCs, it can be equally effective, with minimal risk, when done in an office setting. Commenters also stated that the fact that the service is assigned a 090-day global period does not imply that the code should only be performed in an inpatient setting nor that the service

carries a heightened level of risk, since CPT code 27279 is minimally invasive. Additionally, to support their recommendation to create a nonfacility/office payment for CPT code 27279, the commenters cited the dorsal arthrodesis procedure (Dorsal Sacroiliac Joint Arthrodesis CPT code 27278 (2X000)) for comparison since it also has a 090 global period and a nonfacility-office payment.

Response: We appreciate the comments in support of establishing a nonfacility/office payment for CPT code 27279.

Comment: Several commenters opposed creating a nonfacility/office payment for CPT code 27279 due to patient safety concerns when performed in the office setting. Also, some commenters noted that while the kyphoplasty codes (CPT codes 22513, 22514, 22515) are often cited as an example of codes supporting nonfacility/office payments similar to CPT code 27279, those codes have 010 day global periods and do not have the same level of risk as CPT code 27279. Commenters supported this point by stating that CPT code 27279 is not necessarily minimally invasive because it requires the incision and collection of bone as well as the placement of titanium implants across the sacroiliac joint.

Response: We appreciate the comments opposing the establishment of a nonfacility/office payment for CPT code 27279.

We thank the commenters for the multiple perspectives regarding nonfacility/office payment for these services. We note that there does not appear to be a consensus on whether these services may be safely and effectively furnished in the nonfacility/office setting, which is a primary concern in our policy consideration. Therefore, for CY 2024, we are not finalizing CPT code 27279 as potentially misvalued.

However, after reviewing the public comments, we note a growing number of potentially misvalued code nominations requesting that we establish nonfacility payment rates where there currently are none. We acknowledge that the practice of medicine continues to evolve in ways that, in clinically appropriate and effective circumstances, there may be support for a transition of complex procedures into ambulatory settings. We also acknowledge that PE inputs for such services should be appropriately determined and established to appropriately reflect typical clinical practice. We believe services such as those described by the nominator would benefit from review by other interested parties, such as the AMA RUC and private payors, even as we consider our policies for such services.

We look forward to considering valuation recommendations for such services and additional information that may inform our payment policy considerations in future rulemaking.

(3) CPT Codes 99221, 99222, and 99223

An interested party nominated the Hospital Inpatient and Observation Care visit CPT codes 99221 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.*), 99222 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.*), and 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.)* as potentially misvalued. We note that CMS reviewed these codes in the CY 2023 final rule (87 FR 69588) and established new physician work times and new work RVU payments for these services. The nominator disagreed with these values and asserted that these ''facility-based codes are always inherently (or proportionately) more intense than E/M services provided in other settings [in particular],'' with patients presenting with potentially infectious diseases, such as meningitis; pneumonia; tuberculosis; HIV/AIDS; Ebola virus; Zika virus; and, most recently, SARS-CoV–2 and mpox, and that the inpatient setting has a predominance of more seriously ill patients, who are sometimes immunocompromised and/or have multiple drug interaction issues and/or with comorbidities, making them extraordinarily more complex than those patients typically found in the office setting (with many of these infections being healthcare-associated infections and antibiotic-resistant bacterial infections). We note that these new requests did not offer appreciably new information relative to last year's nomination/consideration.

The nominator sought a new work RVU value of 1.92 for CPT code 99221, a new work RVU of 2.79 for CPT code 99222, and a new work RVU value of 4.25 for CPT code 99223. Currently, CPT code 99221 has a work RVU of 1.63, a reduction of 15.1 percent from its 1.92 work RVU from CY 2022. CPT code 99222 had a work RVU of 2.61 in CY 2022 and is now at 2.60. CPT code 99223 had a work RVU of 3.86 in CY 2022. It now has a value of 3.50, which is a reduction of 9.3 percent. The nominator requested that the work RVU for CPT code 99221 be restored back to 1.92, that the work RVU of CPT code 99222 be increased to 2.79, and that the work RVU of CPT code 99223 be increased to 4.25 (please see Table 8 for a comparison of work RVU values for CY 2022, CY 2023, and of those requested by the nominator).

TABLE 8: A Comparison of Work RVU values for CY 2022, CY 2023, and Those Requested by the Nominator

CPT Code	CY 2022 Work RVU	CY 2023 Work RVU	Requested Work RVU
99221 - 1st hosp ip/obs sf/low 40	1.92	1.63	1.92
99222 - 1st hosp ip/obs moderate 55	2.61	2.60	2.79
99223 - 1st hosp ip/obs high 75v	3.86	3.50	4.25

After consideration of these nominations and their requests for higher work RVUs for CPT codes 99221, 99222, and 99223, we proposed to maintain the values that we finalized for these codes in the CY 2023 PFS final rule (87 FR 69588). Even so, we welcomed comments on the nomination of these codes as potentially misvalued.

The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that CMS should not have accepted the CY 2023 AMA RUC-recommended RVU values for CPT codes 99221, 99222, and 99223 because they resulted in payment decreases for all three services (partially due to a decrease in survey times), due to significant flaws with the AMA RUC evaluation process. Several commenters suggested that the work RVUs for CPT codes 99221, 99222, and 99223 be restored to their original values from before CY 2023 or be increased to mimic the increases that the E/M family of codes has experienced in recent years.

Response: We thank commenters for their feedback.

After consideration of public comments, we do not believe CPT codes 99221, 99222, and 99223 are potentially misvalued since they were recently valued in the CY 2023 final rule (87 FR 69588). In that regulation, we accepted the AMA RUC recommendations. We believe that the AMA RUC recommendations are still appropriate and best reflect the work intensity and time involved in furnishing these services. Therefore, for CY 2024, we are not finalizing CPT codes 99221, 99222, and 99223 as potentially misvalued.

(4) CPT Codes 36514, 36516, 36522

An interested party nominated CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) (all 000 day global codes) as potentially misvalued. The interested party stated that the direct PE of clinical labor L042A, ''RN/LPN'' (for labor rate of $0.525 per minute), was incorrect and should be changed to a more specific entry of ''a therapeutic apheresis nurse specialist (RN)'' (for a labor rate of about $1.06 to $1.14 per minute), which would approximately double all three of these codes' clinical labor PE entries. In addition, the nominator disagreed with the current direct PE of supply item SC085, ''Tubing set, plasma exchange'' at $186.12 per item, and believed that this would be worth $248.77 per item with CPT code 36514, using a quantity of one item. The nominator believed that supply item SC084, ''Tubing set, blood warmer,'' which we currently have listed at $8.01 per item, should be worth $14.71 per item with CPT code 36514, also using a quantity of one item. The nominator submitted sample invoices (not actual invoices) for illustration and support. We welcomed comments on whether these codes were potentially misvalued.

The following is a summary of the comments we received and our responses.

Comment: Several commenters were in favor of establishing a specific new Therapeutic Apheresis Nurse Specialist labor category for CPT codes 36514, 36516, and 36522 because they did not believe the current RN/LPN labor code accurately captured their nurses' specialized skills, experience, work, and time. Commenters pointed out that recruiting and retaining nursing personnel has been challenging, and when competing for an experienced specialized apheresis nurse, salary demands are higher to attract and keep them. The nominator also mentioned that a typical apheresis nurse tends to have an extensive clinical background and specialized therapeutic apheresis experience. Additionally, commenters noted that these nurses spend significant time with patients during apheresis procedures, often not leaving the patient's bedside during the long procedure. Commenters noted that these nurses are trained to set up specialized equipment, work with hospital blood banks to acquire blood products, work with pharmacies for required medications, and consult with medical and nursing staff.

Response: We thank commenters for their detailed description of the typical duties of an apheresis nurse and how they might differ from a general RN/LPN nurse.

Comment: Several commenters opposed the nomination of CPT codes 36514, 36516, 36522 as potentially misvalued and advised us to review the results of the forthcoming AMA PPIS survey before making any changes. One commenter added that there might be a clinical labor type gap that CMS could resolve.

Response: We thank commenters for their feedback and for acknowledging the forthcoming AMA PPIS survey.

After considering the public comments, we believe there may be a possible disparity with the clinical labor type for this service and that these codes would benefit from additional review in future rulemaking. We believe that it is likely that a general RN/LPN labor category is not adequately equivalent to an Apheresis Nurse Specialist and while there is currently no Apheresis Nurse category listed in the PFS, there may be existing nurse categories that can act as a substitute, such as an oncology nurse. Therefore, for CY 2024, we are finalizing CPT codes 36514, 36516, and 36522 as potentially misvalued.

(5) CPT Codes 44205 and 44204

An interested party nominated CPT code 44205 (*Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy*), as potentially misvalued, requesting that payment for this code be made equivalent to the higher payment for CPT code 44204 (*Laparoscopy, surgical; colectomy, partial, with anastomosis*). Both codes are 090 day global codes, currently valued only in the facility setting. CPT code 44204 has a total RVU of 45.62 for CY 2023, and CPT code 44205 has a total RVU of 39.62 for CY 2023, with a difference of 6.00 RVUs. CPT code 44204 is associated with 5 to 6 percent more physician work time: 455.0 minutes in total, compared to 428.5 minutes for CPT code 44205. The

work RVU for CPT code 44204 is also 15 percent higher than the work RVU for CPT code 44205. The direct PE entries for both codes are the same regarding supplies, equipment, and clinical labor, except that in the clinical labor and equipment entries, the number of usage minutes is higher for CPT code 44204.

Though these two codes appear to be similar, they are still different in their purpose, physician work times, and direct PE, with CPT code 44204 involving more time and resources (and having a higher payment, accordingly). For these reasons, we disagreed with the assertion that CPT code 44205 is potentially misvalued when compared to CPT code 44204, and we disagree to modify this payment differential by paying more for CPT code 44205. We solicited feedback regarding the nomination of CPT code 44205 as potentially misvalued.

We did not receive public comments on this provision, and therefore, we are finalizing our proposal not to nominate this service as potentially misvalued.

(6) CPT Codes 93655 and 93657

An interested party nominated CPT codes 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure))* and 93657 *(Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)),* as potentially misvalued. We recently reviewed these add-on codes in the CY 2022 (86 FR 65108) and CY 2023 (87 FR 69516) final rules.

The nominator reiterated that the primary procedures involve ''high intensity clinical decision making, complexity in the intraoperative skills required for treatment, morbidity/mortality risks to the patient, and work intensity'' and that the work RVUs for both of these add-on codes should reflect the AMA RUC recommended work RVU of 7.00. We disagreed with this value in CY 2022 and continued to believe that a work RVU of 5.50 was appropriate for the 60 minutes of physician service time for both codes. We saw no reason to reconsider our valuation of CPT codes 93655 and 93657 for CY 2022 or CY 2023, and we do not consider these codes to be potentially misvalued now and did not propose to nominate these codes as potentially misvalued for CY 2024.

Comment: We received very few comments addressing these two cardiac ablation add-on codes, which were finalized in CY 2023. The commenters urged CMS to accept the AMA RUC's recommendation for CPT codes 93655 and 93657 of 7.00 work RVUs.

Response: We believe the code valuations we established in CY 2023 are accurate and that these codes are not potentially misvalued; however, we will continue to monitor this issue and the Medicare claims data for these codes in the coming years.

We continue to believe that the current code valuations are accurate and most appropriate for these services. Therefore, for CY 2024, we are not finalizing these codes as potentially misvalued.

(7) CPT Code 94762 and 95800

An interested party nominated CPT code 94762 (*Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)*), a PE-only code as potentially misvalued. The nominator noted that the technology behind this code had changed considerably over the last 14 years, and because the PE inputs were last reviewed in 2009, the PE items included in the service no longer reflected current practice. In their submission, the nominator listed equipment items for CPT code 94762, including EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' and EQ353 ''Pulse oximeter 920 M Plus,'' which the nominator asserted are now typically found in a one-time use supply item: SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device) with a cost of $99.00 each (derived from two sample invoices, not actual invoices, included with the nomination). According to our PE supply list, item SD263 costs $73.32, which is $25.68 less than the amounts found in the sample invoices submitted by the nominators. The nominator retained equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'', and replaced equipment item EQ353 with ED021, a ''computer, desktop, w-monitor.

The same interested party who nominated CPT code 94762, also nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*) as potentially misvalued. The nominator requested that CMS update PE items for this code, asserting that the PE inputs were last reviewed in 2017. CPT code 95800 currently includes the entry of a one-time use supply item, SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device), which costs $73.32 per item, in contrast to the pricing in the sample invoice—$99.00 each (case of 12 × $99.00 = $1,188.00).

The nominator excluded the current equipment for this code (EQ335 ''WatchPAT 200 Unit with strap, cables, charger, booklet and patient video'' and EQ336 ''Oximetry and Airflow Device'') and instead included ED021 (''computer, desktop, w-monitor'') in the PE for this code. We noted that we did not previously include ED021 as a specialized equipment item dedicated to this function (and EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' was also not included in the PE for CPT code 95800, as it was with CPT code 94762). The nominator included the PE listings for CPT code 93245 (*Heart rhythm recording, analysis, interpretation and report of continuous external EKG over more than 1 week up to 1 weeks*) as an example of how PE supply items for CPT code 95800 should be structured, but this code included supply item, SD339 ''extended external ECG patch, medical magnetic tape recorder'' and equipment item ED021 ''computer, desktop, w-monitor,'' which is presumed to be used to record the data from the ECG patch and to be used to analyze the data.

There is no clear evidence whether the WatchPAT One Device needs or does not need the specific monitoring and recording system (equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'') for CPT code 95800, as opposed to any other system/process. The interested party requested the PE changes discussed above to support their argument that these CPT codes are potentially misvalued (see Table 9).

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TABLE 9: Listing of Nominator's Practice Expense Items for Addition or Deletion to CPT codes 94762 and 95800

CPT code	Current Equipment Code	Equipment Description	Non-Facility/ Office Equipment PE Cost	Equipment Status	Current Supply Code	Supply Description	Non-Facility/ Office Supply PE Cost	Supply Status
94762	EQ212	pulse oxymetry recording software (prolonged monitoring) (480 min)	$0.7360	Retain				
94762	EQ353	Pulse oximeter 920 M Plus (480 min)	$7.1155	Delete	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Add
95800	EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet, and patient video	$4.7071	Delete				
95800	EQ336	Oximetry and Airflow Device	$4.5454	Delete				
95800	ED021	computer, desktop, w-monitor (assume 480 min)	$2.5339	Add	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Retain

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We welcomed comments as to whether these codes are potentially misvalued.

The following is a summary of the comments we received and our responses.

Comment: One commenter disagreed with the replacement of various PE items with alternative items. For example, for CPT code 94762, the existing pulse oximeter 920 M Plus (CMS equipment item EQ353) would be replaced with the disposable WatchPAT One supply item (SD263). The commenter expressed concern about removing the pulse oximetry devices from CPT code 94762 and whether the WatchPAT One supply item properly assessed and monitored a patient's sleep, as described by the code.

Response: We thank commenters for their feedback. There seems to be a general misunderstanding from the original nomination regarding which PE items should be replaced or retained and which items are considered duplicated, according to the public comments received.

We cannot properly assess if CPT codes 94762 and 95800 are potentially misvalued based on the evidence submitted with the original nomination and subsequent public comments we received in response to the CY 2024 PFS proposed rule. After considering the public comments, it is still unclear whether CPT codes 94762 and 95800 are potentially misvalued. We invite the original nominator or other parties to resubmit their nomination with information providing additional clarity for further consideration in future rulemaking. Therefore, for CY 2024, we are not finalizing CPT codes 94762 and 95800 as potentially misvalued.

(8) CPT Codes 0596T and 0597T

An interested party nominated CPT codes 0596T (*Initial insertion of temporary valve-pump in female urethra*) and 0597T (*Replacement of temporary valve-pump in female urethra*) as potentially misvalued. This nominator generally expressed concern about variability in MAC pricing for the contractor-priced service and requested that CMS establish national pricing to stabilize payments that more accurately reflected the work, professional liability costs, and especially the nonfacility PE for these services, including the costs associated with the Vesiflo inFlow

System, the primary supply included in the procedures described by the two Category III CPT codes. The nominator stated that the MAC-determined payment amounts had been inappropriately low and did not account for the time and the work involved in furnishing the services or all of the PE. In their submission, the nominator discussed their expected inputs for both codes. For CPT code 0596T, the nominator asserted that a physician would typically spend 60 minutes of work inserting the Vesiflo inFlow System. The nominator also discussed the PE items used to furnish the procedure. These specified PE items included a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling to 73 minutes, and a list of supplies summing to $1,902.76, primarily from the inFlow Measuring Device of $140.00, the inflow Device of $495.00, and the inflow Activator Kit of $1,250.00, with the inflow supply items making up about 99 percent of the total cost of supplies.

For CPT code 0597T, the nominator asserted that a physician would typically spend 25 minutes replacing the Vesiflo inFlow System. The specified PE items for this service included a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling 38 minutes, and a list of supplies summing to $505.30, primarily from the inflow device of $495.00, with the inflow supply items making up about 98 percent of the total cost of supplies. A sample invoice was included in this nomination (as opposed to an actual invoice).

We welcomed comments on whether these two temporary category III CPT codes, CPT codes 0596T and 0597T, were potentially misvalued and whether these codes should remain contractor-priced.

The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting our proposal to nominate CPT codes 0596T and 0597T as potentially misvalued. These commenters recommended that we establish national pricing for these services, stating that a change to national pricing would address the misvaluation and pricing variability for the service and allow for the appropriate inclusion of the Vesiflo system in the code's PE.

Response: We note that CPT codes 0596T and 0597T are category III codes and describe relatively new and low-volume services. Generally, category III codes are contractor-priced under the PFS, meaning that each MAC can establish pricing for the code for areas within its jurisdiction. We appreciate the nominators' and commenters' concerns about variability in payment across the different MAC jurisdictions.

After consideration of public comments, we are not finalizing CPT codes 0596T and 0597T as potentially misvalued. These are contractor-priced codes and they will remain contractor priced for the present. However, we encourage interested parties to continue to engage with the MACs and provide accurate and appropriate cost data to inform the MAC's consideration and pricing of these services.

(9) CPT Code 93000

An interested party nominated CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) as potentially misvalued, arguing that we should increase Medicare payment for CPT code 93000 to $35.64 when used in conjunction with other supplies and services, to reflect PE costs equivalent to (1) $6.10 for EKG leads; (2) $21.19 for a nurse visit of typically 5 minutes (as illustrated by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.)*); and (3) $7.64 for the interpretation and report for the EKG service (as illustrated by CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*). While the interested party did not provide invoices or other evidence for consideration, they asked that we value the grouping of these services at $35.64, even though the direct costs for these identified PE inputs total to $34.93.

After consideration of submitted information, we decided not to propose to nominate CPT code 93000 as potentially misvalued for CY 2024. We did not believe that the total of a mix of services is a persuasive indication that one code—in this case, CPT code 93000—was potentially misvalued.

We did not receive public comments on this nomination. Therefore, for CY 2024, we are not finalizing CPT codes code 93000 as potentially misvalued.

(10) 19 Therapy Codes

An interested party nominated 19 therapy codes as potentially misvalued. We noted in the proposed rule that these 19 therapy codes were last reviewed by CMS in the CY 2018 PFS final rule (82 FR 53073 through 53074). The nominators asserted that the direct PE clinical labor minutes, as recommended by the AMA Relative Value Scale Update Committee (RUC) and Healthcare Professional Advisory Committee (HCPAC) Review Board, reflected inappropriate multiple procedure payment reductions (MPPR), which are likely duplicative of the CMS MPPR policy implemented in CMS' claims processing systems.

As discussed in the proposed rule, we reviewed the clinical labor time entries for these 19 therapy codes. We noted that we did not believe a payment reduction should have been applied to the 19 nominated therapy codes' clinical labor time entries (Table 10) since the payment valuation reduction would be duplicative of the MPPR we apply during claims processing. We proposed to nominate these 19 codes as potentially misvalued for CY 2024, as we believed that the valuation of these services would benefit from additional review through the AMA RUC HCPAC valuation process. We also sought comment on our proposal. The following is a summary of the comments we received and our responses.

Comment: Numerous commenters supported our proposal to nominate these 19 therapy codes as potentially misvalued. There were no comments asserting that these codes should not be considered potentially misvalued.

Response: After consideration of the public comments for this issue, we are finalizing our proposal to consider the 19 therapy codes as potentially misvalued for CY 2024.

TABLE 10: 19 "Always Therapy" Service Codes Nominated as Potentially Misvalued for CY 2024

HCPCS 2023	LONG DESCRIPTION	CY 2023 STATUS CODE
97012	Application of mechanical traction	A
97014	Application of electrical stimulation	I
97016	Application of blood vessel compression device	A
97018	Application of hot wax bath	A
97022	Application of whirlpool therapy	A
97032	Application of electrical stimulation with therapist present, each 15 minutes	A
97033	Application of medication using electrical current, each 15 minutes	A
97034	Application of hot and cold baths, each 15 minutes	A
97035	Application of ultrasound, each 15 minutes	A
97110	Therapy procedure using exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes	A
97112	Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes	A
97113	Therapy procedure using water pool to exercises, each 15 minutes	A
97116	Therapy procedure for walking training, each 15 minutes	A
97140	Therapy procedure using manual technique, each 15 minutes	A
97530	Therapy procedure using functional activities	A
97533	Therapy procedure using sensory experiences	A
97535	Training for self-care or home management, each 15 minutes	A
97537	Training for community or work reintegration, each 15 minutes	A
97542	Evaluation for wheelchair, each 15 minutes	A
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	A

Note: Status code A = Active code – separately paid under the PFS. Status code I = Invalid code – not valid for Medicare purposes.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare Telehealth Services List to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site, and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to

reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable signs or symptoms.
- Reduced recovery time.

• *Category 3:* In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the public health emergency (PHE) for the COVID–19 pandemic. This new category describes services that were added to the Medicare Telehealth Services List during the PHE, for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criteria described previously. In this rule, we considered additional requests to add services to the Medicare Telehealth Services List on a Category 3 basis using the previously described Category 3 criteria.

The Medicare Telehealth Services List, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2024, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2023. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare Telehealth Services List, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests to Add Services to the Medicare Telehealth Services List for CY 2024

Under our current policy, we add services to the Medicare Telehealth Services List on a Category 1 basis when we determine that they are similar to services on the existing Medicare Telehealth Services List for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site, and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare Telehealth Services List that resemble those services already on the Medicare Telehealth Services List.

We also note that section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extends the telehealth policies enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) through December 31, 2024, if the PHE ends prior to that date, as discussed in section II.D.c. of this final rule.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. The requested services are listed in Table 11.

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TABLE 11: CY 2024 Requests for Permanent Addition – Services Not Proposed for Permanent Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Cardiovascular Procedures	93793	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed
Cardiovascular and Pulmonary Rehabilitation	93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
	94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)
Deep Brain Stimulation	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
Therapy	90901	Biofeedback training by any modality
	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or

Service Type	HCPCS	Long Descriptor
		measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
Therapy	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
Hospital Care, Emergency Department and Hospital	99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
	99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.
	99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.
	99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.
	99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.
	99236	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.
	99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter
	99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter
	99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional
	99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making
	99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making
Health and Well-Being Coaching	0591T	Health and well-being coaching face-to-face; individual, initial assessment
	0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes
	0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes

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We remind interested parties that the criterion for adding services to the Medicare telehealth list under Category 1 is that the requested services are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below and in the CY 2024 PFS proposed rule (88 FR 52286 to 52298), we found that none of the requested services listed in Table 11 met the Category 1 criterion. Below is a summary of the reasons why we did not propose to add these services to the Medicare Telehealth Services List on a Category 1 basis, the comments on the proposed rule, and our responses:

(1) Cardiovascular Procedures

We received a request to permanently add CPT code 93793 *(Anticoagulant management for a patient taking warfarin, must include review and*

interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed)) to the Medicare Telehealth Services List. We did not consider this service to be a Medicare telehealth service, because the service is not an inherently face-to-face service—a patient need not be present in order for the service to be furnished in its entirety. For example, in many instances, clinical staff will not change a patient's warfarin dosage as a result of the lab INR test result, and they may or may not confirm the need for a follow-up test via phone; either way there is no need for a face-to-face encounter with a practitioner. As we have explained in previous rulemaking (83 FR 59483), certain kinds of services that are furnished remotely using communications technology are not considered Medicare telehealth services and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of section 1834(m) of the Act and do not usually include patient interaction such as the remote interpretation of diagnostic tests. We did not consider CPT code 93793 to be a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we did not propose to add this service to the Medicare Telehealth Services List on a Category 1 basis.

Comment: A few commenters requested that CMS update the status indicator for CPT code 93793 to a covered status indicator such as A, S or V, and that CMS add the service to the telehealth list.

Response: The request for a status indicator change is outside the scope of our telehealth proposals. However, we believe it is important to note that the service elements of CPT code 93793 do not describe an in-person service that could, instead, be furnished as a Medicare telehealth service using interactive communications technology. Because CPT code 93793 does not describe an inherently face-to-face service, it would not be appropriate to consider or recognize it as a telehealth service. We believe that the commenter misunderstands the nature of CPT code 93793.

(2) Cardiovascular and Pulmonary Rehab

We received multiple requests to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 93797 (*Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)*); and
- 94624 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)*).

In the CY 2022 PFS final rule (86 FR 65048), we explained that some services were added temporarily to the Medicare Telehealth Services List on an emergency basis to allow practitioners and beneficiaries to have access to medically necessary care while avoiding both risk for infection and further burdening healthcare settings during the PHE for COVID–19. In the same rule, we considered available evidence and noted that as evidence evolves on this subject matter, we welcomed further discussions with interested parties on the topic. In subsequent cycles of annual rulemaking, we have continued conversations with interested parties that furnish, support, and use Cardiovascular and Pulmonary Rehabilitation services. In our CY 2022 PFS final rule (86 FR 65055), we acknowledged that commenters provided a number of studies on the safety and efficacy of these services when furnished via telehealth, and we added the codes to the list on a temporary, Category 3 basis.

We note that some evidence submissions and ongoing discussions with interested parties have focused on the clinical benefits of patients receiving these services in the home. We note that, while demonstrating the clinical benefits of services is important to our decision whether to add a service to the Medicare Telehealth Services List, there are other considerations when deciding whether to add codes to the list on a permanent basis. For example, while the CAA, 2023, does extend certain COVID–19 PHE flexibilities, including allowing the beneficiary's home to serve as an originating site, such flexibilities are only extended through the end of CY 2024. Under current law, beginning on January 1, 2025, the beneficiary's home can be an originating site only for Medicare telehealth services furnished for: (1) the diagnosis, evaluation, or treatment of a mental health disorder; or (2) a beneficiary with a diagnosed substance use disorder (SUD) for purposes of treatment of the SUD or a co-occurring mental health disorder; or (3) monthly ESRD-related clinical assessments furnished to a beneficiary who is receiving home dialysis, beginning January 1, 2025. Therefore, in the absence of further action by Congress, CPT codes 93797 and 94626 will not be able to be furnished via telehealth to a beneficiary in the home beginning January 1, 2025. As such, we did not propose to include these services permanently on the Medicare Telehealth Services List on a Category 1 basis. We instead proposed to continue to include these services on the Medicare Telehealth Services List through CY 2024. We will then remove CPT codes 93797 and 94626 from the Medicare Telehealth Services List for CY 2025.

Comment: Commenters were generally supportive and included supportive evidence demonstrating possible clinical benefit for the clinical activities described by these codes.

Response: We thank commenters for the feedback.

After consideration of public comments, we are finalizing as proposed. We will continue to include these services on the Medicare Telehealth Services List through CY 2024. We will then remove CPT codes 93797 and 94626 from the Medicare Telehealth Services List for CY 2025.

(3) Deep Brain Stimulation

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*);
- 95983 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional*); and
- 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse*

width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)).

In our CY 2023 proposed rule (85 FR 45891), we explained that these services do not meet the Category 1 criterion for permanent addition to the Medicare Telehealth Services List. Additionally, we discussed concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE to allow additional time for additional information to be gathered and presented. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition under the Category 2 criterion. We proposed to keep these services on the Medicare Telehealth Services List for CY 2024. We stated that we would consider additional evidence in future rulemaking to determine whether to add the services to the Medicare Telehealth Services List on a permanent basis.

Comment: Several commenters explained that early evidence shows that safe remote programming may set devices to a safe mode in instances where remote programming fails. Commenters asserted that because evidence shows that patient safety risks may be mitigated through such controls, and no evidence of patient harm had been found, that CMS should make these services a permanent addition to the Medicare Telehealth Services List.

Response: We consider all evidence submitted and anecdotes shared by commenters. We generally do not question the findings and believe that the services may be safely furnished using only two-way interactive communications technology as a substitute for in-person elements of the service. However, we have not received sufficient evidence to show that the service, when furnished using only virtual interaction, would avoid a subsequent in-person service that addresses instances where the beneficiary received less than the complete service (when the device enters safe mode, remote programming failed, and requires a follow-up in-person visit so that the device may be programmed in-person). We believe more time for further study would be appropriate, and that adding these services to the Medicare Telehealth Services List on a permanent basis beginning in CY 2024 would be premature.

After consideration of public comments, we are finalizing as proposed. We are not adding these codes to the Medicare Telehealth Services List on a permanent basis.

(4) Therapy

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116; Physical Therapy Evaluations: CPT codes 97161 through 97164; Therapy Personal Care services: CPT code 97530; and Therapy Tests and Measurements services: CPT codes 97750, 97763 and Biofeedback: 90901, to the Medicare Telehealth Services List on a Category 1 or 2 basis. We have considered these codes over several years, in multiple cycles of annual rulemaking. In the CY 2017 final rule (81 FR 80198), we first assessed a request to add CPT codes 97110, 97112, and 97116 (the therapy codes) to the Medicare Telehealth Services List. We did not add the codes to the Medicare Telehealth Services List at the time, because there was no emergency waiver providing an exception to the requirements under section 1834(m)(4)(E) of the Act, and physical therapists, occupational therapists, and speech-language pathologists were not eligible telehealth practitioners. In the CY 2018 final rule (82 FR 53008 and 53009), we reiterated our initial assessment that the codes were not appropriate to add to the Medicare Telehealth Services List, because the majority of the therapy codes listed above are furnished over 90 percent of the time by therapy professionals who are not included on the list of distant site practitioners who can furnish telehealth services at section 1834(m)(4)(E) of the Act. We stated that we believed that adding therapy services to the Medicare Telehealth Services List could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth (82 FR 53009).

Section 3703 of Division A, Title III, Subtitle D of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, enacted March 27, 2020) amended section 1135(b)(8) of the Act to give the Secretary emergency authorities to waive or modify Medicare telehealth payment requirements under section 1834(m) of the Act during the PHE for COVID–19. Using this authority, CMS issued a set of emergency waivers that included waiving the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services. This allowed for therapy professionals to furnish telehealth services for the duration of the PHE. In the CY 2022 final rule (86 FR 65051), we reviewed another round of submissions requesting that CMS add therapy codes to the Medicare Telehealth Services List, and we again determined that these codes did not meet the Category 1 criterion for addition to the list. In the CY 2023 PFS final rule (87 FR 69451), through our review of evidence that was submitted by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely.

In reviewing this year's request, the evidence submission includes evidence similar to what was submitted last year, with a few new additions suggesting that some elements of the individual services may have clinical benefit when furnished via telehealth, but not resolving uncertainty about whether other elements of the services can be fully furnished remotely via telehealth. The evidence submitted also suggests that receiving therapy services via telehealth in the home may offer some practical benefits, such as use of actual stairs in therapy exercise instead of artificial stairs, or meal preparation instructions focused on available kitchen tools and equipment. However, the evidence submitted for review leaves open questions as to whether such differences in the setting of care translate to a clinical benefit that is more than minor or incidental, in typical circumstances for the typical population of beneficiaries who may receive therapy services via telehealth.

We note that for any submission, including submissions received for these therapy services, we consider all elements of a service as described by a particular HCPCS code and apply our

review criteria to the specific code. While some submitted information may focus on an individual service within one specific clinical scenario and furnished within one specific individual model of care delivery, that information may not be generalizable to the varied settings and scenarios under which the service would be typically furnished via telehealth. We reiterate that available evidence should give a reasonable degree of certainty that all elements of the service could fully and effectively be furnished by a remotely-located clinician using two-way, audio/video telecommunications technology.

Based on the evidence we reviewed, we continue to question whether the findings from therapy studies that focused on a specific clinical issue for a narrow population (for example, joint replacement of a specific joint) translate to clinical benefit for some or many of the various other clinical issues that would typically be addressed when therapists furnish therapy services via telehealth to beneficiaries. Despite the evidence, we are still uncertain as to whether all of the elements of a therapy service could typically be furnished through use of only real-time, two-way audio/video communications technology. Because we continue to have these questions, we did not propose to add these services to the Medicare Telehealth Services List on a Category 1 or 2 basis, for the same reasons described in our CY 2018 through CY 2023 rulemaking cycles. Also, we continue to believe that adding these therapy services to the Medicare Telehealth Services List permanently would potentially generate confusion. As discussed in last year's final rule, we note that we do not have authority to expand the list of eligible Medicare telehealth practitioners to include therapists (PTs, OTs, or SLPs) after CY 2024 (87 FR 69449 through 69451). We note that the CAA, 2023, did not permanently change the list of practitioners who can furnish and bill for telehealth services; rather, the CAA, 2023, extended the current telehealth flexibilities through the end of CY 2024. That said, we proposed to keep these therapy services on the Medicare Telehealth Services List until the end of CY 2024. We will consider any further action with regard to these codes in future rulemaking.

Comment: Commenters requested that CMS continue coverage of the therapy codes even though physical therapists, occupational therapists, and speech therapists are not currently permitted by statute to provide telehealth services after CY 2024.

Response: We direct readers to our discussion of these codes in the proposed rule, and we reiterate that we are still uncertain as to whether all of the elements of a therapy service could typically be furnished through use of only real-time, two-way audio/video communications technology. Further, we note that the scope of our proposals did not include coverage status of the codes, merely whether CMS should change the status of the codes on the telehealth list.

After consideration of public comments, we are finalizing as proposed. These therapy services will remain on the Medicare Telehealth Services List until the end of CY 2024.

(5) Hospital Care, Emergency Department and Hospital

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*)
- 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*)
- 99223 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*)
- 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)
- 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.*)
- 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.*)
- 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter*)
- 99239 (*Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter*)
- 99281 (*Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional*)
- 99282 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*)
- 99283 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making*)

In the March 31, 2020 interim final rule with comment period (IFC–1) (85 FR 19234), we added the above services to the Medicare Telehealth Services List on a Category 2 basis for the duration of the PHE for COVID–19, for telehealth services with dates of service beginning March 1, 2020 through the end of the PHE (including any renewals of the PHE). When we previously considered adding these services to the Medicare Telehealth Services List, either through a public request or through our own internal review, we considered whether these services met the Category 1 or Category 2 criteria. In many cases, we reviewed requests to add these services to the Medicare Telehealth Services List on a Category 1 basis but did not receive or identify information that allowed us to determine whether these services should be added on a Category 2 basis (CY 2017 PFS final rule, at 81 FR 80194 to 80197). We reiterated that, while we do not believe the context of the PHE for COVID–19 changes the assessment of whether these services meet the Category 1 criterion, we reassessed all of these services to determine whether they meet the criteria for inclusion on

the Medicare Telehealth Services List on a Category 2 basis, in the context of the widespread presence of COVID–19 in the community. Given the exposure risks for beneficiaries, the health care work force, and the community at large, in-person interaction between professionals and patients posed an immediate potential risk that would not have been present when we previously reviewed these services in 2017. This risk created a unique circumstance where health care professionals needed to weigh the risks associated with disease exposure. For further background, in the CY 2021 final rule (FR 84506 through 84509), we explained the reasoning and considerations necessary for assigning a Category 3 status to certain codes that were added to the Medicare Telehealth Services List on a temporary basis during the PHE for COVID–19. We believe that some risk of COVID–19 remains, but also remain uncertain that available evidence gives clear support for continuing to include these services on a permanent basis under the Category 2 criterion.

As discussed in the CY 2023 PFS final rule (86 FR 69450), we believe these hospital and emergency department services may continue to be furnished safely via two-way, audio-video communication technology. We did not propose to add these services to the list on a permanent basis at this time, but we did propose that they would remain available on the Medicare Telehealth Services List through CY 2024.

Comment: Several commenters stated that because CMS had adopted the AMA CPT Editorial Committee's consolidation of E&M inpatient and observation codes that CMS should change their status on the telehealth list to make these codes permanent.

Response: We acknowledge the CPT Editorial Panel deleted seven observation care codes and revised nine codes effective January 1, 2023, to create a single set of codes for inpatient and observation care and also made changes to codes for inpatient and observation discharge. We adopted the E/M inpatient/observation revisions in the CY 2023 PFS final rule. For further background, refer to 87 FR 69586 through 69587. In the CY 2023 PFS final rule, when we finalized new valuations based on AMA RUC recommendations which included a change in code descriptors to reflect ''patient history and/or physical exam'' as one element of the service, we removed the legacy codes from the list and replaced these with the new code set. To reiterate, we have open questions of patient safety that we expect future submissions to address in full, as evidence generation builds (for example, publication of peer-reviewed literature, updates clinical practice guidelines, further study of hospital patient safety risks). We note that the initial impetus for including these services on the Medicare Telehealth Services List focused on the unique circumstance where health care professionals needed to weigh the risks associated with disease exposure during PHE for COVID–19. Now that the PHE has ended, we expect that future evidence submissions would address study of the appropriateness of furnishing these services via telehealth outside the context of a global pandemic. We note that we have no immediate evidence of patient safety risks associated specifically with furnishing these services via telehealth but we remain cautious and intend to monitor these services moving forward because of possible larger issues of patient safety.[3] With regard to the code consolidation, we reiterate our concerns above, and note that prior to consolidation, none of the separate ''legacy'' codes, which are now consolidated, were on the Medicare Telehealth Services List on a permanent basis.

After consideration of public comments, we are finalizing as proposed and will keep these hospital and emergency department services on the Medicare Telehealth Services List temporarily through CY 2024. We note that CPT codes 99231 through 99233 are codes that describe subsequent services, and are part of the same Hospital or Observation Care code family (CPT codes 99218–99236), and have permanent status on the Medicare Telehealth Services List. We continue to believe that new patients should be seen in person when the temporary telehealth flexibilities end, and as a result we are not changing determinations of the status of any of these codes.

(6) Health and Well-Being Coaching

We received a request to permanently add the following three Health and Well-being Coaching services to the Medicare Telehealth Services List:

- CPT code 0591T (*Health and well-being coaching face-to-face; individual, initial assessment*);
- CPT code 0592T (*Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes*); and
- CPT code 0593T (*Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes*).

We did not propose to add these health and well-being coaching services to the Medicare Telehealth Services List on a permanent basis, but we proposed to add them to the list on a temporary basis for CY 2024. The evidence included in the submitter's request notes that these codes are similar to others already available on the Medicare Telehealth Services List. Further, it appears that all elements of these services may be furnished when using two-way interactive communications technology to replace the face-to-face elements of the service. The submission, which contained two published metanalyses of literature on the clinical topic and an additional pre-publication meta-analysis that focuses on outcomes and benefits of the delivery of virtual health and well-being coaching, leaves some open questions as to whether Medicare beneficiaries would receive meaningful clinical benefit from receiving virtual-only health and well-being coaching. While the evidence is clearly evolving, it does suggest that these services could possibly meet Category 2 criteria for inclusion on the Medicare Telehealth Services List as more evidence builds. We also noted in the proposed rule that the published meta-analyses in the submission make clear that further study is necessary for a broader range of medical professionals, because conceptual articles and research and existing practice articles focus on nurses but are sparse or silent about other general categories of medical professionals. We stated that we would expect that any evidence in support of adding these codes on a permanent basis should also establish clinical benefit when delivered directly by or under the supervision of the types of professionals who are Medicare telehealth practitioners. The metanalyses demonstrate that health coaching only requires a few hours of training, and few articles submitted to CMS discussed the intensity of health coach training at all. The pre-publication metanalysis submitted for review had less than definitive conclusions about ''potential benefits'' of health and well-being coaching and hedged that the authors, ''did not find evidence of long-term benefit, possibly due to the paucity of studies examining longer-term outcomes. We caution that the certainty in the evidence for the majority of outcomes was either very low or low, primarily due to high risk of bias, heterogeneity, and impression.'' The submission and its content were

[3] Fleisher, L. A., Schreiber, M., Cardo, D., & Srinivasan, A. (2022). Health Care Safety during the pandemic and beyond — building a system that ensures resilience. *New England Journal of Medicine, 386*(7), 609–611. *https://doi.org/10.1056/nejmp2118285*.

sufficient to serve as a basis for adding the codes to the Medicare Telehealth Services List on a temporary basis, and we appreciated the thoughtful and transparent way the submission laid out gaps in available evidence. More time is needed to potentially close these gaps. We are not aware of any evidence to suggest that it would be inappropriate to assign a temporary status to these codes. Therefore, we proposed to add the services to the Medicare Telehealth Services List on a temporary basis.

Comment: Many commenters requested that CMS change the status of these codes to permanent. The commenters referenced that the National Board of Health and Wellness Coaches, which is an affiliate of the National Board of Medical Examiners, along with other standard-setting organizations, represent 28,000 qualified coaching professionals; additional evidence submitted addresses the rigor of training and certification requirements, as well as findings on clinical effectiveness of health and wellness coaching services delivered via telehealth to treat chronic disease prevalent in the Medicare population (for example, obesity, hypertension, diabetes, and COPD). The commenters asserted that over 9,500 health professionals have completed a certification exam, and approximately 20 percent of those holding certification also hold a clinical State license of some kind.

Response: We thank commenters for the feedback and additional evidence submission. We acknowledge the findings presented in the additional evidence, and the qualifications required to achieve certification that comments referenced. We note that there are over 4 million NPIs in the NPPES NPI Registry (*http://npiregistry.cms.hhs.gov*), and that we do not consider the number of certified individuals providing a service in determining the status of a service on the Medicare Telehealth List. Rather, when pointing to gaps in the available evidence supporting inclusion of a service on the list, we ask whether further study is necessary to establish the clinical benefit of a service for the Medicare population when the individual service is performed using only two-way interactive communications technology as a substitute for face-to-face interactions between the telehealth practitioner and the patient. The clinical value of the service is not at issue when CMS determines whether or how to include a service on the Medicare Telehealth Services List.

We remind readers that one purpose of the telehealth review, and our ongoing claims monitoring process that examines utilization of telehealth services, is for CMS to act as an appropriate safeguard to ensure that beneficiaries can receive all of the elements and benefits of a service when that service is furnished via telehealth rather than in-person. CMS asks whether it is likely that a typical beneficiary receiving the service would receive any clinical benefit beyond mere incidental or minor clinical benefits when the service is performed by the typical telehealth practitioner. When assessing the clinical benefit of a service when furnished as a telehealth service, long-term and careful study over a period of years may be necessary. We believe the commenters are suggesting that there is potential clinical benefit to providing these services via telehealth, and we agree. Our initial review of evidence also indicates that these services can and should retain their current status on the Medicare Telehealth Services List for CY 2024. However, we remain cautious because the evidence and analyses provided by commenters appear anecdotal. In future evidence submissions, we would expect to see peer-reviewed literature, where the study population is typical of the Medicare population (for example, specific age bands in study populations), and the methods focus on evaluating utilization and outcomes (for example, claims data and analysis that includes the specific codes at issue). In summary, there is still a lack of scientific study that focuses on use of these codes via telehealth, and in clinical practice. We acknowledge that health coaches may have many types of backgrounds, and we note that we did not intend to question the standards and training of health coaches when we mentioned the variation in their credentialling in the proposed rule. We agree with commenters that suggested many eligible health practitioners would furnish these services to Medicare beneficiaries if they remained on the Medicare Telehealth Services List permanently. Even so, the clinical benefits of these services when furnished as telehealth services for the target population remain an open question in need of further study. We believe that this response should provide further clarity for the public as to the sorts of data that CMS would like to receive and review in future submissions.

After consideration of public comments, we are finalizing as proposed. We will add these health and well-being coaching services to the Medicare Telehealth List on a temporary basis for CY 2024.

(7) CMS Proposal To Add New Codes to the List

We proposed to add HCPCS code G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes*) to the Medicare Telehealth Services List. Our proposal to add HCPCS code G0136 to the list was contingent upon finalizing the service code description we proposed in section II.E. of the proposed rule. We refer readers to the proposal in section II.E. of the proposed rule for further background (88 FR 52293). We proposed that HCPCS code G0136, if finalized as proposed, would receive a permanent status on the Medicare Telehealth Services List. One element of the service describes a face-to-face encounter between the clinician and beneficiary. Practitioners use clinical judgement to determine whether to complete the SDOH screening with or without direct patient interaction. Because the service description, as defined in section II.E. of the CY 2024 proposed rule and finalized in section II.E. of this final rule, expects that a patient encounter may be necessary for accurate and complete screening, we believe that this element of the service describes an inherently face-to-face clinical activity. Further, using two-way interactive audio-video technology as a substitute for in-person interaction means an analogous level of care in that using either modality would not affect the accuracy or validity of the results gathered via a standardized screening tool. As discussed in section II.E. of the proposed rule, we proposed that this service must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Therefore, we noted that we believe HCPCS code G0136 describes a service that is sufficiently similar to services currently on the Medicare Telehealth Services List, specifically E/M services, and that this service should be added to the list on a permanent basis.

Comment: Many commenters supported our proposals to include G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes*) on the Medicare Telehealth List as a permanent code.

Response: We thank commenters for the feedback.

After consideration of public comments, we are finalizing as proposed and assigning HCPCS code G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes*) permanent status on the Medicare Telehealth List, beginning in CY 2024.

Comment: Many commenters requested that CMS add Principal Illness Navigation (PIN) and Community Health Integration (CHI) services to the Medicare Telehealth List.

Response: We refer readers to our discussion of the PIN and CHI services in section II.E. of this final rule. We did not propose to add these services to the Medicare Telehealth Services List for CY 2024 because the elements of the individual services in the code descriptors may not typically require a face-to-face interaction, and therefore PIN (G0023, G0024, G0140, and G0146) and CHI (G0019, G0022) would not be considered as potential Medicare telehealth services under section 1834(m) of the Act. We note that the possible use of asynchronous communications technology to support the provision of these services suggests that our policies for other communications-based technology services should apply instead.

c. Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

1. Overview

In CY 2020, CMS issued an array of waivers and new flexibilities for Medicare telehealth services to respond to the serious public health threats posed by the spread of COVID–19 (85 FR 19230). Our goal was to give individuals and entities that provide services to Medicare beneficiaries the flexibility to respond effectively to the serious public health threats posed by the spread of COVID–19. Recognizing the urgency of this situation and understanding that some pre-existing Medicare payment rules (including the statutory restrictions on telehealth originating sites and telehealth practitioners) needed to be modified to allow patients and practitioners to have access to necessary care while mitigating the risks from COVID–19, we used waiver and regulatory authorities to change certain Medicare payment rules during the PHE for COVID–19 so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics (RHCs), and federally qualified health centers (FQHCs) would be allowed broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community.

In 2003, as required by section 1834(m)(4)(F)(ii) of the Act, we established a process for adding or deleting services from the Medicare Telehealth Services List, which included consideration under two categories of criteria (Categories 1 and 2) (67 FR 79988). We finalized revisions to the Category 2 review criterion in the CY 2012 PFS final rule (76 FR 73102). Prior to CY 2020, CMS had not added any service to the Medicare Telehealth Services List on a temporary basis. In CY 2020, in response to the PHE for COVID–19, we revised the criteria for adding or removing services on the Medicare Telehealth Services List using a combination of emergency waiver authority and interim final rule making, so that some services would be available for the duration of the PHE on a ''temporary Category 2 basis.'' (85 FR 19234). In the CY 2021 PFS final rule (85 FR 84507), we created a third, temporary category for services included on the Medicare Telehealth Services List on a temporary basis. This new Category 3 includes many, but not all of the services that we added temporarily to the Medicare Telehealth Services List during the COVID–19 PHE. Specifically, we reviewed the services we added temporarily in response to the COVID–19 PHE and identified those for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to add the services as permanent additions to the list. Services added to the Medicare Telehealth Services List on a temporary, Category 3 basis will ultimately need to meet the Category 1 or 2 criteria in order to be added to the Medicare Telehealth Services List on a permanent basis.

Between CY 2020 and CY 2023, we added many services to the Medicare Telehealth List on a temporary basis during the PHE, and through rulemaking, we also added many of these services on a Category 3 basis. Subsequent requests and evidence submitted to CMS supported possible status changes for some of the services that are currently included on the Medicare Telehealth Services List on a Category 3 basis. However, submissions sometimes confused our use of waiver authority and regulatory flexibilities tied to the COVID–19 PHE which allow us to temporarily add services to the Medicare Telehealth Services List through the end of the PHE, with the generally applicable categories and criteria we use to consider changes to the Medicare Telehealth Services List outside the circumstances of the COVID–19 PHE. Now that the PHE for COVID–19 has ended, we intend to clarify and modify our process for making changes to the Medicare Telehealth Services List. We believe these clarifications will help address potential confusion among interested parties that submit requests for additions to the Medicare Telehealth List stemming from the distinction between services that were added to the telehealth list on the basis of COVID–19 PHE-related authorities versus services that were added temporarily on a Category 3 basis, which does not rely on any PHE-related authority. Specifically, we created the Category 3 basis for considering changes in the Medicare Telehealth Services List as part of the process we are required to establish under section 1834(m)(4)(F)(2) for considering changes to the list in part because, with the significant expansion of remotely-furnished services in response to the COVID–19 PHE, we recognized the emergence of new data suggesting that there may be clinical benefit when certain services are delivered via telehealth, but more time is needed to develop additional evidence to support potential addition of the services on a permanent, Category 1 or Category 2 basis. Under Category 3, services are added to the list on a temporary basis to allow them to continue to be furnished via telehealth while additional evidence is developed.

In brief, throughout the COVID–19 PHE, we have reviewed all requests to add services to the Medicare Telehealth Services List and assessed whether the services in question should be added to the list, temporarily or permanently, under any of the criteria for Category 1, 2, or 3. Further, we did not reject any submissions from interested parties simply because they requested consideration under a specific category, and the submitted data did not support adding the service to the Medicare Telehealth Services List on that basis. Instead, we considered whether the service(s) should be added to the Medicare Telehealth Services List on any basis.

To avoid potential continuing confusion among those who submit requests to add services to the Medicare Telehealth Services List, and as we consider the expiration of the Medicare telehealth flexibilities extended by the CAA, 2023 through the end of CY 2024, we believe it would be beneficial to simplify our current taxonomy and multicategory approach to considering submitted requests. Further, we believe that simplification toward a binary

classification approach could address the confusion we have noticed from interested parties submitting requests during the PHE. The simplification restores the simple binary that existed with Category 1 and 2, without displacing or disregarding the flexibility of Category 3. We are finalizing our proposal to simply classify and consider additions to the Medicare Telehealth Services List as either permanent, or provisional.

As we discussed in our CY 2024 proposed rule (88 FR 52262), to consider a request to add a service to the Medicare Telehealth Services List, we need evidence that supports how the telehealth service is either clinically equivalent to a telehealth service already permanently on the list, or evidence that presents studies where findings suggest a clinical benefit sufficient for the service to remain on the list to allow time for confirmative study. We reemphasize the need for clinical evidence because that evidence serves as the principal basis for our consideration of a request; and it is sometimes missing from submissions we receive.

For example, we have received some submissions requesting the addition of services to the Medicare Telehealth Services List that are essentially framed as position papers advocating for changes in statutory requirements of section 1834(m) of the Act. While we do give such requests due consideration, the omission of clinical evidence to support the addition of a service to the Medicare Telehealth Services List using our established criteria generally leads us to conclude that the service should not be proposed for addition to the list. A fair and consistent review process for any and all submissions relies on a standard application of uniform, repeatable procedures for any individual submission, just as sound evidence should describe repeatable methods and replicable findings. Submissions that rely on narrative arguments for changes in the substantive requirements do not fit within such a fair and consistent review process. Therefore, we believe the following restatement of requirements and our review process is appropriate. We also proposed some procedural refinements to the review process, specifically incorporating additional considerations into our evaluation of services, that we believe would serve to maintain scope and focus in a post-PHE context. We discussed these proposed changes in detail in the CY 2023 PFS proposed rule and in the following section.

Section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m). As specified at § 410.78(f), with the exception of a temporary policy that was limited to the PHE for COVID–19, we make changes to the list of Medicare telehealth services through the annual physician fee schedule rulemaking process. The proposed revisions to our current permanent policies, specifically our proposed assignment of a ''permanent'' or ''provisional'' status to a service and changes in status as described below, reflect the stepwise method by which we proposed to consider future requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning for the CY 2025 Medicare Telehealth Services List, which will include submissions received no later than February 10, 2024.

2. Proposed Steps of Analysis for Services Under Consideration for Addition, or Removal, or a Change in Status, as Updates to the Medicare Telehealth Services List

Step 1. *Determine whether the service is separately payable under the PFS.*

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we proposed to first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS. Under section 1834(m)(1) of the Act, Medicare telehealth services are limited to those for which payment can be made to the physician or practitioner when furnished using an interactive telecommunications system notwithstanding that the practitioner furnishing the services is not in the same location as the beneficiary; and under section 1834(m)(2)(A) of the Act, Medicare pays the same amount for a telehealth service as if the service is furnished in person. As such, Medicare telehealth services are limited to those services for which separate Medicare payment can be made under the PFS.

Thus, through Step 1, we would answer the threshold question of whether a service is separately payable under the PFS. During the PHE, many submissions for addition to the Medicare Telehealth Services List advocated for CMS to change the definition of ''Medicare telehealth service'' for their specific service; some of those submissions were for services that were not separately payable under the PFS.[4] (87 FR 69449). In the proposed rule, we anticipated that Step 1, if finalized, would encourage submissions that focus on a separately payable PFS service, and that the evidence included with those submissions will show how use of interactive, two-way, audio/video telecommunications technology allows a practitioner to complete an entire, specific service, described by a HCPCS code, that is equivalent to an in-person service.

We recognize that certain codes that had non-payable or bundled (not separately payable) status under the PFS before the PHE for COVID–19 were temporarily included on the Medicare Telehealth Services List to facilitate access to health care services during the PHE. However, the PHE for COVID–19 has now expired.

We believe that proposed Step 1, if finalized, would lessen the administrative burden of our telehealth services review process for both CMS and the public. We note that before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files). For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, section 30.2.2) and the Addendum for the MPFSDB File Record Layout. Researchers and others preparing submissions should also refer to the data dictionaries available at *https://resdac.org/cms-data/files/carrier-ffs/data-documentation*, to review whether the methodology and conclusions contained in supporting evidence, or a submission itself, applies an appropriate methodology to study both individual services and individuals that are representative of the Medicare population.

We further proposed that, if we find that a service identified in a submission is not separately payable under the PFS, we would not conduct any further

[4] Services on the Medicare Telehealth List are used in the definition of Medicare telehealth. Some submissions may have conflated the distinction. Step 1 clarifies. Refer to the CMS website instructions for a Request for Addition at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition.*

review of that service. We would identify the code submitted for consideration and explain that we did not propose it for addition. CMS sends confirmation from *CMS_telehealthreview@cms.hhs.gov* when we receive a submission requesting addition of a service to, removal of a service from, or a change in status for a service included on, the Medicare Telehealth Services List. We proposed to inform each submitter in the confirmation whether the submission was complete, lacking required information, or outside the scope of issues we consider under the process for considering changes in the Medicare Telehealth Services List. We noted that we also expect submissions to include copies of any source material used to support assertions, which has been the longstanding direction included in our website instructions. For further background, refer to details available on our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition*.

Step 2. *Determine whether the service is subject to the provisions of section 1834(m) of the Act.*

If we determine at Step 1 that a service is separately payable under the PFS, we propose to apply Step 2 under which we would determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of those face-to-face elements of the service are furnished using an interactive telecommunications system as defined in § 410.78(a)(3). The aim of this step is to determine whether the service is, in whole or in part, inherently a face-to-face service. As we discussed in the CY 2018 PFS final rule (83 FR 59483), it has long been the case that certain services that are furnished remotely using communications technology are not considered Medicare telehealth services and are not subject to the requirements of section 1834(m) of the Act. We proposed Step 2 to emphasize the circumstances under which the criteria under section 1834(m) of the Act apply, and also highlight circumstances in which the criteria under section 1834(m) of the Act do not apply. As previously noted, section 1834(m) of the Act provides for payment to a physician or practitioner for a service furnished via an interactive telecommunications system notwithstanding that the furnishing practitioner and patient are not in the same location at the same amount that would have been paid if the service was furnished without the telecommunications system. We read this to mean that the scope of section 1834(m) of the Act is limited to services that would ordinarily be furnished with the furnishing practitioner and patient in the same location.

Our application of Step 2 remains consistent with longstanding policy. We reiterate that there is a range of services delivered using certain telecommunications technology that do not fall within the scope of Medicare telehealth services, though they are separately payable under the PFS. Such services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter, for example, to assess whether an in-person or telehealth visit is needed or to transmit health information to the practitioner.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we will consider whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit. For interested parties preparing a request to add a service to the Medicare Telehealth Services List, we believe this Step 2 clarifies that a service must be inherently a face-to-face service. We believe reframing this Step 2 has the practical advantage of refining and improving consistency. We do not believe it would be appropriate to add a service to the Medicare Telehealth Services List if it is not subject to section 1834(m) of the Act. We would explain our finding in notice and comment rulemaking.

Step 3. *Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).*

We believe that the proposed Step 3 is fundamental to our commitment to health equity, as this step could have a beneficial impact on access to care for vulnerable populations. Step 3 is corollary to Step 2, and used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from submitters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed. We note that completing each element of the defined service is a different question than whether a beneficiary receives any benefit at all from the telehealth-only form of a candidate service. The practical basis for Step 3 mirrors the practical basis for proposed Step 1 and 2, which is a consistent application of review criteria. Many submissions that CMS received during the PHE lacked evidence indicating that some or all elements of a service could be completed using an interactive telecommunications system without still requiring an in-person interaction with a patient to furnish the complete service. We note that studies of patient satisfaction alone, and submissions with an excessive focus on patient satisfaction alone, present risks of bias in many ways, possibly complicating or obfuscating the question of whether it is possible, or potentially safe, to deliver an inherently face-to-face service via telehealth. Step 3 is integral to avoiding the possible unintended consequences of creating new gaps in care when telehealth is used as a substitute for in-person care.

Step 4. *Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.*

The purpose of the proposed Step 4 of our analysis is to simplify and reduce the administrative burden of submission and review. For Step 4, we proposed to consider whether the service elements of a code that we are considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and has a permanent status, because any code that satisfies this criterion would require no

further analysis: if a code describes a service that maps to the service elements of a code that is included on the Medicare Telehealth Services List on a permanent basis, we would add the code to the Medicare Telehealth Services List on a permanent basis.

We note that section 1834(m)(4)(F)(i) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services (as identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary. Over the years, CMS has assigned Category 1 (permanent) status to services that were either included in the list of codes specified in section 1834(m)(4)(F)(i) of the Act or added as successor codes to those enumerated by statute. Successor codes are updates to or replacements for the codes listed in section 1834(m)(4)(F)(i) of the Act. Therefore, this proposed step would ensure that CMS includes successor codes on the Medicare Telehealth Services List. We note that even if a code that we are considering for addition to the Medicare Telehealth Services List is not a successor code, we would consider whether the service described in the submission is similar to professional consultations, office visits, and office psychiatry services that are already on the Medicare Telehealth Services List on a permanent basis. While we have not previously found that the elements of service we are considering for addition to the list map to the elements of a service that was previously added to the list on a permanent basis using the Category 2 criteria, we believe that it would be appropriate to apply this step 4 analysis to compare the candidate service with *any permanent code that is on the list on a permanent basis.* As such, in step 4, we proposed to maintain any previous analytical determinations from Steps 1 through 3 and directly map the successor code to a code on the list that has a permanent status described in previous final rulemaking. For example, if a code currently categorized as a finalized Category 2 permanent code was replaced or revised by a successor code in a future year, CMS would ensure that these revisions did not change the Step 1–3 results and add the successor code under Step 4. We further proposed that if we find that the service we are considering satisfies Step 4, we would end our review and propose to add the service to the Medicare Telehealth Services List on a permanent basis in the next PFS proposed rule. When Step 4 is met, further evidence review is not necessary. We proposed to continue to Step 5 if Step 4 was not met.

Step 5. *Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.*

Similar to Steps 3, 4, and 5 above, the purpose of the proposed step 5 is to simplify and reduce the administrative burden. Under proposed Step 5, we would review the evidence provided with a submission to determine the clinical benefit of a service. We would then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. Proposed Step 5 would continue the existing standard that we have applied when considering whether to add a code to the Medicare Telehealth Services List on a Category 2 basis. We further proposed that: if there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS would assign the code a ''provisional'' status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS would assign the code ''permanent'' status on the Medicare Telehealth Services List, even if the code's service elements do not map to the service elements of a service that already has permanent status.

We reminded readers that our evidentiary standard of demonstrated clinical benefit does not include minor or incidental benefits (81 FR 80194), and if finalized, our proposal would not alter or displace this longstanding requirement. We will review the evidence submitted by interested parties, and other evidence that CMS has on hand. The evidence should indicate that the service can be safely delivered using two-way interactive audio-video communications technology. Clinical practice guidelines, peer-reviewed literature, and similar materials, should illustrate specifically how the methods and findings within the material establish a foundation of support that each element of the defined, individual service described by the existing face-to-face service code has been studied in the typical setting of care, typical population of beneficiaries, and typical clinical scenarios that practitioners would encounter when furnishing the service using only interactive, two-way audio-video communications technology to complete the visit or encounter with Medicare beneficiaries. This analysis is fundamental to either of the current Category 1 or Category 2 descriptions.

General evidence may also answer the question of whether a certain beneficiary population requiring care for a specific illness or injury may benefit from receiving a service via telehealth versus receiving no service at all, but must establish that the service is a substitute for an equivalent in-person service. Evidence should demonstrate how all elements described by the individual service code can be met when two-way, interactive audio-video communications technology is used as a complete substitute for any face-to-face interaction required between the patient and practitioner that are described in the individual code descriptor. We further remind readers that submissions reflecting practitioner services furnished to Medicare beneficiaries are helpful in our considerations.

Proposed Assignment of ''Permanent'' or ''Provisional'' Status to a Service and Changes in Status

We proposed to assign ''permanent'' or ''provisional'' status to any services for which the service elements map to the service elements of a service on the list that has a permanent status described in previous final rulemaking (see proposed step 4) or for which there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the service is furnished via telehealth by an eligible Medicare telehealth physician or practitioner (see proposed step 5). These two designations (that is, ''permanent'' or ''provisional'') are intended to replace the Category 1–3 taxonomy that CMS currently uses. This proposed change is intended to reduce confusion regarding the status of codes on the Medicare Telehealth Services List and to simplify the outcome of our analysis. After a code receives the ''provisional'' status, as evidence generation builds, we may assign ''permanent'' status in a future year, or we may remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. We would revisit provisional status through our regular annual submissions and rulemaking processes where a submission provides new evidence, or our claims monitoring shows anomalous activity, or as indicated by patient safety

considerations. CMS would handle changes in status by revisiting the same steps 1 through 5 above.

Summary and Request for Feedback on Proposals To Update the Process of Review for Adding, Removing, or Changing the Status of Services on the Medicare Telehealth List

In the proposed rule, we noted that the timeline for our proposed process to analyze submissions would remain the same. CY 2025 submissions would be due by February 10, 2024. Additionally, we would continue to address each submitted request for addition, deletion, or modification of services on the Medicare Telehealth Services List through annual notice and comment rulemaking.

As the end of the PHE for COVID–19 was uncertain at the time of last year's rule, many of the submissions for both CY 2023 and CY 2024 involved requests to change the status of services on the Medicare Telehealth Services List from temporary to permanent. In other words, many requestors requested that CMS consider changing the status of one or more services from Category 3 to Category 1 or 2. Based on the number of requests we received asking that CMS assign a different status to a given service, we believe a clarification is necessary to remind readers of the steps that we take when analyzing a given service for addition to, removal from, or a change in status on the Medicare Telehealth Services List. Through this proposal, we intended to refine our process and reduce confusion going forward.

To reiterate some of our discussion above, our proposals are consistent with the existing principles that CMS has applied to requests to add, remove, or change the status of a code during the COVID–19 PHE. When reviewing submissions during the PHE, in the absence of evidence supporting clinical benefit, but public comment expressing support for possible clinical benefit, CMS would generally accept a temporary addition to the Medicare Telehealth Services list, allowing more time for evidence generation. We anticipated that our approach would generally remain consistent with this particular point of flexibility if this proposal were finalized; a code could potentially receive provisional status on the Medicare Telehealth Services List in such a situation, with the caveat that our proposed Steps 1, 2, and 3, are thresholds for inclusion on the Medicare Telehealth Services List. If CMS finds that a service is not separately payable under the PFS (see proposed step 1) or it is not subject to section 1834(m) of the Act (see proposed Step 2), that service would not be added to the Medicare Telehealth Services List on any basis (and notice of the rejection would be provided to the submitter, as noted above). We do not intend to reject a submission based solely on the fact that the requestor did not request the appropriate basis for consideration; we would still analyze the submission based on the proposed steps, and then we would propose to add, remove, or change the status of the service, or we would explain why we were not doing so.

We received comments on our proposed analysis procedures for additions to, removals from, or changes in status for services on the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters agreed with our proposal. Many commenters expressed general support for our proposal to simplify our process for managing updates to the telehealth list. We did not receive any comments that requested CMS delay or forgo the proposed changes. Some commenters requested more clarity about the timing of updates and requested greater visibility into determinations of permanent or provisional services. Several commenters expressed concern that a static list may not be able to keep pace with innovation or asserted that CMS has not gone far enough with its temporary services policies to allow room for experimentation.

Response: We note that our flexibility to make subregulatory changes to the Medicare Telehealth Services List expired at the end of the PHE. As a result, CMS must effectuate any change to the list through notice and comment rulemaking. Further, as we explained in our restatement of the longstanding criteria in this year's proposed rule, the points of evaluation, and timing of review period, both remain unchanged under our proposal. However, we believe modifications to our procedures may result in less confusion. Study and observation of these services in clinical practice add to available evidence, thereby continuing to address gaps in evidence. A revised process lends greater opportunity to focus on evidence generation. Whether a service has an appropriate valuation or whether a clinical action is appropriate as described in the service itself are not open questions, so submissions need not take up those questions. The matter at hand, is whether audio-video communication can fully substitute in-person interactions and still complete the service while providing clinical benefit. Submissions should include verifiable and transparent studies that compare the typical beneficiary populations who receive the in-person service versus the telehealth service, and set forth methods, analysis, observations, and conclusions that address any differences in receiving in-person versus telehealth service.

Comment: Some commenters suggested that CMS need not go beyond Step 3 to determine whether a service should be included on the list. One commenter requested clarification as to whether Step 3 requires, ''substantial clinical improvement.''

Response: We disagree with commenters that only Steps 1–3 are necessary and remind readers that section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m) of the Act. Since we added many services to the Medicare Telehealth List during the PHE, maintaining any of these additional services after the PHE would become difficult to administer in future years without Steps 4 and 5 (or something analogous) because Steps 1–3 only consider whether 1834(m) may apply, whereas later steps help us decide whether there is clinical benefit for a service when face-to-face interactions are substituted with the use of two-way audio-video communications technology.

Stopping at Step 3 would leave us without some basis that the full service could be performed without fundamentally changing the design, meaning, and RVUs already established in making the code payable under the PFS, for any given code we review for consideration on our Medicare Telehealth List. Analysis of the effects of complete substitution of any and all of the otherwise in-person elements in a given code happens in two ways. If the individual code is so similar to the statutorily enumerated codes described in section 1834(m) of the Act, then the code may be added without further examination (that is, without Step 4).

Responsive to concerns that the review process may not keep pace with innovation, we disagree that Steps 4 and 5 threaten innovation. We also do not believe that the update and review process for the Medicare Telehealth List should be the driver for innovation. We note this Step 3 analysis is different from any substantial clinical improvement analysis. Our process is

intended to strike a balance between the uncertainty of innovation, which may not be well-accounted for in the framework of section 1834(m) of the Act, with our recent history of regulations promulgated to implement the statutory requirements of section 1834(m) of the Act.

Comment: A few commenters expressed concern that we have hesitated or declined to extend telehealth flexibilities over the past 3 years and have added significant qualifiers, including in-person requirements, to mental health services. Other commenters expressed concern that maintaining the PHE flexibilities may interfere with the doctor-patient relationship or create the unintended consequence of reducing access and clinical benefits of in-person care. There remains a diversity of opinions across various interested parties.

Response: We note that CMS has implemented a broad range of telehealth flexibilities and related policies to expand access to services and address gaps in care, including a focus on expanding access to behavioral health. We believe it is important to note that Congress mandated the in-person requirements for Medicare telehealth services for diagnosis, evaluation, or treatment of a mental health disorder through the CAA, 2021, and has twice delayed the requirement in the CAA, 2022 and CAA, 2023. As a result, we have not yet enforced the in-person requirement for telehealth services for diagnosing, evaluating, or treating a mental health disorder.

We are finalizing, as proposed, our consolidation of categories for services currently on the Medicare Telehealth List, as described in the following section.

d. Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List

We also proposed consolidating Categories 1, 2, and 3, as proposed above, for all services currently on the Medicare Telehealth Services List. For CY 2024, we proposed to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to the proposed new ''permanent,'' category while any services currently added on a ''temporary Category 2'' or Category 3 basis would be assigned to the ''provisional'' category. We believe redesignations in this calendar year would help ease confusion in future years, including in the event of subsequent legislation regarding Medicare telehealth services.

Furthermore, for a code that receives provisional status, as evidence generation builds, we may grant the code a permanent status in a future year or remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. Our proposal did not set any specific timing for reevaluation of services added to the Medicare Telehealth Services List on a provisional basis because evidence generation may not align with a specific timeframe. Our proposal not to establish any specific timing for considering changes from provisional to permanent status avoids a potential situation in which we must remove provisional services from the Medicare Telehealth Services List because the set period tolls, only to later find evidence demonstrating that the removed service should receive permanent status. Under our proposal, we would assign a provisional status for codes that satisfy the proposed threshold steps (1, 2, and 3), and then the evidence available leaves a ''close call'' between permanent and provisional status. We do not assign provisional status when it is improbable that the code would ever achieve permanent status.

We received comments on our proposal to consolidate categories for services currently on the Medicare Telehealth List. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters expressed support for our proposal to consolidate categories for services currently on the list. Some commenters requested that CMS set a specific timing, with more transparency about the change in status of provisional codes. Commenters also asserted that CMS should broaden its narrow interpretation of the requirements of section 1834(m) of the Act. Many commenters referenced the *CONNECT for Health Act,* HR 3875/S. 2016 (refer to *congress.gov/bill/118th-congress/house-bill/3875/committees?s=1&r=38*).

Response: We reiterate our discussion of timing and note that CMS has no plans to remove any provisional service from the current telehealth list where evidence generation remains in-process, and the individual code is subject to section 1834(m) of the Act. We would remove a provisional service from the list if evidence demonstrated patient safety issues. Our consideration of provisional services requires us to balance the statutory requirements of section 1834(m) of the Act with the availability of clinical evidence. The statutory and clinical research landscapes may change on a different timing and cadence.

Regarding the timing and change in status of a provisional code to a permanent code, this change in status would depend on a few factors. For example, if we become aware of updated clinical guidelines reflecting changes that show it is appropriate for the Medicare population to receive a telehealth service identified as provisional, then we would consider that evidence as support for a potential change from provisional to permanent status. For further background, we refer readers to the section that follows. We disagree with commenters who suggested that our interpretation of section 1834(m) of the Act is excessively narrow.

We believe it remains important to underscore that the purpose of designations of permanent versus provisional services on the Medicare Telehealth List is to signal where more study is necessary while avoiding the unintended consequence where a change in status itself drives the formation of new clinical standards or practices.

Table 11 lists codes we are finalizing for the Medicare Telehealth Services List and includes the simplified categorization of each service as either provisional or permanent. The provisional services are those that are currently temporary, while the permanent services are those that are currently permanent as category 1 or 2. As in Medicare Telehealth Services Lists included in previous PFS final rules and posted on our website at *https://www.cms.gov/medicare/coverage/telehealth/list-services*, the audio-only column designates those services that may be furnished using audio-only technology, including telehealth services for mental health (including SUD). We are finalizing our proposal to use the simplified ''provisional'' or ''permanent'' designations for the current year, and to apply our revised review process beginning with reviews for the CY 2025 PFS proposed rule.

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TABLE 11: CY 2024 Medicare Telehealth Services List

HCPCS	Short Description	Audio-Only?	Category
0362T	Bhv id suprt assmt ea 15 min		provisional
0373T	Adapt bhv tx ea 15 min		provisional
90785	Psytx complex interactive	Yes	permanent
90791	Psych diagnostic evaluation	Yes	permanent
90792	Psych diag eval w/med srvcs	Yes	permanent
90832	Psytx w pt 30 minutes	Yes	permanent
90833	Psytx w pt w e/m 30 min	Yes	permanent
90834	Psytx w pt 45 minutes	Yes	permanent
90836	Psytx w pt w e/m 45 min	Yes	permanent
90837	Psytx w pt 60 minutes	Yes	permanent
90838	Psytx w pt w e/m 60 min	Yes	permanent
90839	Psytx crisis initial 60 min	Yes	permanent
90840	Psytx crisis ea addl 30 min	Yes	permanent
90845	Psychoanalysis	Yes	permanent
90846	Family psytx w/o pt 50 min	Yes	permanent
90847	Family psytx w/pt 50 min	Yes	permanent
90853	Group psychotherapy	Yes	permanent
90875	Psychophysiological therapy		provisional
90901	Biofeedback train any meth		provisional
90951	Esrd serv 4 visits p mo <2yr		permanent
90952	Esrd serv 2-3 vsts p mo <2yr		permanent
90953	Esrd serv 1 visit p mo <2yrs		provisional
90954	Esrd serv 4 vsts p mo 2-11		permanent
90955	Esrd srv 2-3 vsts p mo 2-11		permanent
90956	Esrd srv 1 visit p mo 2-11		provisional
90957	Esrd srv 4 vsts p mo 12-19		permanent
90958	Esrd srv 2-3 vsts p mo 12-19		permanent
90959	Esrd serv 1 vst p mo 12-19		provisional
90960	Esrd srv 4 visits p mo 20+		permanent
90961	Esrd srv 2-3 vsts p mo 20+		permanent
90962	Esrd serv 1 visit p mo 20+		provisional
90963	Esrd home pt serv p mo <2yrs		permanent
90964	Esrd home pt serv p mo 2-11		permanent
90965	Esrd home pt serv p mo 12-19		permanent
90966	Esrd home pt serv p mo 20+		permanent
90967	Esrd svc pr day pt <2		permanent
90968	Esrd svc pr day pt 2-11		permanent
90969	Esrd svc pr day pt 12-19		permanent
90970	Esrd svc pr day pt 20+		permanent
92002	Eye exam new patient		provisional
92004	Eye exam new patient		provisional
92012	Eye exam establish patient		provisional
92014	Eye exam&tx estab pt 1/>vst		provisional
92507	Speech/hearing therapy	Yes	provisional
92508	Speech/hearing therapy	Yes	provisional
92521	Evaluation of speech fluency	Yes	provisional
92522	Evaluate speech production	Yes	provisional
92523	Speech sound lang comprehen	Yes	provisional
92524	Behavral qualit analys voice	Yes	provisional
92526	Oral function therapy		provisional
92550	Tympanometry & reflex thresh		provisional
92552	Pure tone audiometry air		provisional
92553	Audiometry air & bone		provisional
92555	Speech threshold audiometry		provisional

HCPCS	Short Description	Audio-Only?	Category
92556	Speech audiometry complete		provisional
92557	Comprehensive hearing test		provisional
92563	Tone decay hearing test		provisional
92565	Stenger test pure tone		provisional
92567	Tympanometry		provisional
92568	Acoustic refl threshold tst		provisional
92570	Acoustic immitance testing		provisional
92587	Evoked auditory test limited		provisional
92587	Evoked auditory test limited		provisional
92587	Evoked auditory test limited		provisional
92588	Evoked auditory tst complete		provisional
92588	Evoked auditory tst complete		provisional
92588	Evoked auditory tst complete		provisional
92601	Cochlear implt f/up exam <7		provisional
92602	Reprogram cochlear implt <7		provisional
92603	Cochlear implt f/up exam 7/>		provisional
92604	Reprogram cochlear implt 7/>		provisional
92607	Ex for speech device rx 1hr		provisional
92608	Ex for speech device rx addl		provisional
92609	Use of speech device service		provisional
92610	Evaluate swallowing function		provisional
92625	Tinnitus assessment		provisional
92626	Eval aud funcj 1st hour		provisional
92627	Eval aud funcj ea addl 15		provisional
93750	Interrogation vad in person		provisional
93797	Cardiac rehab		provisional
93798	Cardiac rehab/monitor		provisional
94002	Vent mgmt inpat init day		provisional
94003	Vent mgmt inpat subq day		provisional
94004	Vent mgmt nf per day		provisional
94005	Home vent mgmt supervision		provisional
94625	Phy/qhp op pulm rhb w/o mntr		provisional
94626	Phy/qhp op pulm rhb w/ mntr		provisional
94664	Evaluate pt use of inhaler		provisional
95970	Alys npgt w/o prgrmg		provisional
95971	Alys smpl sp/pn npgt w/prgrm		provisional
95972	Alys cplx sp/pn npgt w/prgrm		provisional
95983	Alys brn npgt prgrmg 15 min		provisional
95984	Alys brn npgt prgrmg addl 15		provisional
96105	Assessment of aphasia		provisional
96110	Developmental screen w/score		provisional
96112	Devel tst phys/qhp 1st hr		provisional
96113	Devel tst phys/qhp ea addl		provisional
96116	Nubhvl xm phys/qhp 1st hr	Yes	permanent
96121	Nubhvl xm phy/qhp ea addl hr	Yes	permanent
96125	Cognitive test by hc pro		provisional
96127	Brief emotional/behav assmt	Yes	provisional
96130	Psycl tst eval phys/qhp 1st	Yes	provisional
96131	Psycl tst eval phys/qhp ea	Yes	provisional
96132	Nrpsyc tst eval phys/qhp 1st	Yes	provisional
96133	Nrpsyc tst eval phys/qhp ea	Yes	provisional
96136	Psycl/nrpsyc tst phy/qhp 1st	Yes	provisional
96137	Psycl/nrpsyc tst phy/qhp ea	Yes	provisional
96138	Psycl/nrpsyc tech 1st	Yes	provisional
96139	Psycl/nrpsyc tst tech ea	Yes	provisional
96156	Hlth bhv assmt/reassessment	Yes	permanent

HCPCS	Short Description	Audio-Only?	Category
96158	Hlth bhv ivntj indiv 1st 30	Yes	permanent
96159	Hlth bhv ivntj indiv ea addl	Yes	permanent
96160	Pt-focused hlth risk assmt	Yes	permanent
96161	Caregiver health risk assmt	Yes	permanent
96164	Hlth bhv ivntj grp 1st 30	Yes	permanent
96165	Hlth bhv ivntj grp ea addl	Yes	permanent
96167	Hlth bhv ivntj fam 1st 30	Yes	permanent
96168	Hlth bhv ivntj fam ea addl	Yes	permanent
96170	Hlth bhv ivntj fam wo pt 1st		provisional
96171	Hlth bhv ivntj fam w/o pt ea		provisional
97110	Therapeutic exercises		provisional
97112	Neuromuscular reeducation		provisional
97116	Gait training therapy		provisional
97129	Ther ivntj 1st 15 min		provisional
97130	Ther ivntj ea addl 15 min		provisional
97150	Group therapeutic procedures		provisional
97151	Bhv id assmt by phys/qhp		provisional
97152	Bhv id suprt assmt by 1 tech		provisional
97153	Adaptive behavior tx by tech		provisional
97154	Grp adapt bhv tx by tech		provisional
97155	Adapt behavior tx phys/qhp		provisional
97156	Fam adapt bhv tx gdn phy/qhp		provisional
97157	Mult fam adapt bhv tx gdn		provisional
97158	Grp adapt bhv tx by phy/qhp		provisional
97161	Pt eval low complex 20 min		provisional
97162	Pt eval mod complex 30 min		provisional
97163	Pt eval high complex 45 min		provisional
97164	Pt re-eval est plan care		provisional
97165	Ot eval low complex 30 min		provisional
97166	Ot eval mod complex 45 min		provisional
97167	Ot eval high complex 60 min		provisional
97168	Ot re-eval est plan care		provisional
97530	Therapeutic activities		provisional
97535	Self care mngment training	Yes	provisional
97537	Community/work reintegration		provisional
97542	Wheelchair mngment training		provisional
97750	Physical performance test		provisional
97755	Assistive technology assess		provisional
97760	Orthotic mgmt&traing 1st enc		provisional
97761	Prosthetic traing 1st enc		provisional
97763	Orthc/prostc mgmt sbsq enc		provisional
97802	Medical nutrition indiv in	Yes	permanent
97803	Med nutrition indiv subseq	Yes	permanent
97804	Medical nutrition group	Yes	permanent
98960	Self-mgmt educ & train 1 pt		provisional
98961	Self-mgmt educ/train 2-4 pt		provisional
98962	Self-mgmt educ/train 5-8 pt		provisional
98966	Hc pro phone call 5-10 min	Yes	provisional
98967	Hc pro phone call 11-20 min	Yes	provisional
98968	Hc pro phone call 21-30 min	Yes	provisional
99202	Office/outpatient visit new		permanent
99203	Office/outpatient visit new		permanent
99204	Office/outpatient visit new		permanent
99205	Office/outpatient visit new		permanent
99211	Office/outpatient visit est		permanent
99212	Office/outpatient visit est		permanent

HCPCS	Short Description	Audio-Only?	Category
99213	Office/outpatient visit est		permanent
99214	Office/outpatient visit est		permanent
99215	Office/outpatient visit est		permanent
99221	Initial hospital care		provisional
99222	Initial hospital care		provisional
99223	Initial hospital care		provisional
99231	Subsequent hospital care		permanent
99232	Subsequent hospital care		permanent
99233	Subsequent hospital care		permanent
99234	Observ/hosp same date		provisional
99235	Observ/hosp same date		provisional
99236	Observ/hosp same date		provisional
99238	Hospital discharge day		provisional
99239	Hospital discharge day		provisional
99281	Emergency dept visit		provisional
99282	Emergency dept visit		provisional
99283	Emergency dept visit		provisional
99284	Emergency dept visit		provisional
99285	Emergency dept visit		provisional
99291	Critical care first hour		provisional
99292	Critical care addl 30 min		provisional
99304	Nursing facility care init		provisional
99305	Nursing facility care init		provisional
99306	Nursing facility care init		provisional
99307	Nursing fac care subseq		permanent
99308	Nursing fac care subseq		permanent
99309	Nursing fac care subseq		permanent
99310	Nursing fac care subseq		permanent
99315	Nursing fac discharge day		provisional
99316	Nursing fac discharge day		provisional
99341	Home visit new patient		provisional
99342	Home visit new patient		provisional
99344	Home visit new patient		provisional
99345	Home visit new patient		provisional
99347	Home visit est patient		permanent
99348	Home visit est patient		permanent
99349	Home visit est patient		provisional
99350	Home visit est patient		provisional
99406	Behav chng smoking 3-10 min	Yes	permanent
99407	Behav chng smoking > 10 min	Yes	permanent
99441	Phone e/m phys/qhp 5-10 min	Yes	provisional
99442	Phone e/m phys/qhp 11-20 min	Yes	provisional
99443	Phone e/m phys/qhp 21-30 min	Yes	provisional
99468	Neonate crit care initial		provisional
99469	Neonate crit care subsq		provisional
99471	Ped critical care initial		provisional
99472	Ped critical care subsq		provisional
99473	Self-meas bp pt educaj/train		provisional
99475	Ped crit care age 2-5 init		provisional
99476	Ped crit care age 2-5 subsq		provisional
99477	Init day hosp neonate care		provisional
99478	Ic lbw inf < 1500 gm subsq		provisional
99479	Ic lbw inf 1500-2500 g subsq		provisional
99480	Ic inf pbw 2501-5000 g subsq		provisional
99483	Assmt & care pln pt cog imp		permanent
99495	Trans care mgmt 14 day disch		permanent

HCPCS	Short Description	Audio-Only?	Category
99496	Trans care mgmt 7 day disch		permanent
99497	Advncd care plan 30 min	Yes	permanent
99498	Advncd care plan addl 30 min	Yes	permanent
G0136	SDOH risk assessment, 5-15 min	Yes	permanent
G0108	Diab manage trn per indiv	Yes	permanent
G0109	Diab manage trn ind/group	Yes	permanent
G0270	Mnt subs tx for change dx	Yes	permanent
G0296	Visit to determ ldct elig	Yes	permanent
G0316	Prolonged hospital inpatient or observation care		permanent
G0317	Prolonged nursing facility evaluation and management service		permanent
G0318	Prolonged home or residence evaluation and management		permanent
G0396	Alcohol/subs interv 15-30mn	Yes	permanent
G0397	Alcohol/subs interv >30 min	Yes	permanent
G0406	Inpt/tele follow up 15	Yes	permanent
G0407	Inpt/tele follow up 25	Yes	permanent
G0408	Inpt/tele follow up 35	Yes	permanent
G0410	Grp psych partial hosp 45-50		provisional
G0420	Ed svc ckd ind per session	Yes	permanent
G0421	Ed svc ckd grp per session	Yes	permanent
G0422	Intens cardiac rehab w/exerc		provisional
G0423	Intens cardiac rehab no exer		provisional
G0425	Inpt/ed teleconsult30	Yes	permanent
G0426	Inpt/ed teleconsult50	Yes	permanent
G0427	Inpt/ed teleconsult70	Yes	permanent
G0438	Ppps, initial visit	Yes	permanent
G0439	Ppps, subseq visit	Yes	permanent
G0442	Annual alcohol screen 15 min	Yes	permanent
G0443	Brief alcohol misuse counsel	Yes	permanent
G0444	Depression screen annual	Yes	permanent
G0445	High inten beh couns std 30m	Yes	permanent
G0446	Intens behave ther cardio dx	Yes	permanent
G0447	Behavior counsel obesity 15m	Yes	permanent
G0459	Telehealth inpt pharm mgmt	Yes	permanent
G0506	Comp asses care plan ccm svc	Yes	permanent
G0508	Crit care telehea consult 60		permanent
G0509	Crit care telehea consult 50		permanent
G0513	Prolong prev svcs, first 30m	Yes	permanent
G0514	Prolong prev svcs, addl 30m	Yes	permanent
G2086	Off base opioid tx 70min	Yes	permanent
G2087	Off base opioid tx, 60 m	Yes	permanent
G2088	Off base opioid tx, add30	Yes	permanent
G2211	Complex E/M visit add on	Yes	permanent
G2212	Prolong outpt/office vis	Yes	permanent
G3002	Chronic pain tx monthly b		permanent
G3003	Addition 15m pain mang		permanent
G9685	Acute nursing facility care		provisional

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e. Implementation of Provisions of the CAA, 2023

(1) Overview and Background

The CAA, 2022 included several provisions that extend certain Medicare telehealth flexibilities adopted during the COVID–19 PHE for 151 days after the end of the PHE. Specifically, sections 301 through 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that were on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). The CAA, 2022, temporarily removed restrictions on telehealth originating sites for those services to allow telehealth services to patients located in any site in the United States at the time of the telehealth service, including an individual's home;

expanded the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delayed the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services to a beneficiary in their home, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued to provide for payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2020, that are furnished via an audio-only telecommunications system. A full discussion of these policies available in the CY 2023 PFS final rule at 87 FR 69462.

In addition, section 309 of the CAA, 2022 authorized the Secretary to implement the amendments described above, made by sections 301 through 305, through program instruction or otherwise. In the CY 2023 PFS final rule (87 FR 69446), we finalized specific telehealth policies to conform to and align with amendments made by the CAA, 2022. In our CY 2023 PFS final rule (87 FR 69462–69464), we described how CMS would issue program instructions to implement specific requirements of the CAA, 2022. We also implemented the provisions enacted in the CAA, 2022 for a 151-day extension period of certain telehealth flexibilities (discussed previously in this final rule). On December 29, 2022, the President signed the CAA, 2023 into law. Section 4113 of the CAA, 2023 further extends the previously-extended PHE-related telehealth policies; it requires CMS to extend the telehealth flexibilities that were previously extended (initially for 151 days after the end of the PHE) under the CAA, 2022, through December 31, 2024.

We seek to address various telehealth policies that we finalized in the CY 2023 final rule, in light of the CAA, 2023. For example, the 151-day extension period for certain flexibilities discussed in our CY 2023 final rule (and previously in this final rule) no longer applies, since section 4113 of the CAA, 2023 extends these flexibilities until December 31, 2024 (the extended flexibilities include: temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home; expansion of the definition of eligible telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued coverage and payment of telehealth services included on the Medicare Telehealth Services List as of March 15, 2020) until December 31, 2024. Both the CAA, 2022 and CAA, 2023 have the same operative effect on the scope of Medicare telehealth services; both the CAA, 2022 and CAA, 2023 give the Secretary the authority to implement the relevant telehealth provisions outside of notice and comment rulemaking through program instruction or otherwise. We intend to implement the provisions discussed above, as enacted by the CAA, 2023.

Similar to the goals of our telehealth policies addressed in last year's final rule, for CY 2024, we again seek to retain payment stability, reduce confusion, and burden, and conform to all statutory requirements without unnecessary restrictions on beneficiaries' access to telehealth care. Our discussion here does not alter payment amounts or billing rules that are in effect as of January 1, 2023, and those policies will remain in effect through December 31, 2024. Instead, it is our intent in this final rule to clarify that certain telehealth flexibilities that were previously extended until 151 days after the end of the PHE, by the CAA, 2022, have been extended until December 31, 2024, in accordance with the amendments made by provisions of the CAA, 2023.

(2) In-Person Requirements for Mental Health Telehealth

Section 4113(d)(1) of section FF, Title IV, Subtitle B of the CAA, 2023 amends section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on January 1, 2025. In addition, 4113(d)(2) of section FF, Title IV, Subtitle B of the CAA, 2023 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we proposed to revise the regulatory text at § 410.78(b)(3)(xiv) and (b)(4)(iv)(D) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until January 1, 2025, rather than until the 152nd day after the end of the PHE, to conform with the CAA, 2023. See section III.B. of this final rule for our provision to implement similar changes for RHC and FQHC mental health visits.

We received public comments on the proposal to delay in-person requirements for mental health telehealth. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposals to extend the delay of in-person requirements for mental health telehealth. We received many form letters in a coordinated response from state health organizations that requested we make the delay permanent. Some commenters highlighted that recent data suggest that even in complex patients with significant behavioral health issues, virtual-only care does not result in worse outcomes. The feedback also cited findings of significant behavioral healthcare workforce shortages that are likely to persist.[5]

Response: We thank commenters for the feedback. We understand why some commenters might want us to extend the delay of in-person requirements for mental health telehealth permanently, but we remind commenters that we are simply revising the regulations to conform to the requirements in section

[5] Many commenters made general statements about shortages without specific studies or data. We did receive form letter responses with various sources for statistic, and some with sources unavailable. CMS staff found the following resource referenced in some comments, but at a different location. ''In 2021, health centers employed 17,415 full-time behavioral health staff, with psychiatrists and licensed clinical psychologists making up 10% of that workforce at 5% each. Document at *https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf.*

4113(d) of section FF, title IV, Subtitle B of the CAA, 2023, which only delays in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder through the end of CY 2024.

Comment: Some commenters stated that CMS should implement the in-person requirements when the delay mandated by the CAA, 2023 expires. One life sciences company expressed concern that in absence of regular in-person care, practitioners may not appropriately manage therapy regimens for patients who receive medication to treat certain mental health conditions. A State-wide medical professional organization with a significant rural population cautioned against further delay of requirements and noted concern that direct-to-consumer telehealth entities may be engaging with beneficiaries in ways that raise concerns.[6] One commenter stated that an indefinite delay of in-person requirements may risk communication benefits that come with in-person interactions important in the Medicare population.[7]

Response: We thank commenters for the feedback, and we direct them to the statutory requirements specified in the CAA, 2023 and described in further detail previously in this section.

We are finalizing as proposed our policy to delay in-person requirements for telehealth behavioral health services until January 1, 2025.

We remind suppliers of behavioral health services who furnish telehealth services to beneficiaries for purposes of diagnosis, treatment, and management of behavioral health conditions (including SUD), that the in-person requirements for behavioral telehealth services set forth in our regulations at § 410.78(b)(3)(xiv) are set to take effect beginning for CY 2025. Section 410.78(b)(3)(xiv)(A) requires that the initial telehealth service shall be furnished only after an in-person visit within 6 months of the initial telehealth service; § 410.78(b)(3)(xiv)(B) requires that any subsequent telehealth service, that is, for established patients with both a prior in-person visit, and an initial telehealth visit, must be furnished only when the beneficiary has received an in-person service no longer than 12 months prior; and § 410.78(b)(3)(xiv)(B) provides flexibility to recognize beneficiary preferences, including that concerns of privacy or other burdens and risks may dictate a longer interval between the most recent in-person visit and a subsequent telehealth visit, when circumstances dictate an exception, the documentation substantiating the need for such an exception must be documented in the medical record; and § 410.78(b)(3)(xiv)(C) specifies that either in-person requirement (initial or subsequent) may be met by another practitioner of the same specialty and subspecialty in the same group as the practitioner that furnishes the telehealth services only when the practitioner who furnishes the telehealth service is not available.

We reiterate rules that we finalized and discussed at length in previous rulemaking (87 FR 69463 and 69464; 86 FR 65055 through 65059), in response to some confusion expressed by commenters on the scope of the in-person requirements, and divergent views on possible unintended consequences of maintaining or eliminating the in-person requirements. The regulations at § 410.78(b)(3)(xiv) describe two exceptions to the in-person requirements that will go into effect on January 1, 2025: beneficiaries who already receive telehealth behavioral health services and have circumstances where in-person care may not be appropriate would have an exception and groups with limited availability for in-person behavioral health visits would have available the flexibility to arrange for practitioners to furnish in-person and telehealth visits with different practitioners, based on availability.

(3) Originating Site Requirements

Section 4113(a)(2) of the CAA, 2023 amended section 1834(m)(4)(C)(iii) of the Act to temporarily expand the telehealth originating sites for any service on the Medicare Telehealth Services List to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. The list of telehealth originating sites remains as listed in our regulation at § 410.78(b)(3).

We received public comments on the proposal to temporarily expand telehealth originating sites to include the patient's home, for any non-mental health telehealth service on the Medicare Telehealth Services List through December 31, 2024. The following is a summary of the comments we received and our responses.

Comment: Commenters urged CMS to maintain the definition of ''the patient's home'' under § 410.78(b)(3) to broadly include homeless shelters, group homes, or other settings that the beneficiary identifies as their home or residence, whether permanent or temporary.

Response: As discussed in the CY 2022 PFS final rule (FR 86 65059), our definition of home, both in general and for this purpose, continues to include temporary lodging such as hotels and homeless shelters. As stated in that final rule, for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished ''in the home of an individual'' for purposes of section 1834(m)(4)(C)(ii)(X) of the Act.

Comment: We received many comments that requested CMS clarify policies related to, but separate from, our originating site proposals. Commenters expressed concerns regarding the expiring flexibility for telehealth practitioners to use their currently enrolled location instead of their home address when providing services from their home. CMS issued an FAQ, available at *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf*, which extended the flexibility through December 31, 2023. We also met with a coalition of interested parties to receive feedback on this particular issue, during the comment period. The interested parties suggested that expiration of this flexibility poses a potential and imminent threat to public safety (that is, the safety of the health care workforce). In these comments and our meeting with the coalition, interested parties voiced concerns about the safety and privacy of health professionals who work from home and furnish telehealth services. Commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners did not have to list their home addresses on enrollment forms. The commenters also cited recent examples of workplace violence in health care facilities, where direct harm to nurses and other medical staff occurred. As an additional consideration, interested parties explained that a significant number of practices and providers would need to change billing practices or add their home address to the Medicare enrollment file, coordinating with the

[6] The commenter included a link to investigative journalism focused on the issue, available at *https://www.codastory.com/waronscience/pseudohealth/telehealth-companies-misinformation/#:~:text=Bypassing%20traditional%20healthcare,your%20health%20itself.*

[7] The commenters referenced recent peer-reviewed literature available at *https://journals.sagepub.com/doi/full/10.1177/10748407211031980.*

appropriate Medicare Administrative Contractor in their jurisdiction.

Response: We thank commenters for bringing this issue to our attention. Through CY 2024, we will continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. We will also consider this issue further for future rulemaking and request that interested parties provide clear examples of how the enrollment process shows material privacy risks to inform future enrollment and payment policy development. We request further information from interested parties to better understand the scope of considerations involved with including a practitioner's home address as an enrolled practice location when that address is the distant site location where they furnish Medicare telehealth services.

(4) Telehealth Practitioners

Section 4113(b) of the CAA, 2023 amends section 1834(m)(4)(E) of the Act to require that qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists continue to be included as telehealth practitioners beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. Therefore, the list of telehealth practitioners remains as described in our CY 2023 final rule. We will also recognize marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners, effective January 1, 2024, in accordance with amendments made by section 4121 of the CAA, 2023. That section of the CAA, 2023 amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for marriage and family therapist services (as defined in section 1861(lll)(1)) of the Act and mental health counselor services (as defined in section 1861(lll)(3) of the Act). Further, section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners to whom Medicare payment may be made for their services on a reasonable charge or fee schedule basis only on an assignment-related basis. Because the definition of practitioners in section 1834(m)(4)(E) of the Act for purposes of Medicare telehealth services includes the practitioners described in section 1842(b)(18)(C) of the Act, this provision also has the effect of adding MFTs and MHCs as practitioners who can furnish telehealth services.

We proposed to amend § 410.78(b)(2) to add new paragraphs (xi) and (xii) to specify that a marriage and family therapist as described in proposed § 410.53 and a mental health counselor as described in proposed § 410.54 are included as distant site practitioners for purposes of furnishing telehealth services.

We received public comments on the proposal to permanently add MFTs and MHCs as distant site practitioners for purposes of furnishing telehealth services. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for our proposals.

Response: After consideration of public comments, we are finalizing our proposal to add MFTs and MHCs as distant site practitioners for purposes of furnishing telehealth services. We are finalizing our proposed amendments to add MFTs and MHCs to the list of distant site practitioners in the telehealth regulation at § 410.78(b)(2)(xi),(xii).

(5) Audio-Only Services

Section 4113(e) of Division FF, Title IV, Subtitle C of the CAA, 2023 amends section 1834(m)(9) of the Act to require that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024. This provision applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are permitted to be furnished via audio-only technology as of the date of enactment of the CAA, 2023 (that is, December 29, 2022).

As discussed below in the section titled ''Other Clarifications for Appropriate Billing,'' CPT codes 99441 through 99443 are on the Medicare Telehealth Services List and will remain actively priced through 2024. We proposed to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024.

e. Place of Service for Medicare Telehealth Services

When a physician or practitioner submits a claim for their professional services, including claims for telehealth services, they include a Place of Service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate, which applies when the service is furnished in hospital or skilled nursing facility (SNF) setting, and the non-facility rate, which applies when the service is furnished in an office or other setting. The PFS non-facility rate is the single geographically adjusted fee schedule amount paid to a physician or other practitioner for services furnished in their office or other non-facility outpatient setting. The PFS facility rate is the single, geographically adjusted amount paid to a physician or other practitioner when a service is furnished in a hospital or SNF setting where Medicare is making a separate payment for the services to the facility in addition to the payment to the billing physician or practitioner for their professional services. This separate payment to the facility (hospital or SNF), often referred to as a ''facility fee,'' is made under other payment systems and reflects the facility's costs associated with the service (clinical staff, supplies, equipment, overhead) and is paid in addition to what is paid to the professional under the PFS.

Prior to CY 2017, Medicare telehealth services were reported using the GT modifier. In the CY 2017 PFS final rule, we finalized creation of a new Place of Service (POS) code to identify services furnished as Medicare telehealth services, POS ''02'' (81 FR 80199–80201). In the CY 2022 PFS final rule, we created a new POS code ''10'' to identify Medicare telehealth services for which the patient's home is the originating site (87 FR 70110 and 70111).

In response to the PHE for COVID–19, we adopted temporary policies for POS codes and PFS payment rates applicable to Medicare telehealth services. As discussed in the March 31, 2020 IFC, (85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for COVID–19, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who billed for Medicare telehealth services to report the POS code that they would have reported had the service been furnished in-person. This would allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for COVID–19, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this

change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which is applied to claim lines that describe services furnished via telehealth; and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth. This allowed telehealth services to be paid at the PFS non-facility rate.

We further noted that we were maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for COVID–19. In the CY 2023 PFS final rule (87 FR 69467), we finalized that we would continue to maintain payment at the rate for a service had the service been furnished in person, and that this would allow payments to continue to be made at the non-facility based rate for Medicare telehealth services through the latter of the end of CY 2023 or the end of the calendar year in which the PHE ends.

In the CY 2023 PFS final rule (87 FR 69467), we finalized that, following the end of the end of the calendar year in which the PHE ends, practitioners will no longer bill claims with Modifier '95' along with the POS code that would have applied had the service been furnished in person, and telehealth claims will instead be billed with the POS indicators:

- POS ''02''—is redefined as Telehealth Provided Other than in Patient's Home (Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology.); and
- POS ''10''—Telehealth Provided in Patient's Home (Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.).

We recognize that, beginning with the PHE for COVID–19, behavioral health services that otherwise would have been furnished in-person have been furnished via telehealth in the patient's home. With few exceptions, prior to the PHE for COVID–19, originating sites were limited to sites such as physician's offices and hospitals. Now that behavioral health telehealth services may be furnished in a patient's home, which now may serve as an originating site, we believe these behavioral health services are most accurately valued the way they would have been valued without the use of telecommunications technology, namely in an office setting. There was an increase in utilization of these mental health services during the PHE that has persisted throughout and after expiration of the PHE for COVID–19. It appears that practice patterns for many mental health practitioners have evolved, and they are now seeing patients in office settings, as well as via telehealth. As a result, these practitioners continue to maintain their office presence even as a significant proportion of their practice's utilization may be comprised of telehealth visits. As such, we stated that we believe their practice expense (PE) costs are more accurately reflected by the non-facility rate.

Therefore, we proposed that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) would be paid at the non-facility PFS rate. When considering certain practice situations (such as in behavioral health settings, where practitioners have been seeing greater numbers of patients via telehealth), practitioners will typically need to maintain both an in-person practice setting and a robust telehealth setting. We expect that these practitioners will be functionally maintaining all of their PEs, while furnishing services via telehealth. When valuing services, we believe that there are few differences in PE when behavioral health services are furnished to a patient at home via telehealth as opposed to services furnished in-person (that is, behavioral health settings require few supplies relative to other healthcare services). Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate beginning on January 1, 2024, as we believe those services will be furnished in originating sites that were typical prior to the PHE for COVID–19, and we continue to believe that, as discussed in the CY 2017 PFS final rule (81 FR 80199 through 80201), the facility rate more accurately reflects the PE of these telehealth services; this applies to non-home originating sites such as physician's offices and hospitals. In this way, we believe we would be protecting access to mental health and other telehealth services by aligning with telehealth-related flexibilities that were extended via the CAA, 2023, as we will be more accurately recognizing the resource costs of behavioral health providers, given shifting practice models.

We received public comments on the proposal that claims billed with POS 10 be paid at the non-facility PFS rate, and claims billed with POS 02 will continue to be paid at the facility rate. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that our proposal would enhance patient access and protect payment parity. Other commenters supported paying claims billed with POS 10 at the non-facility rate but opposed maintaining payment for claims billed with POS 02 at the facility rate, stating that this will reduce access to telehealth services by disincentivizing office-based practices by paying a lower PE RVU in instances where there is a site of service differential. A few commenters opposed paying the non-facility rate for any telehealth service, stating that the facility rate more accurately reflects the resource-based costs of telehealth services. Some commenters urged us to continue allowing practitioners to report the POS code that they would have used had the service been furnished in person. One commenter urged us to gather more data on the PE resource costs associated with telehealth services for a range of services before paying the higher, non-facility rate; this commenter stated that if rates for telehealth services continue to be set equal to rates for in-office services, providers may face a strong financial incentive to favor these services over comparable in-person services, even when an in-person service may be more clinically appropriate. A commenter requested that CMS wait until the potential implementation of the telemedicine codes that CPT is considering for 2025 until revising the current place of service policy for telehealth services.

Response: Telehealth services that are not furnished in the patient's home will continue to be furnished in the same types of originating sites in which they were furnished prior to the PHE, such as hospitals or rural health clinics; therefore, the resource costs associated with these services will resemble those of services furnished in person in a facility setting as they did prior to the PHE. As discussed in the 2017 final rule (81 FR 80199–80200), for telehealth services, we believe that facility costs (clinical staff, supplies, and equipment) associated with furnishing the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at

the distant site. The statute requires Medicare to pay a fee to the site that hosts the patient. This is analogous to the circumstances under which the facility PE RVUs are used to pay for services under the PFS. That is why we believe that the facility PE RVUs most accurately reflect the resource costs for telehealth services when the home is not the originating site. We note that beginning in 2025, most telehealth services will once again be subject to the statutory restrictions under section 1834(m)(4), including the limitation on payment for telehealth services to those furnished in specified originating sites and in areas that are designated as a rural health professional shortage area or in a county that is not included in a Metropolitan Statistical Area and to sites that are certain medical facilities such as physician offices, hospitals, and skilled nursing facilities. Following 2024, mental health telehealth services, as previously noted, as well as certain other services including End-Stage Renal Disease (ESRD)-related services for home dialysis, will continue to be paid when furnished in the patient's home without geographic restrictions. They will more likely be furnished by office-based mental health practitioners. Practitioners furnishing mental health services via telehealth will more typically be practicing in non-facility based settings, rather than in facility settings that are associated with originating sites that were eligible originating sites prior to the addition of the home as an originating site, and they are therefore more likely to have office-based practices and so are incurring all of those resource costs. Beginning in 2025, in-person visit requirements will apply for mental health services furnished via telehealth. This includes a required in-person visit within the six months prior to the initial telehealth treatment as well as the requirement that subsequent in-person visits be furnished at least every 12 months. Therefore, mental health practitioners necessarily will be maintaining offices as they will be required to have in-person visits, and we believe they will be incurring the PE costs of maintaining these hybrid models. We also note that claims data indicate that during the PHE, the majority of mental health services that were furnished via telehealth were billed with the POS associated with the office setting. We believe that for mental health services furnished via telehealth, resource costs will be incurred by the distant site provider, where the practitioner is located, and not by the originating site, unlike other telehealth services for which we believe the resource costs will continue to be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site. Therefore, we continue to believe that paying for claims billed with POS 10 at the non-facility rate while continuing to pay for claims billed with POS 02 at the facility rate most accurately captures the resource costs inherent in these types of telehealth visits.

Comment: A commenter requested that CMS clarify that CMS will pay the PFS non-facility rate for any service appended with POS 10, not just mental health services.

Response: We clarify that any service appropriately billed with POS 10 will be paid at the non-facility rate.

Comment: A few commenters requested that CMS clarify the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home, and whether we require that facility-based clinicians should report POS 02.

Response: We wish to clarify that for telehealth services, when the clinician is in the hospital and the patient is in the home, the billing practitioner should use a hospital POS code along with modifier '95.'

Comment: Some commenters requested that CMS confirm that all outpatient therapy telehealth services will continue to be paid at the non-facility rate regardless of the POS code, citing manual language in Chapter 12 Section 20.4.2 that states: ''Non-facility rates are applicable to outpatient rehabilitative therapy procedures, including those relating to physical therapy, occupational therapy and speech-language pathology, regardless of whether they are furnished in facility or non-facility settings.''

Response: We wish to clarify that, for outpatient therapy services furnished via telehealth by PT, OT, or SLP distant site practitioners, the furnishing practitioner should continue to append the 95 modifier to identify them as telehealth services rather than a telehealth POS code. We also note that payment will continue to be made for telehealth services furnished by distant site PTs, OTs, or SLPs through the end of CY 2024, and that these services will continue to be paid the non-facility rate.

Comment: Some commenters expressed uncertainty about whether use of POS 10 would be appropriate when furnishing telehealth services to beneficiaries located in their homes for reasonable and necessary care related to the treatment of an injury or illness for something not related to the diagnosis, treatment, or management of an ongoing behavioral health, mental health, or SUD issue.

Response: After consideration of public comments, we are finalizing as proposed that beginning in CY 2024, claims for telehealth services billed with POS 10 will be paid at the non-facility PFS rate. Claims billed with POS 02 will continue to be paid at the facility rate. In addition, we are clarifying that modifier '95' should be used when the clinician is in the hospital and the patient is in the home, as well as for outpatient therapy services furnished via telehealth by PT, OT, or SLP.

f. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain restrictions on how frequently a service may be furnished via Medicare telehealth. These limitations include a limit of once every 3 days for subsequent inpatient visits, added in in the CY 2011 PFS final rule (75 FR 73317 through 73318), and once every 14 days for subsequent nursing facility (NF) visits, added in the CY 2016 final rule (80 FR 71062) furnished via Medicare telehealth and a limit of once per day for critical care consultation services; in establishing these limits, we cited concerns regarding the potential acuity of these patients. End-stage renal disease (ESRD)-related clinical assessments may be furnished via telehealth, subject to the frequency limitations in section 1881(b)(3)(B) of the Act, which provides that patients must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

In the March 31, 2020 COVID–19 IFC (85 FR 19241), we stated that as it was our assessment that there was a patient population who would otherwise not have had access to clinically appropriate in-person treatment, and we did not believe these frequency limitations were appropriate or necessary under the circumstances of the PHE. Therefore, we removed the frequency restrictions for certain subsequent inpatient visits, subsequent NF visits, and for critical care consultations furnished via Medicare telehealth for the duration the PHE for COVID–19. The frequency limitations resumed effect beginning on May 12, 2023, (upon expiration of the PHE), in accordance with the March 31, 2020

IFC. However, we stated that, pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020,[8] we were exercising enforcement discretion and will not consider these frequency limitations through December 31, 2023; and that we anticipated considering our policy further through our rulemaking process. As discussed below, we proposed once again remove these telehealth frequency limitations beginning CY 2024. We proposed to remove the telehealth frequency limitations for the following codes:

1. Subsequent Inpatient Visit CPT Codes

- 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. when using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);
- 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*
- 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. when using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*);
- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. when using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);
- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and
- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes

- G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.*); and
- G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.*)

We proposed to remove the frequency limitations for these codes for the duration of CY 2024, which aligns with other telehealth-related flexibilities extended by the CAA, 2023. CMS is broadly assessing our telehealth regulations, in light of the way practice patterns may have changed in the roughly 3 years of the PHE for COVID–19 and, while we engage in this assessment, we believe it is reasonable to pause certain pre-pandemic restrictions, such as these frequency limitations, to allow us to gather more information. We are seeking information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE.

We received public comments on our proposals to remove frequency limitations for Medicare Telehealth Subsequent Care Services in Nursing Facility Settings, Subsequent Nursing Facility Visit, and Critical Care Consultations. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to remove frequency limitations for 2024 for Medicare Telehealth Subsequent Care Services in Nursing Facility Settings, Subsequent Nursing Facility Visit, and Critical Care Consultations, stating that these frequency limitations are arbitrary and would result in decreased access to care, potentially leading to negative clinical outcomes. Some commenters urged us to remove these limits permanently; according to one such commenter, practitioners should be allowed to use their clinical judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met. A commenter stated that the lifting these limitations during the PHE has been instructive and demonstrates the value of continuing such flexibilities. Another commenter stated that removing frequency limitations helps practitioners keep patients in SNFs from being unnecessarily evaluated in Emergency Departments and prevents readmissions. In response to our concerns regarding patient safety and program integrity, a commenter urged the agency to closely monitor utilization patterns to determine whether the elimination of these limitations leads to an increase in inappropriate utilization. A few commenters did not support this proposal, stating that continuing to waive these limitations without any guardrails will compromise patient safety, as they do not believe that it is best practice for patients in acute care settings (unless such settings are in rural or underserved areas) to be treated daily via non-face-to-face telehealth visits/consultations in lieu of in-person visits. Similarly, another commenter stated that telehealth patient assessments and evaluations are never the same as in-person, hands on visits and should not be considered a viable replacement with no limitations for in-person care.

Response: We believe that continuing to suspend these frequency limitations on a temporary basis for CY 2024 will allow us more time to continue to evaluate patient safety while preserving access in a way that is not disruptive to practice patterns that were established during the PHE. We look forward to evaluating the information received in response to this comment solicitation, as well as utilization data and other data as we consider the most appropriate way to balance patient safety concerns with the interest of supporting healthcare access. We expect to address in future rulemaking.

Comment: A commenter stated that we should exercise enforcement discretion for telehealth frequency limitations for home dialysis clinical assessment while gathering information and evaluating changing practice

[8] *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf.*

patterns. The commenter noted that, without explanation, CMS is again not extending the enforcement discretion to ESRD clinical assessments, even though there has similarly been a change in practice patterns for nephrologists during the PHE.

Response: We appreciate the commenters' concern; however, outside of the circumstances of the PHE for COVID–19, we are continuing to enforce the statutory requirement for in-person visits associated with ESRD-related clinical assessments as established at section 1881(b)(3)(B) of the Act which requires that an individual determined to have end stage renal disease receiving home dialysis receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3months

After consideration of public comments, we are finalizing as proposed our proposal for CY 2024 to continue the removal of Medicare telehealth services frequency limitations for Subsequent Inpatient Visit, Subsequent Nursing Facility Visit, and Critical Care Consultation Services.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner. For most services furnished by auxiliary personnel incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), direct supervision by a physician, PA, NP, or CNS is required (see also § 410.27(a)(1)(iv)(B)(*1*) for hospital outpatient services). Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)). Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of Medicare telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners were previously only able to bill Medicare for telehealth services under Medicare telehealth waivers that were effective during the PHE for COVID–19 (based on the emergency waiver authority established in section 1135(b)(8) of the Act), until the CAA, 2023 extended the time period during which these practitioners could bill for Medicare telehealth services through December 31, 2024. We noted that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth services. After December 31, 2024, the types of clinicians who may furnish and bill for Medicare telehealth services include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We note that this will include mental health counselors (MHCs) and marriage and family therapists (MFTs) beginning January 1, 2024.

We noted in the CY 2021 PFS final rule (85 FR 84539) that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure; this was the case during the PHE, and will continue to be the case following the PHE. Under current policy as described in the CY 2021 final rule (85 FR 84539 and 84540, after December 31, 2023, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception allowing immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their professional services, will no longer apply after CY 2023.

We are concerned about an abrupt transition to our pre-PHE policy that defines direct supervision under § 410.32(b)(3)(ii) to require the physical presence of the supervising practitioner beginning after December 31, 2023, given that practitioners have established new patterns of practice during the PHE for COVID–19. In the absence of evidence that patient safety is compromised by virtual direct supervision, we believe that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as those furnished incident—to a physician's service. We believe physicians and practitioners will need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Recognizing these concerns, we proposed to continue to define direct supervision to permit the presence and ''immediate availability'' of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024. We believe that extending this definition of direct supervision through December 31, 2024 would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. We proposed to revise the regulatory text at § 410.32(b)(3)(ii) to state that, through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

We believe this additional time will allow us further opportunity to collect information through the coming year as we consider an appropriate more permanent approach to direct supervision policy following the PHE for COVID–19. We solicited comment on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we stated that we were interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have regarding this policy.

In the proposed rule, we noted that one potential approach to direct supervision which we could consider for future rulemaking, could be to extend or permanently establish this virtual presence flexibility for services that are valued under the PFS based on the presumption that they are nearly always performed in entirety by auxiliary personnel. Such services would include any service wholly furnished incident to a physician or practitioner's professional service, as well as the Level I office or other outpatient evaluation and management visit for established patients and the Level I Emergency Department visit. Allowing virtual presence for direct supervision of these services may balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals while considering potential quality and program integrity concerns. We solicited comment on this potential approach for CY 2025, as well as any other approaches by which direct supervision could occur virtually that would both protect patient access and safety, as well as quality of care and program integrity concerns following CY 2024.

We received public comments on our proposals to extend the flexibilities for virtual direct supervision. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to continue to define 'immediate availability' to include availability through virtual means, stating that it will benefit healthcare providers while greatly enhancing patient access to quality care, particularly in underserved areas. Many stated that removing overly restrictive supervision requirements will help practices free up personnel to ensure more Americans have timely access to care. A commenter stated that there has been no evidence that this type of direct supervision has caused patient safety or quality concerns, and that virtual supervision makes workflows more efficient by freeing up practitioners' time. A commenter submitted data that they say indicates no clinically meaningful statistical difference in patient outcomes for virtual direct supervision as compared to direct supervision. Some commenters stated that we should extend this flexibility permanently; one such commenter stated that failure to allow supervision via interactive telecommunications could mean that a patient would be unable to receive the service at all, rather than forcing in-person supervision to occur. The commenter stated that both patients and CMS rely on physicians' professional judgment to determine the most appropriate services to deliver; the same principle should apply to how supervision is provided. Another commenter encouraged CMS to consider permanently permitting the use of remote direct supervision for Level 2 diagnostic tests, and that, absent a permanent change, CMS should consider extending current flexibilities through at least 2025. Some commenters stated that the ''immediate availability'' requirement should be defined as including virtual means permanently for Intensive Cardiac Rehabilitation (ICR) and cardiac rehab (CR) services, as well as for pulmonary rehabilitation (PR) stating that evidence from the PHE demonstrated that virtual supervision is safe and effective for the delivery of these services. Many commenters noted the importance of this flexibility in protecting access specifically for ICR, CR, and PR services. One such commenter submitted studies that the commenter says demonstrates the effectiveness and safety of virtual CR and PR services as well as that virtual and hybrid delivery of CR and PR services provided by staff are safe, improve health outcomes and adherence, and address barriers to access. Some commenters stated that this should be permanently established for external counterpulsation (ECP) therapy (HCPCS code G0166). One such commenter stated that as this is a service that is entirely provided by auxiliary personnel that it would be consistent with our suggested approach included in our comment solicitation as discussed above. A commenter submitted information on the clinical benefits of ECP and argued that ECP is underutilized and that the in-person direct supervision requirement presents an access barrier. Some commenters specified that this should be established permanently for mental health and substance use disorder related services. In response to our patient safety concerns, a commenter stated that if CMS were to extend this policy permanently, it should be limited to circumstances where the billing practitioner is supervising clinical staff who are not authorized to bill the Medicare program directly, consistent with MedPAC's recommendations in their June 2019 report. A few commenters reacted to the potential approach we suggested of permanently establishing this virtual presence flexibility for services that are valued under the PFS based on the presumption that they are nearly always performed in entirety by auxiliary personnel. One such comment stated that this approach may prove a conservative place to start or could be attempted through pilot tests to collect more data to inform future decision-making. Another stated that this approach would be overly restrictive and would be contrary to the principles of a successful telehealth model, such as increasing workforce capacity and reducing patient travel.

Response: We appreciate the support of commenters, as well as the comments received in response to our comment solicitation. We look forward to considering this and other information as we consider the most appropriate way to balance patient safety concerns with the interest of supporting access that we expect to address in future rulemaking. We continue to believe that it is appropriate to continue to permit direct supervision via virtual means using audio/video real-time communications technology through the end of CY 2024 given that many telehealth flexibilities adopted to address the PHE for COVID–19 are set to expire under the statute following this time period. We believe that this is the most appropriate way to balance patient safety with access while avoiding confusion for 2024.

Comment: A commenter requested that CMS clarify whether, to meet the direct supervision requirement using real-time audio-visual technology, the physician needs to be constantly present on the real-time audio-visual technology during the entirety of the provision of

an ''incident to'' service by their clinical staff.

Response: As direct supervision as defined at § 410.32 requires the supervising practitioner's immediately available to furnish assistance and direction throughout the performance of the procedure, but not that the supervising practitioner must be present in the room when the procedure is performed, when the supervising practitioner provides direct supervision using real-time audio-visual technology, the supervising practitioner likewise does not need to be virtually present throughout the performance of the procedure, but they need to be immediately available to provide the virtual presence whenever necessary.

After consideration of public comments, we are finalizing as proposed. We will continue to define direct supervision to permit the immediate availability of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024.We will consider addressing this topic in possible future rulemaking.

(1) Teaching Physician Billing for Services Involving Residents in Teaching Settings

In the CY 2021 PFS final rule (85 FR 84577 through 84584), we established a policy that, after the end of the PHE for COVID–19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites that are located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). We made this location distinction consistent with our longstanding interest to increase beneficiary access to Medicare-covered services in rural areas and noted the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing, and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. For a more detailed description of our specific concerns, we referred readers to the CY 2021 PFS final rule (85 FR 84577 through 84584). At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents in order to be paid for the service under the PFS, in locations that were within a MSA. This policy applied to all services, regardless of whether the patient was co-located with the resident or only present virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties expressed concerns regarding the requirement that the teaching physician have a physical presence with the resident when a service is furnished virtually within a MSA (that is, as a Medicare telehealth service). Some interested parties stated that during the PHE for COVID–19, when residents provided telehealth services and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. As stated in section II.D.2.a. of this final rule, we were concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services, and we understood that practitioners gained clinical experience during the PHE for COVID–19, and could identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient, with a virtual presence during the key portion of the virtual service. Given these considerations, we proposed to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the virtual service for which payment is sought, through audio/video real-time communications technology, for all residency training locations through December 31, 2024. The virtual presence policy would continue to require real-time observation (not mere availability) by the teaching physician, and excludes audio-only technology. The documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the virtual service, this includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. This policy does not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians should still use discretion to determine whether it is appropriate to have a virtual presence rather than in person, depending on the services being furnished and the experience of the particular residents involved.

We announced that we were exercising enforcement discretion to allow teaching physicians in all residency training sites, to be present through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving residents. We exercised this enforcement discretion through December 31, 2023, as we considered our virtual presence policies for services involving teaching physicians and residents further through our rulemaking process for CY 2024. For more background we referred readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

We sought comment and information to help us consider how virtual services could be furnished in all residency training locations beyond December 31, 2024, to include what other clinical treatment situations are appropriate to permit the virtual presence of the teaching physician. Specifically, we anticipated considering various types of teaching physician services, when it is appropriate for the teaching physician and resident to be co-located, and how virtual presence could support patient safety for all patients, particularly at-risk patients. We also invited commenters to provide data or other information on how the teaching physician's virtual presence could continue to support patient safety, while meeting the clinical needs for all patients, and ensure burden reduction

without creating risks to patient care or increasing opportunities for fraud.

We received public comments on our proposal to allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually, through December 31, 2024. The following is a summary of the comments we received and our responses.

Comment: Some commenters thanked CMS for exercising enforcement discretion to allow teaching physicians in all residency training sites to be present through audio/video real-time communications technology, for purposes of billing under the PFS, for services they furnish involving residents through 2024.

Response: We appreciate the support from commenters but reiterate that we are only exercising enforcement discretion through December 31, 2023.

Comment: One commenter stated that CMS should not reimburse anesthesiologists that are not providing actual anesthesia care, through billing for remote so-called ''supervision'' services.

Response: As stated in our regulation at § 415.172(a)(1), for surgical, high risk, interventional, endoscopic, or other complex procedures the teaching physician must not only be present for the critical portions of the procedure, but also immediately available to furnish services during the entire procedure in order for PFS payment to be made for the service. Similarly, § 415.178 requires a teaching physician to be present during critical (or key) portions of the procedure and immediately available to furnish anesthesia services during the entire service. We continue to believe the requirements for the presence of the teaching physician during all key or critical portions of the procedure and immediate availability to furnish services during the entire service or procedure is necessary for patient safety given the risks associated with these services.

Comment: One commenter requested clarification on whether the proposal to allow teaching physicians to have a virtual presence, only in clinical instances when the service is furnished virtually, would also include instances where the resident and patient are in one location and the supervising physician is in another. The commenter stated that the resident should be able to ''dial-in'' the supervising physician in these instances.

Response: The proposed policy would continue to permit PFS payment when the teaching physician is present virtually only when the service is furnished virtually. The example we provided in the proposed rule is a 3-way Medicare telehealth visit, with all parties in separate locations. In this situation, the teaching physician and resident would not need to be physically co-located during the telehealth service that is furnished remotely to the patient. The teaching physician would have a virtual presence during the key portion of that Medicare telehealth service for which payment is sought, through audio/video real-time communications technology. In the example provided by the commenter, the service would be furnished with the resident in person at the same location with the patient, and only the teaching physician would be present virtually through the use of real-time audio/video communications technology, and this scenario was not included in the proposal. In the commenter's example, the teaching physician would be required to have a physical presence with the resident, unless the residency training location is outside a MSA. The policy continues to exclude audio-only technology.

Comment: Several commenters requested that CMS consider permanently expanding the list of services that can be furnished under the so-called primary care exception set forth at § 415.174 to include high-value primary care services. These commenters stated that the flexibilities allowed during the PHE for COVID–19, which allowed level 4 and 5 E/M visits to be furnished under the primary care exception benefitted both patients and primary care training programs. The commenters noted that they believe that the absence of high-value services under the primary care exception could negatively impact resident training and patient outcomes in the long term, and provided a list of suggested services to be permanently included under the primary care exception.

Response: The primary care exception permits the teaching physician to bill for certain lower and mid-level complexity physicians' services furnished by residents in certain types of residency training settings even when the teaching physician is not present with the resident during the services as long as certain conditions are met, including that the services are furnished by residents with more than 6 months of training in the approved residency program; and that the teaching physician directs the care of no more than four residents at a time, remains immediately available and has no other responsibilities while directing the care, assumes management responsibility for beneficiaries seen by the residents, ensures that the services furnished are appropriate, and reviews certain elements of the services with each resident during or immediately after each visit. We believe the primary care exception was intended to broaden opportunities for teaching physicians to involve residents in furnishing services under circumstances that preserve teaching physician direction of the care, and promote safe, high quality patient care. Although we temporarily modified the scope of services that could be provided under the primary care exception to address the circumstances of the PHE for COVID–19, we did not propose to broaden the array of services that meet the conditions for PFS payment set forth in our regulations at § 415.174. For a more detailed description of the finalized primary care exception policy, we refer readers to the CY 2021 PFS final rule (85 FR 84585 through 84590).

Comment: Many commenters supported the proposal to allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually, which then permits teaching physicians to have a virtual presence during the key portion of that Medicare telehealth service, through audio/video real-time communications technology, for all residency training locations through December 31, 2024. However, several commenters encouraged CMS to include in-person services to promote access to care and to establish this policy permanently. These commenters stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. In addition, commenters recommend that CMS consider the Accreditation Council for Graduate Medical Education (ACGME) rules that allow teaching physicians to concurrently monitor patient care through appropriate telecommunication technology when the teaching physician and/or patient is not physically present with the resident.

Response: At this time, we are not extending the proposed policy to include in-person services furnished by residents. We may consider other clinical instances that could allow teaching physicians to have a virtual presence in future rulemaking, and will contemplate the comments received to ensure the teaching physician is rendering sufficient personal services to exercise full, personal control of the key portion of the case. We thank commenters for providing information

on certain ACGME rules. We note that the ACGME regulates residency training programs and their rules ensure that there is appropriate teaching physician involvement in care delivery for educational purposes. However, our regulations determine when PFS payment is appropriate when teaching physicians furnish services that involve residents, and the teaching physician has personal oversight and involvement over the management of the portion of the case for which the payment is sought.

After consideration of public comments, we are finalizing the policy as proposed, to allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually. This permits teaching physicians to have a virtual presence during the key portion of the virtual service for which payment is sought, through audio/video real-time communications technology, for all residency training locations through December 31, 2024. As finalized in the CY 2021 PFS final rule (84577 through 84581), the required physical presence of a teaching physician in order to bill under the PFS for their services at a residency training site that is located outside of a MSA, can be met through interactive, audio/video real-time communications technology, and does not include audio-only technology.

b. Clarifications for Remote Monitoring Services

(1) Background and Overview

In recent years, we have established payment for two code families that describe certain remote monitoring services: remote physiologic monitoring (RPM) and remote therapy monitoring (RTM).

Remote Physiologic Monitoring

- 99453 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*);
- 99454 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*);
- 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*); and
- 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)*).

Remote Therapeutic Monitoring

- 98975 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); initial set-up and patient education on use of equipment*);
- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

In our CY 2018 PFS final rule, we summarized feedback from a comment solicitation aimed at informing new payment policies that would allow for separate payment for remote monitoring services (82 FR 53014). In our CY 2019 PFS final rule (83 FR 59574 to 59576), we established valuations and payment policy for the RPM code family. In our CY 2020 PFS final rule (84 FR 62697–8), we explained that the RPM code family describes chronic care RPM services that involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan and the managing of a patient under the treatment plan. (84 FR 62697). In our CY 2020 PFS final rule, we also discussed that remote monitoring codes would be designated as care management services, which means our rules for general supervision would apply (84 FR 62698). In our CY 2023 PFS final rule, in response to comments, we clarified that RTM or RPM services could be billed concurrently with Chronic Care Management (CCM), Transitional Care Management TCM, Principal Care Management (PCM), Chronic Pain Management (CPM), or Behavioral Health Integration (BHI) (86 FR 69528–69539).

We have received many questions from interested parties about billing scenarios and requests for clarifications on the appropriate use of these codes in general. We believe it is important to share with all interested parties a restatement/clarification of certain policies. We refer readers to the CY 2021 PFS final rule (85 FR 84542 to 84546) for further discussion and explanation of the basis for interim policies that expired on the last day of the PHE for COVID–19.

(2) New vs. Established Patient Requirements

In the CY 2021 PFS final rule (85 FR 84542–6), we established that, when the PHE for COVID–19 ends, we again will require that RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during PHE are considered established patients for purposes of the new patient requirements that are effective after the last day of the PHE for COVID–19.

(3) Data Collection Requirements

We have received various comments and inquiries about our temporary exception to minimum data collection for remote monitoring. As discussed in our CY 2021 final rule, we are not extending beyond the end of the PHE the interim policy to permit billing for remote monitoring codes, which require data collection for at least 16 days in a 30-day period, when less than 16 of days data are collected within a given 30-day period. (85 FR 84542 through 84546). As of the end of the PHE, the 16-day monitoring requirement was reinstated. Monitoring must occur over at least 16 days of a 30-day period. We proposed to clarify that the data collection minimums apply to existing RPM and RTM code families for CY 2024.

The following remote monitoring codes currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions:

- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

We remind readers that our discussion in the CY 2021 PFS final rule addresses the interim policy on data collection minimums, and provides notice and the rationale for the data collection policy that is in effect now that the PHE for COVID–19 has ended. Remotely monitored monthly services should be reported only once during a 30-day period—and only when reasonable and necessary. As a clarification for either RPM or RTM, only one practitioner can bill CPT codes 99453 and 99454, or CPT codes 98976, 98977, 98980, and 98981, during a 30-day period, and only when at least 16 days of data have been collected on at least one medical device as defined in section 201(h) of the FFDCA.

We reiterate our analysis described in the CY 2021 PFS final rule, in which we explained that CPT code descriptor language suggests that, even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected (85 FR 84545). We refer readers to our CY 2021 PFS final rule (85 FR 84545) for additional background.

(4) Use of RPM, RTM, in Conjunction With Other Services

Practitioners may bill RPM or RTM, but not both RPM and RTM, concurrently with the following care management services: CCM/TCM/BHI, PCM, and CPM. These various codes, which describe other care management services, may be billed with RPM or RTM, for the same patient, if the time or effort is not counted twice. As specified in the CY 2023 PFS final rule, if all requirements to report each service are met, without time or effort being counted more than once, RPM or RTM (not both RPM and RTM) may be billed in conjunction with any one of CCM, TCM, BHI, PCM, or CPM codes. According to the 2023 CPT Codebook (pg. 849), CPT code 98980 (*RTM treatment management*) cannot be reported in conjunction with CPT codes 99457/99458 (*RPM treatment management*). Our intention is to allow the maximum flexibility for a given practitioner to select the appropriate mix of care management services, without creating significant issues of possible fraud, waste, and abuse associated with overbilling of these services. We continue to gain experience with each family of remote monitoring codes, and request feedback from commenters that would provide additional context that could inform us as we continue to develop and clarify our payment policies for these services.

We proposed to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services. In instances where the same patient receives RPM and RTM services, there may be multiple devices used for monitoring, and in these cases, we will to apply our existing rules, which we finalized when establishing the RPM code family, meaning that the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary (85 FR 84544 through 84545).

(5) Other Clarifications for Appropriate Billing

We have received inquiries from interested parties during public forums regarding use of remote monitoring during global periods for surgery. In the proposed rule, we clarified that, in circumstances where an individual beneficiary may receive a procedure or surgery, and related services, which are covered under a payment for a global period, RPM services or RTM services (but not both RPM and RTM services concurrently) may be furnished separately to the beneficiary, and the practitioner would receive payment for the RTM or RPM services, separate from the global service payment, so long as other requirements for the global service and any other service during the global period are met. For an individual beneficiary who is currently receiving services during a global period, a practitioner may furnish RPM or RTM services (but not both RPM or RTM services) to the individual beneficiary, and the practitioner will receive separate payment, so long as the remote monitoring services are unrelated to the diagnosis for which the global procedure is performed, and as long as the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure—meaning that the remote monitoring services address an underlying condition that is not linked to the global procedure or service.

We solicited comments on the proposed clarifications, as well as issued a request for general feedback from the public that may be useful in further development of our payment policies for remote monitoring services that are separately payable under the current PFS. The following is a summary of the comments we received and our responses.

Comment: Commenters requested changes be made to RPM and RTM coding and service requirements and requested that interim policies that expired on the last day of the PHE for COVID–19 become permanent.

Response: We thank commenters for the general feedback that may be useful in further development of our payment policies for remote monitoring services that are separately payable under the current PFS. We refer readers to the CY 2021 PFS final rule (85 FR 84542 through 84546) for further discussion and explanation of the basis for interim policies that expired on the last day of the PHE for COVID–19.

Comment: Several commenters requested clarification on patient requirements for remote therapeutic monitoring. One commenter requested clarification on new patients receiving RPM from the end of the PHE forward.

Response: We are offering additional clarification regarding the new patient

requirement and that RPM, not RTM, services require an established patient relationship after the end of the PHE. While we have not specified in rulemaking whether the RTM services require an established patient relationship, we believe that similar to RPM, such services would be furnished to a patient after a treatment plan had been established. Presumably, a billing practitioner would establish such treatment plan after some initial interaction with the patient. We will work to clarify this policy further in future rulemaking. We hope to continue dialogue with interested parties who may have information that could inform our rulemaking. Patients who received initial remote monitoring services during the PHE are considered established patients for purposes of the new patient requirements that are effective after the last day of the PHE for COVID–19. Per our existing policy, any patients receiving RPM services from the end of the PHE forward will need to be established patients before beginning RPM services.

Comment: Many commenters inquired about whether RPM or RTM used in physical and occupational therapy services were excluded from the global period rules for surgery.

Response: We would like to clarify that the policy that prohibits RPM or RTM services being furnished during the global period only applies to billing practitioners who are receiving the global service payment. Practitioners, such as therapists, who are not receiving a global service payment because they did not furnish the global procedure, would be permitted to furnish RPM or RTM services during a global period. After consideration of public comments, we are finalizing that providing RTM or RPM services during the global period is permitted if the practitioner is not receiving global service payment because they did not furnish the global procedure.

We note that in the CY 2024 PFS proposed rule, we inadvertently listed all of the RTM codes (88 FR 53204) in our discussion of these services and had made a general statement about the applicability of the 16-day data collection requirement. We would like to offer clarification that the 16 day data collection requirement does not apply to CPT codes 99457, 99458, 98980, and 98981. These CPT codes are treatment management codes that account for time spent in a calendar month and do not require 16 days of data collection in a 30-day period.

c. Telephone Evaluation and Management Services

In the March 31st COVID–19 IFC (85 FR 19264 through 19265), we finalized separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. CPT codes 99441 through 99443 are on the Medicare Telehealth Services List and will remain actively priced through 2024. CPT codes 98966 through 98968; however, describe telephone assessment and management services provided by a qualified non-physician healthcare professional, and they were added on a subregulatory basis during the PHE. We proposed to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024 to align with telehealth-related flexibilities that were extended via the CAA, 2023, specifically section 4113(e) of the CAA, 2023, which permits the provision of telehealth services through audio-only telecommunications through the end of 2024.

We received comments on our proposals to keep active payment status for CPT codes 98966 through 98968 for CY 2024 to align with policy extensions under the CAA, 2023. The following is a summary of the comments received and our responses.

Comment: Commenters were supportive of our proposal to continue to pay for physician and non-physician telephone services through December 31, 2024, and to continue to assign active payment status to CPT codes 99441 through 99443 as well as to CPT codes 98966 through 98968, which they stated supports payment for audio-only visits. The commenters stated that these services are a critical component of how care is provided to patients and are particularly valuable in connecting with patients living in rural areas where regular internet connection and/or cellular reception may be entirely unavailable or unreliable.

Response: In response to comments, we are finalizing our proposal to continue active payment status for CPT codes 98966 through 98968. These services will be available through the end of CY 2024.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. We proposed to update the telehealth originating site facility fee for telehealth services by the expected increase in the MEI of 4.5 percent for CY 2024. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the final rule. Therefore, the final MEI increase for CY 2024 is 4.6 percent and is based on the most recent historical percentage increase of the 2017-based MEI reflecting historical data through for the second quarter of 2023.

Therefore, for CY 2024, the final payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $29.96. Table 12 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period. We did not receive any comments on this proposal and are finalizing as proposed.

TABLE 12: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64
2024*	4.6	$ 29.96

*Reflects the most recent estimate of the CY 2024 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2023.

4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

a. Background on Outpatient Therapy Services, Diabetes Self-Management Training and Medical Nutrition Therapy

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under part A but have exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A), and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A ''certified provider'' of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled ''Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements.'' In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2000 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279).

During the PHE for COVID–19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to

beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority to expand the range of practitioners that can serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and § 410.78 (b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists in private practice, as well as for outpatient therapy services, DSMT, and MNT to be furnished via Medicare telehealth to beneficiaries in urban, as well as rural, areas, including to beneficiaries located in their homes.

When therapists (PTs, OTs and SLPs) were added as distant site telehealth practitioners using waiver authority during the PHE for COVID–19, CMS generally took the position for services furnished in HOPDs that waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while maintaining that waiver authority was needed to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those used for Medicare telehealth services. For further background, we refer readers to *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The CAA, 2023 extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID–19 under emergency waiver authorities, including adding physical and occupational therapists and speech-language pathologists as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID–19 along with the HWW waivers. However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we are considering whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

b. Proposal To Extend Billing Flexibilities for Certain Remotely Furnished Services Through the End of CY 2024 and Comment Solicitation

While we consider how we might address this ambiguity in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we proposed to continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID–19 through the end of CY 2024. We sought comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We sought comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking.

For DSMT specifically, the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under section 1834(m) of the Act; but we also understand that DSMT may be provided by other types of staff. Accordingly, we noted in sub-regulatory guidance that we are exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

As we review our telehealth policies following the end of the PHE for COVID–19, and consider care delivery and beneficiary access concerns raised by practitioners and beneficiary advocates, we broadly considered billing and payment for telehealth services in institutional settings, including when these services are furnished by practitioners who have reassigned their rights to bill under and receive payment from the Medicare program (billing rights) to an institution. We acknowledge that one such setting where this billing arrangement exists includes Critical Access Hospitals (CAHs), where a practitioner has reassigned their billing rights to the CAH, and CMS makes payment for the practitioner's services under an optional payment method, referred to as CAH method II (Pub. 100–04, Chapter 4, Section 250.2). We note that in situations when a practitioner is furnishing a telehealth service and has reassigned their billing rights to a CAH under Method II, CMS makes payment for the telehealth service at the same rate generally paid for other in-person services (100 percent of the PFS payment amount) rather than the payment amount established under the optional method as discussed in Pub. 100–04, Chapter 4, Section 250.2. We are interested in and solicited comment on how telehealth services furnished under CAH method II arrangements are furnished, and whether they would be most accurately characterized in the context of section 1834(m) of the Act or services of the CAH under Method II.

Comment: Many commenters supported our proposal to continue to allow institutional providers to provide remote outpatient PT, OT, SLP, DSMT, and MNT services in patients' homes through CY 2024. Some of these commenters told us these services are invaluable for their patients who cannot attend on-site services due to, for example, a mobility impairment, cancer-related fatigue, they reside in rural and underserved areas that are less accessible and lack caregiver transport to the healthcare facility.

Response: We appreciate the commenters support and feedback.

Comment: Several commenters supported our proposal for outpatient physical therapy, occupational therapy, and speech-language pathology services being furnished by other institutional providers of Part B services—including comprehensive outpatient rehabilitation facilities, rehabilitation agencies, skilled nursing facilities, outpatient hospitals, critical access hospitals (CAHs) and home health agencies (HHAs) (for individuals not under a HH plan of care)—and their being able to continue to bill for these services when furnished remotely through CY 2024 in the same manner they have during the COVID–19 PHE and CY 2023. Several of these commenters requested that CMS clarify how to document the use of telehealth on the institutional claim form (UB–04), since it lacks a POS field. These commenters requested that CMS permit the use of the 95 modifier and instruct contractors to accept modifier 95 for telehealth on the institutional claim. Several commenters requested that if the 95 modifier could not be used that it would cause unsustainable organizational realignment (that is, different workflows, EHR modules, billing processes, accounting systems, etc.) to migrate hospital-based therapists to CMS–1500 claims forms.

Response: We clarify that it is not necessary to migrate claims for PT, OT, or SLP services provided in institutional settings, including the hospital, to the 1500 claim form. This is because of statutory provisions that require (a) therapists in private practice to furnish services only in their offices and in an individual's home (section 1861(p) of the Act for outpatient PT services (and through sections 1861(g) and 1861(ll)(2) of the Act for outpatient OT and SLP services, respectively)), (b) institutional providers to bill for them (sections 1833(a)(8) and (9) of the Act), and (c) CMS to make payment for them at PFS rates (section 1834(k)(3) of the Act). As we will finalize below, CMS will instruct institutional providers to use the 95 modifier on the 1450 claim form (UB–04) for these services.

Comment: A number of commenters responded to our request for information about their current practice of billing for these services, such as how much they continue to provide remotely. One commenter stated that although there has been a significant reduction in the number of services furnished as telehealth, 10–20 percent of these services are currently provided via telehealth by their hospital. The same commenter stated that these telehealth therapies allow patients throughout the State increased access to care. Another commenter stated they are located in a health professional shortage area where people oftentimes drive for hours to reach their center for in-person treatment—they currently provide services to between 500–700 patients per day via telehealth. Another commenter stated that their post-acute telehealth program (launched in 2018) in response to CMS's Comprehensive Care for Joint Replacement (CJR) program is on pace for more than 5,500 telehealth PT visits in 2023, slightly less than those in 2022. This commenter also transitioned some of their in-person visits to telehealth during the COVID–19 PHE declining each year after 2020 when it was ~35 percent of telehealth services decreased to 9 percent, 5 percent, and 4 percent of total visits in 2021 through 2023, respectively. Many commenters, while not specifying the amount of outpatient therapy, DSMT, and/or MNT services they furnish, remarked that patients would lose an invaluable resource should their ability to bill for these services as telehealth be discontinued. Additionally, some commenters cited studies to show the efficacy of telehealth services.

Response: We appreciate the commenters feedback.

Comment: Many commenters questioned whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other authorities that might be relevant for us to consider in future rulemaking. Some commenters requested that CMS make these flexibilities permanent and urged CMS to work with Congress to gain the statutory authority needed for the institutional settings to provide these important services via telehealth. Several commenters agreed that the telehealth/virtual outpatient therapy, DSMT and MNT services furnished by staff in outpatient hospitals and other facilities appropriately fall within the scope of Medicare telehealth at section 1834(m) of the Act. We also heard from several commenters that suggested we create new remote G-codes for all these services to be billed through the OPPS starting January 1, 2025.

Response: We thank the many commenters for their feedback.

Comment: Some commenters requested that CMS provide additional clarity in the final rule on how institutional providers should bill for these services in CY 2024, including the specific use of modifiers. Several of these commenters questioned if these instructions would be different from the CMS subregulatory policy found in the online instruction given for CY 2023, which did not include the use of a modifier. The commenters stated that the instruction essentially states: ''Through the end of CY2023, hospital and other providers of PT, OT, SLP, DSMT, and MNT services that remain on the telehealth list, can continue to bill for these services when furnished remotely in the same way they have been during the PHE, except that beneficiaries' homes will no longer need to be registered as provider-based departments of the hospital to allow for hospitals to bill for these services.''

Response: The commenters are correct that our billing policy for CY 2024 will reflect the online billing policy for CY 2023 that is found at: *https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf*. However, with respect to the use of modifiers, we are clarifying that for services furnished beginning in CY 2024 that we require the use of the 95 modifier to be applied to claims from outpatient hospitals, as soon as hospitals can update their systems—in addition to the continued use of the 95 modifier for outpatient therapy services discussed above for all other institutional providers furnishing outpatient therapy services via telehealth under Part B. This policy will facilitate our ability to track all services in the same manner. Although we did not receive comments specifically from CAHs electing Method II, these CAHs will continue their longstanding practice of using the GT/GQ modifier, as appropriate.

In addition, we received several public comments that were outside the scope of the proposals made in the CY 2024 PFS proposed rule. Consequently, we did not summarize or respond to those comments.

After reviewing the comments, we are finalizing our proposal, with one amendment for modifiers, to allow outpatient hospitals and other providers of physical therapy, occupational therapy, and speech-language pathology, DSMT and MNT services that remain on the Medicare Telehealth Services List for CY 2024 to bill for these services when furnished remotely in the same way they have been during the COVID–19 PHE and through the end of CY 2023, including that for hospitals, beneficiaries' homes will no longer need to be registered as provider-based departments of the hospital to allow for hospitals to bill for these services. Additionally, our final subregulatory policy requires all institutional providers that bill for therapy, DSMT, and/or MNT services, with the exception of Method II CAHs, to apply the 95 modifier on each applicable line if these services are furnished via telecommunication technology once

hospitals that need to do so can update their systems. For CAHs opting for payment under Method II, these CAHs will continue their long-standing practice of using the GT/GQ modifier, as appropriate, when billing for their services furnished via telehealth.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of the proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component

as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar

codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2024 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with CMS' reference to older work time sources and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times and note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. Commenters recommended that CMS embrace the clinical input from practicing physicians when valid surveys were conducted and provide a clinical rationale when proposing crosswalks for valuation of services.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

We recognize that it would not be appropriate to develop work RVUs solely based on time, given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2024 PFS final rule, CPT codes 76987 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report*), 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and 99497 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate*) all share the same total work time of 40 minutes. However, these codes had very different proposed work RVUs of 1.62, 1.00 and 1.50, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key references or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information).

With regard to the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters raised the issue of the refinement panel which was last reformed in CY 2016. Commenters stated that the refinement panel was not obsolete and was not mutually exclusive with the change to include all proposed valuations in each year's proposed rule. Commenters stated that for 2 decades, the refinement panel process was considered by interested parties to be an appeals process and its elimination discontinued CMS' reliance on outside interested parties to provide accountability through a transparent appeals process. Commenters requested that CMS consider these issues and create an objective, transparent and consistently applied formal appeals process that would be open to any commenting organization.

Response: We did not propose any changes to the refinement panel for CY 2024. As we stated in the CY 2016 PFS final rule (80 FR 70917 and 70918), the refinement panel was established to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in balancing the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. When developing the CY 2016 proposed rule, and continuing to the present, we did not believe that the refinement panel had generally served as the kind of ''appeals'' or reconsideration process that some interested parties envisioned in their comments. We also believe that the refinement panel was not achieving its intended purpose. Rather than providing us with additional information, balanced across specialty interests, to assist us in establishing work RVUs, the refinement panel process generally served to rehash the issues raised and information already discussed at the RUC meetings and considered by CMS. In contrast to the prior process of establishing interim final values and using a refinement panel process that generally was not observed by members of the public, we continue to believe that the current process of proposing the majority of code values in a proposed rule, giving the public the opportunity to comment on those proposed values, and then finalizing those values in a final rule offers greater transparency and accountability.

We also note that we did not finalize our proposal to eliminate the refinement panel completely in CY 2016. We retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. We also remind interested parties that we have established an annual process for the public nomination of potentially misvalued codes. This process, described in the CY 2012 PFS final rule (76 FR 73058), provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. (83 FR 59515) We note that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 14 contains a list of codes and descriptors for which we are finalizing work RVUs for CY 2024; this includes all codes for which we received RUC recommendations by February 10, 2023. The proposed work RVUs, work time and other payment information for all CY 2024 payable codes are available on the CMS website under downloads for the CY 2024 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's

recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 15 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this final rule, we also note that many of the refinements listed in Table 14 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2024 are displayed in the CY 2024 direct PE input files, available on the CMS website under the downloads for the CY 2024 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2024 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input

database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2024 we received invoices for several new supply and equipment items. Tables 17 and 18 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 17 and 18 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We noted that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2024 are available on the CMS website under downloads for the CY 2024 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2024, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined previously in this final rule for purposes of this cap. Beginning for CY 2024, we proposed to include the following services on the list of codes to which the OPPS cap applies: CPT codes 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*), 76984 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 76987 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer*), 76988 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 76989 (*Intraoperative epicardial cardiac (e.g.,)*

echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only), 93584 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a* second *contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*), 93585 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure)*), 93586 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)*), 93587 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)*), and 93588 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition to code for primary procedure)*). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap. We note that we previously proposed to add CPT code 76883 to the list of codes to which the OPPS cap applies in the CY 2023 PFS proposed rule, but we did not finalize its addition, noting that it was not within the statutory scope of services to which the OPPS cap applies, as it could not be split into professional and technical components at that time (87 FR 69475). Since that time, we have reinstated CPT code 76883's PC/TC split based on feedback from billing practitioners, therefore we proposed to add it to the OPPS cap list for CY 2024.

Comment: Some commenters requested that CMS remove CPT code 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*) from the OPPS cap list because it does not include an associated PC or physician interpretation and it is primarily utilized in the physician office setting. Commenters also noted that this service falls outside the scope of the definition of ''imaging services'' under the DRA. One commenter stated that, while it may be appropriate for the technical components of CPT codes 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral*) and 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral*) to be on the OPPS Cap List, the same logic does not apply to CPT code 92229 despite all three codes being in the same family of codes and representing the same imaging service, only differentiated by the modality of review and interpretation.

Response: We appreciate the commenters' feedback regarding CPT code 92229. We note that CPT codes 92227, 92228, and 92229 have been subject to the OPPS cap since their addition to the OPPS cap list for CY 2021 and we did not make any proposals related to CPT code 92229 for CY 2024, therefore these comments are considered to be out of scope of the proposed rule. We will consider the commenters' suggestions for future rulemaking.

We did not receive public comments on the proposed additions to the OPPS cap list for CY 2024. We are finalizing the addition of the services listed above to the list of codes to which the OPPS cap applies, as proposed.

4. Valuation of Specific Codes for CY 2024

(1) Dorsal Sacroiliac Joint Arthrodesis (CPT Code 27278)

In September 2022, CPT deleted category III CPT code 0775T (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]*) and created a new Category I CPT code 27278 (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]), without placement of transfixation device*), which was surveyed for the January 2023 RUC meeting. CPT codes 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) and 27280 (*Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed*) were added as family codes to the level of interest (LOI) form for the RUC to review. However, the specialty societies indicated that they do not consider CPT codes 27279 and 27280 as part of the same code family and requested that they not be re-reviewed by the RUC for the January 2023 meeting. The RUC agreed with the specialty societies and did not review these codes at the January 2023 meeting. The RUC stated in their recommendations for 27278 that the clinical nature of CPT codes 27279 and 27280 is extensively disparate from 27278 for both the surgical approach and the specialties that perform the procedures. Additionally, they stated that no substantive changes were made to CPT codes 27279 and 27280 at the September 2022 CPT panel meeting and 27279 has been reviewed by the RUC as recently as 2018.

We proposed the RUC-recommended work RVU of 7.86 for CPT code 27278. We also proposed the RUC-recommended direct PE inputs without refinement.

Comment: Several commenters supported CMS' proposed valuation of 7.86 work RVUs for CPT code 27278. They also supported CMS' proposed RUC-recommended direct PE inputs for the non-facility site of service as they noted that current study data has sufficiently demonstrated safety and efficacy in the non-facility setting. However, several commenters expressed concern that the non-facility site of service is not appropriate for this procedure. They stated that the procedure is new and without a pre-established safety record.

Response: We thank commenters for their support of our proposed work RVU and non-facility direct PE inputs. However, we also acknowledge other commenters' concerns regarding CPT code 27278 being performed in the non-facility setting. At this time, we agree with the RUC's recommended valuations, including the non-facility direct PE inputs. However, given consideration of all comments received, we believe that CPT code 27278 could benefit from additional future review by the RUC, as a service that includes a new technology supply item (dorsal SI joint arthrodesis implant), as well as considerations for the site of service. If we were to receive new RUC recommendations at a future date, we would consider that information and any discussions with interested parties for rulemaking.

Comment: Some commenters expressed concerns about the cost of the direct PE supply item, dorsal SI joint arthrodesis implant, valued at $11,500.

They stated that the high cost of this supply will negatively impact PE RVUs and cause undesirable effects on the PFS budget neutrality as a service with one of the highest costs on the fee schedule. Commenters were also concerned with the potential overutilization of the service in the non-facility setting.

Response: The payment for the dorsal SI joint arthrodesis implant is based on invoices received from the manufacturer and a formal review to determine if each direct PE input is typical and medically necessary, which is part of our standard code review process. While we acknowledge that the supply is a high-cost item, we do not believe it is appropriate to undervalue a service to minimize impacts on budget neutrality. We also remind commenters that the utilization for this new CPT category I code is crosswalked from CPT code 0775T. As such, we do not anticipate a large impact on budget neutrality and will continue to monitor utilization as part of our standard ratesetting process.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 7.86 and direct PE inputs as proposed for CPT code 27278.

(2) Vertebral Body Tethering (CPT Codes 22836, 22837, and 22838)

At the September 2022 CPT Panel meeting, two new Category I CPT codes, 22836 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments)* and 22837 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments)* were established for thoracic tethering. In addition, another new Category I CPT code, 22838 (*Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed*) was established for tether revision, replacement or removal. This code family was then surveyed for the January 2023 RUC meeting.

We proposed the RUC-recommended work RVUs of 32.00 for CPT code 22836, 35.50 for CPT code 22837, and 36.00 for CPT code 22838. We also proposed the RUC-recommended direct PE inputs without refinement.

Comment: We received comments in support of the proposed work RVU and direct PE inputs for this code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing our work RVU and direct PE inputs for the codes in the Vertebral Body Tethering family as proposed.

(3) Total Disc Arthroplasty (CPT Codes 22857 and 22860)

In September 2021, the CPT Editorial Panel created CPT Category I code 22860 to describe *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)* and replace CPT Category III code 0163T (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)*), which prompted CPT codes 22860 and 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar*) to be surveyed for the January 2022 RUC meeting. At the January 2022 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for both CPT codes 22857 and 22860 were erroneous and that the codes should be resurveyed for the April 2022 RUC meeting. Therefore, we proposed and finalized to maintain the RUC-recommended work RVU of 27.13 for CPT code 22857 and contractor pricing for CPT code 22860 for CY 2023.

For CY 2024, we proposed the April 2022 RUC-recommended work RVU of 27.13 for CPT code 22857, which represents no change from the current work RVU. For CPT code 22860, we disagreed with the April 2022 RUC-recommended survey median work RVU of 7.50 and proposed the survey (with experience) 25th percentile work RVU of 6.88. We noted that, of the 46 ZZZ-codes with an intraservice time of 60 minutes, only 4 have a work RVU higher than the RUC-recommended 7.50.

We noted that our proposed work RVU of 6.88 will maintain relativity with CPT codes 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) (work RVU = 6.50, 45 minutes intra-service and 50 minutes total time), which is an anterior approach spine procedure that requires less time, and CPT code 22208 (*Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)*) (work RVU = 9.66, 120 minutes intra-service and 135 minutes total time). As the RUC mentioned in their recommendations, these codes appropriately bracket CPT code 22860 and demonstrate relativity among similar surgical spine add-on codes. The RUC noted that their recommended work RVU of 7.50 reflects the increased intensity of spine procedures performed from an anterior approach, but we note that CPT code 22226 (*Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)*), which represents an anterior approach, and CPT code 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)*), which represents a posterior or posterolateral approach, are both valued at 6.03 work RVUs and have identical IWPUTs of 0.1005. CPT codes 22216 and 22226 are ZZZ codes and have identical times as CPT code 22860, and therefore, we believe the proposed survey (with experience) 25th percentile work RVU of 6.88 for CPT code 22860 is more appropriate than the RUC recommended work RVU.

We proposed the RUC-recommended direct PE inputs for both codes without refinement.

Comment: Some commenters disagreed with the proposed work RVU of 6.88 for CPT code 22860 and encouraged CMS to finalize the RUC-recommended work RVU of 7.50. Some commenters reiterated that CPT codes 22552 and 22208 appropriately bracket CPT code 22860, with work RVUs of 6.50 and 9.66, respectively. Some commenters also stated that the exposure of the second interspace (represented by CPT code 22860) is technically more difficult than the initial interspace (represented by CPT code 22857) and more intense compared to an osteotomy of the spine (represented by CPT codes 22208 and 22226). Commenters generally disagreed with the comparison of CPT code 22860 to CPT codes 22216 and 22226 because they were valued over 25 years ago and had limited survey responses.

Response: We agree with the commenters that the intensity of the second interspace exposure (CPT code 22860) is greater than the identically timed CPT code 22226, which represents an anterior approach osteotomy of the spine, and the technical difficulty of the first interspace exposure (CPT code 22857). The proposed work RVU of 6.88 for CPT

code 22860 accurately values the surgeon's 60 minutes of intraservice time more than the identical 60 minutes of intraservice time for CPT code 22226 and yields a higher intensity (IWPUT) of 0.115 for CPT code 22860 for the exposure of the second interspace compared to exposure of the first interspace in CPT code 22857 of 0.092. Commenters were supportive of bracketing a work RVU of 7.50 with CPT codes 22552 and 22208, with work RVUs of 6.50 and 9.66, respectively, but we note that the proposed work RVU of 6.88 is also appropriately bracketed by these codes as well.

After consideration of the public comments, we are finalizing a work RVU of 27.13 for CPT code 22857 and a work RVU of 6.88 for CPT code 22860, as proposed. We are also finalizing the direct PE inputs as proposed.

(4) Phrenic Nerve Stimulation System (CPT Codes 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, and 93153)

In September 2022, the CPT Editorial Panel created eight new Category I CPT codes to describe the insertion, repositioning, removal, and removal and replacement of a phrenic nerve stimulator system, as well as adding four additional new Category I codes to describe activation, interrogation, and programming of a phrenic nerve stimulator system. These new codes will replace thirteen Category III codes, 0424T–0436T. The twelve new Category I codes were surveyed and then reviewed for the January 2023 RUC meeting.

We proposed the RUC-recommended work RVU for all twelve codes in the Phrenic Nerve Stimulation System family. We proposed a work RVU of 9.50 for CPT code 33276 (*Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed*), a work RVU of 5.43 for CPT code 33277 (*Insertion of phrenic nerve stimulator transvenous sensing lead*), a work RVU of 9.55 for CPT code 33278 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)*), a work RVU of 5.42 for CPT code 33279 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only),* a work RVU of 3.04 for CPT code 33280 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only*), a work RVU of 6.00 for CPT code 33281 (*Repositioning of phrenic nerve stimulator transvenous lead(s)*), a work RVU of 6.05 for CPT code 33287 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator*), a work RVU of 8.51 for CPT code 33288 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; transvenous stimulation or sensing lead*), a work RVU of 0.85 for CPT code 93150(*Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming*), a work RVU of 0.80 for CPT code 9X046 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*X047 (), and a work RVU of 0.43 for CPT code 93153 (*Interrogation, without programming of implanted phrenic nerve stimulator system*).

We proposed to refine the CA039 Post-operative visits (total time) for CPT code 33287 from 36 minutes to 53 minutes to reflect the fact that this code has a Level 4 office visit and not a Level 3 office visit included in its global period; we believe that this was an unintended technical error in the RUC recommendation. We also proposed to refine the equipment time for the exam table (EF023) equipment from 36 minutes to 53 minutes for CPT code 33287 to conform to this change in clinical labor time. For all other codes, we proposed the direct PE inputs as recommended by the RUC without refinement.

Comment: Several commenters stated that they supported the CMS proposal of the RUC's recommended work RVUs for all twelve codes in the family. Several commenters also stated that they agreed with the correction of a clerical error in the CA039 Post-operative visits (total time) for CPT code 33287 and otherwise supported the CMS proposal of the RUC's recommended direct PE inputs.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the code family as proposed.

(5) Posterior Nasal Nerve Ablation (CPT Codes 30117, 30118, 31242, and 31243)

In September 2022, the CPT Editorial Panel created two new endoscopy codes for ablation of the posterior nasal nerve: CPT code 31242 (*Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve*), and CPT code 31243 (*Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve*). In preparation for the January 2023 RUC meeting, both new posterior nasal nerve codes, 31242 and 31243, as well as family CPT codes 30117 and 30118, were surveyed. For CY 2024, the RUC recommended a work RVU of 3.91 for CPT code 30117, a work RVU of 9.55 for CPT code 30118, and a work RVU of 2.70 for both CPT codes 31242 and 31243.

We proposed the RUC-recommended work RVU of 3.91 for CPT code 30117. We proposed to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30117. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We proposed to remove this clinical labor as it would be duplicative with the communications already taking place under the CA036 activity code. We proposed to delete supply item SB027 (*gown, staff, impervious*) because supply items SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the direct PE inputs for CPT code 30117.

We disagreed with the RUC-recommended work RVU of 9.55 for CPT code 30118 and proposed a work RVU of 7.75, based on a direct crosswalk from CPT code 28298 (*Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method*) which has the same 60 minutes of intra-service time and similar total time as CPT code 30118. We believe the work RVU should be lower than the RUC recommendation of 9.55 to reflect the decrease in intra-service time from 105 minutes to 60 minutes, and the decrease in total time from 288 minutes to 211 minutes. In the case of CPT code 30118, the intra-service work time is decreasing by 43 percent and the total work time is decreasing by 27 percent but the RUC-recommended work RVU is only decreasing by 4 percent. Although we do not imply that the decrease in time

as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in the surveyed work time should be reflected in commensurate decreases to work RVUs.

We also noted that at the RUC-recommended work RVU of 9.55, the intensity of CPT code 30118 would be increasing by more than 50 percent. We disagreed that there would be such a significant increase in the intensity for the procedure, as it is transitioning from inpatient to outpatient status which suggests that the intensity has remained the same or decreased over time. We also disagreed that this would be the case since the intensity for CPT code 30117 is decreasing at the RUC-recommended work RVU of 3.91. Therefore, we also proposed a work RVU of 7.75 because it maintains the current intensity of CPT code 30118 instead of resulting in an increase in intensity. The work RVU of 7.75 is supported by the reference CPT codes we compared to CPT code 30118 with the same 60 minutes of intra-service time and similar total time as CPT code 30118; reference CPT code 11970 (*Replacement of tissue expander with permanent implant*) has a work RVU of 7.49, and reference CPT code 19325 (*Breast augmentation with implant*) has a work RVU of 8.12. We believe the RVU of 7.75 is a more appropriate value overall than 9.55 when compared to the range of codes with the same intra-service time and similar total time.

We proposed to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30118. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We proposed to remove this clinical labor from CPT code 30118 as it would be duplicative with the communications already taking place under the CA036 activity code.

We proposed the RUC-recommended work RVU of 2.70 for CPT codes 31242 and 31243. Both CPT codes 31242 and 31243 are endoscopic procedures; therefore, we proposed CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) as the endoscopic base code for both of these codes because the description of these procedures includes what is described for CPT code 31231, with the additional component of the posterior nasal nerve ablation. Both of these procedures are performed with an endoscope. CPT codes 31242 and 31243 are not add-on codes, and both have a 0-day global period. The endoscopic base code that we are assigning to CPT codes 31242 and 31243 is used in a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

We proposed to refine the RUC-recommended direct PE inputs for both CPT codes 31242 and 31243. For CPT code 31242, we are refining the equipment time for the ES031 equipment (*scope video system (monitor, processor, digital capture, cart, printer, LED light)*) from 39 minutes to 32 minutes. The RUC used the CA025 (*clean scope*) time of 10 minutes instead of the CA024 (*clean room/equipment by clinical staff*) time of 3 minutes in the Scope Systems formula, when the time for CA024 is the standard; we believe that this was an unintended technical error in the RUC recommendation. We are similarly refining the equipment time for ES031 from 39 minutes to 34 minutes for CPT code 31243.

For CPT code 31243, we are refining the equipment time for the ES040 equipment (*PROXY endoscope, rigid, sinoscopy (0 degrees)*) from 39 minutes to 41 minutes because the RUC used 18 minutes of intra-service time for CA018 (*Assist physician or other qualified healthcare professional—directly related to physician work time (100%)*) instead of 20 minutes in the standard Scope formula. Also, for both CPT codes 31242 and 31243, we proposed to delete supply item SB027 (*gown, staff, impervious*) because SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the PE inputs for CPT codes 31242 and 31243.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported CMS' proposal of the RUC-recommended work RVUs for CPT codes 30117, 31242, and 31243.

Response: We thank the commenters for their support, and we are finalizing the RUC-recommended work RVU of 3.91 for CPT code 30117, and the work RVU of 2.70 for CPT codes 31242 and 31243, as proposed.

Comment: For CPT code 30118, we received a few comments that disagreed with CMS' proposed work RVU of 7.75. The commenters stated that the proposed work RVU of 7.75 fails to maintain relativity within the code family of CPT codes 30117, 30118, 31242 and 31243, and it does not account for the higher clinical complexity and intraoperative intensity for CPT code 30118. Commenters stated that the intra-service time required for CPT code 30118 is twice as long as CPT code 30117, which is attributable to the difficulty of this procedure. One commenter stated that the intensity (IWPUT) for CPT code 30118 is 0.079, which is more than four times the typical intensity of work compared to the IWPUT of 0.018 for CPT code 30117. Commenters stated that the proposed CMS crosswalk of CPT code 28298 was completely inappropriate in terms of intensity, and the skill needed to perform CPT code 30118 is greater than CPT code 28298. Although CPT code 28298 has similar intra-service time and total time, it has an IWPUT of 0.047 which is considerably less than the IWPUT for CPT code 30118. In addition, commenters stated that the two comparison codes that CMS chose as support for the CPT code 28298 crosswalk (CPT codes 11970 and 19325) do not compare in intensity to CPT code 30118, even though they have similar intra-service time and total time. Commenters also stated that CPT code 30118 was undervalued in terms of its intensity during the initial Harvard valuation.

Response: We disagree with the commenters and continue to believe that a direct crosswalk from CPT code 28298 is appropriate since it has the same 60 minutes of intra-service time and similar total time as CPT code 30118. We also believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. The work RVU for CPT code 30118 should be lower than the RUC recommendation of 9.55 to reflect the decrease in intra-service time from 105 minutes to 60 minutes, and the decrease in total time from 288 minutes to 211 minutes. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in the surveyed work time should be reflected in commensurate decreases to work RVUs.

The intensity of CPT code 30118 would increase by more than 50 percent with the RUC-recommended RVU of 9.55. However, we disagree that the intensity for CPT code 30118 would increase in such a significant way

because this procedure is transitioning from an inpatient to an outpatient status. We also note that the intensity for CPT code 30117 has decreased with the RUC-recommended work RVU of 3.91. Therefore, we believe that our proposed work RVU of 7.75, which maintains the current intensity of CPT code 30118 instead of resulting in an increase in intensity, is the most accurate valuation for this service. We continue to believe that the proposed work RVU of 7.75 is a more appropriate value overall than the RUC's recommended work RVU of 9.55 when compared to the range of codes with the same intra-service time and similar total time. Therefore, we are finalizing the proposed work RVU of 7.75 for CPT code 30118.

Comment: For CPT code 31243, one commenter disagreed with the scope video system PE input equipment time refinement from 39 minutes to 34 minutes for ES031 and requested that we accept the RUC recommendation of 39 minutes, which they stated was the appropriate value for this input.

Response: We disagree with the commenter. The standard Scope Systems equipment formula the RUC used was incorrect. For CPT code 31243, the RUC initially recommended 39 minutes for PE input ES031. However, the RUC used the CA025 clinical labor task instead of CA024 in the formula; this was in error since CA024 is in the standard Scope Systems formula and CA025 is not. Using CA024 results in 7 minutes less time for ES031. Also, the RUC inadvertently used 18 minutes of intra-service time for CA018 in the formula instead of 20 minutes. Using the correct time of 20 minutes for CA018 results in an increase of 2 minutes. The net result of these corrections is 34 minutes for ES031 ((39 + 2) − 7 = 34). We also note that the RUC comments on the PE inputs for CPT code 31243 agreed with our proposed refinement for ES031. Therefore, for CPT code 31243 we are finalizing the equipment time refinement of 34 minutes for ES031 as proposed.

Comment: For CPT codes 30117 and 30118, some commenters disagreed with the proposal to remove the clinical labor for the CA037 activity code from the direct PE inputs. Commenters stated that this is a follow-up phone call by staff to see how the patient is doing, 1 to 2 days after the procedure, and should be included in both the facility and non-facility settings. The commenters stated that this staff contact with the patient is completely different than, and separate from, what occurs the day of the procedure for CA036. While a follow-up phone call is outside of the 090-day global standard, this type of postoperative communication is evolving and reflects best practice.

Response: We continue to believe that the CA037 clinical labor task should not be included in the PE inputs for CPT codes 30117 and 30118 since the standard for the post-operative period for 010-day and 090-day global procedures does not include clinical labor for phone calls as a separate direct PE input, and both of these codes are 090-day global procedures. We also continue to believe that CA037 is duplicative with the communications already taking place under the CA036 clinical labor activity. Therefore, we are finalizing the PE input refinement to remove the CA037 clinical labor from CPT codes 30117 and 30118.

After consideration of the public comments, we are finalizing the work RVU values for the Posterior Nasal Nerve Ablation code family (CPT codes 30117, 30118, 31242, and 31243) as proposed. We are also finalizing the direct PE inputs for CPT codes 30117, 30118, 31242, and 31243 as proposed.

(6) Cystourethroscopy With Urethral Therapeutic Drug Delivery (CPT Code 52284)

In September 2022, the CPT Editorial Panel replaced Category III code 0499T (*Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed*) with the new Category I CPT code 52284 (*Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed*) to describe cystourethroscopy with mechanical urethral dilation and urethral therapeutic drug delivery. For CY 2024, the RUC recommended a work RVU of 3.10 for CPT code 52284.

We proposed the RUC-recommended work RVU of 3.10 for CPT code 52284. We also proposed the RUC-recommended direct PE inputs for CPT code 52284 without refinement.

Since this is an endoscopic procedure, we proposed CPT code 52000 (*Cystourethroscopy (separate procedure)*) as the endoscopic base code for CPT code 52284 because the description of this procedure includes what is described for CPT code 52000 with the additional component of the urethral therapeutic drug delivery. This procedure is performed with a cystoscope. CPT code 52284 is not an add-on code, it has a 0-day global period. The endoscopic base code that we assigned to CPT code 52284 is a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

The following is a summary of the comments we received and our responses.

Comment: The commenters supported CMS' proposal of the RUC-recommended work RVU and direct PE inputs.

Response: We thank the commenters for their support and are finalizing as proposed.

After consideration of the public comments, we are finalizing the work RVU of 3.10 for the CPT code 52284 as proposed. We are also finalizing the direct PE inputs for code 52284 without refinement.

(7) Transcervical RF Ablation of Uterine Fibroids (CPT Code 58580)

In September 2022, the CPT Editorial Panel deleted Category III code 0404T (*Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency*) and created a new Category I CPT code 58580 (*Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency*) to report and describe transcervical radiofrequency ablation of uterine fibroid(s) which prompted CPT code 58580 to be surveyed for the January 2023 RUC meeting. At the January 2023 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for CPT code 58580 showed that the survey 25th percentile work RVU of 7.21 appropriately recognizes the work involved in this service.

We proposed the RUC-recommended work RVU of 7.21 for CPT code 58580. We note that the RUC recommended in their review that CPT code 58580 be placed on the New Technology list to be re-reviewed by the RUC in 3 years to ensure correct valuation and utilization assumptions. We will revisit the valuations of CPT code 58580 in future rulemaking as needed, based on our typical annual review process.

CPT code 58580 includes a medium instrument pack (EQ138) as one of the practice expense inputs for this code. Since the medium instrument pack is classified as equipment, it should include time for cleaning the surgical instrument package. We noted a mistake in one of the equipment time formulas for the medium instrument pack (EQ138), which used the CA024 clean room/equipment by clinical staff time instead of the CA026 clean surgical instrument package time in the equipment formula. Therefore, we proposed to refine the medium

instrument pack equipment time from 65 minutes to 77 minutes to conform to our established policy for surgical instrument packs; otherwise, we proposed the RUC-recommended direct PE inputs without refinement.

Comment: Several commenters supported the CMS proposal of the RUC-recommended work RVU of 7.21. Commenters also agreed with the proposed refinement to the medium instrument pack (EQ138) equipment time.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: A few commenters disagreed with the CMS proposal of the RUC-recommended work RVU of 7.21 for CPT code 58580. The commenters stated that the RUC's recommendation of a work RVU of 7.21 for this procedure was insufficient and suggested that CPT code 58674, to which CMS has assigned a work RVU of 14.08, would be more appropriate. Another commenter suggested that CMS increase the work RVU for CPT code 58580 to 8.00 to bring the valuation in line with CPT code 22514, which has a work RVU of 7.99 and which the RUC used as a comparator code.

Response: We thank the commenters for their suggestions; however we disagree with the commenters and continue to agree with the RUC that a work RVU of 7.21 is the most accurate valuation for CPT code 58580. The suggestion from commenters to assign a work RVU of 14.08 based on a crosswalk to CPT code 58674 would not be appropriate for CPT code 58580, as CPT code 58674 is a surgical laparoscopy with more than double the intraservice work time. The alternate suggestion of finalizing a work RVU of 8.00 based on a near-match of CPT code 22514 is a better fit, as this code shares the same intraservice work time and similar total work time with CPT code 58580. However, we believe that CPT code 22514 is a more intensive procedure as compared with CPT code 58580 due to its nature as a percutaneous vertebral augmentation, which justifies having a higher work RVU.

At the January 2023 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for CPT code 58580 showed that the survey 25th percentile work RVU of 7.21 appropriately recognizes the work involved in this service. To justify a work RVU of 7.21, the RUC also referenced top key reference code CPT code 58356 (*Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed)* with a work RVU= 6.41, intra-service time of 45 minutes, total time of 167 minutes, and noted that although both services involve identical intra-service time, the majority of survey respondents that selected this key reference code indicated the surveyed code was a more intense and complex service to perform (94 percent). While we do not always agree with the RUC, we believe that the proposed work RVU of 7.21 accurately captures the work completed in this service.

Comment: One commenter stated that the proposed non-facility practice expense RVU for CPT code 58580 would be insufficient for the costs expected in an office setting.

Response: We appreciate the concerns raised by the commenter; however, the commenter did not specify which additional PE expenses were not being captured in the proposed valuation for CPT code 58580. If the commenter has reason to believe that the RUC's recommended direct PE inputs failed to capture the costs associated with this procedure, we encourage them to consider nominating CPT code 58580 as potentially misvalued for addition review. (We direct readers to the Potentially Misvalued Services Under the PFS (section II.C.) earlier in this final rule for additional details).

Comment: Several commenters recommended that CMS increase the malpractice RVU for CPT code 58580, as they stated that the proposed value was insufficient to cover malpractice costs.

Response: The malpractice RVU for each service is a derived valuation largely based on the work RVU and the risk factors associated with the specialties reporting that service in claims data. We do not propose specific malpractice RVUs which are derived as a result of our larger ratesetting process; for additional information, we direct readers to the Determination of Malpractice Relative Value Units (RVUs) (section II.H.) in last year's final rule (87 FR 69634 through 69641).

After consideration of the public comments for CPT code 58580, we are finalizing the RUC-recommended work RVU of 7.21 as proposed. We are also finalizing our proposal to refine the medium instrument pack equipment time from 65 minutes to 77 minutes to conform to our established policy for surgical instrument packs. Otherwise, we are finalizing the RUC-recommended direct PE inputs without refinement.

(8) Suprachoroidal Injection (CPT Code 67516)

In September 2022, the CPT Editorial Panel introduced category I CPT code 67516 as a new code. CPT code 67516 describes suprachoroidal injection, which is the injection of medication into the space between the choroid and the sclera of the eye with procedure-specific needles and an injection kit. CPT code 67516 replaces temporary category III CPT code 0465T (*Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)*), which was contractor priced. While there are other existing general CPT codes for injections to the eye, the AMA RUC is adding CPT code 67516 (*Suprachoroidal space injection of pharmacologic agent (separate procedure) (Report medication separately*)) to describe a more specific service to better distinguish this procedure from the rest of the codes for eye injections in this family. CPT code 67516 is a 000-day global code and currently, there is only one FDA-approved medication to treat macular edema associated with uveitis which is reported separately with HCPCS J-code J3299 triamcinolone acetonide (Xipere®).

We proposed the RUC-recommended work RVU of 1.53 for CPT code 67516. We also proposed the RUC-recommended direct PE inputs for the code without refinement.

Comment: We received a few comments for CPT code 67516 in favor of establishing this code as a permanent category I code with active pricing. We received no comments opposing CPT code 67516.

Response: We thank commenters for taking the time to submit comments.

After reviewing the comments, we are finalizing the proposed work RVU and direct PE inputs for CPT code 67516.

(9) Skull Mounted Cranial Neurostimulator (CPT Codes 61889, 61891, and 61892)

In February 2022, the CPT Editorial Panel created codes 61889, 61891, and 61892 to describe Skull-Mounted Cranial Neurostimulator, and these codes were surveyed for the October 2022 RUC meeting.

We proposed the RUC-recommended work RVU of 25.75 for CPT code 61889 (*Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)*), the RUC-recommended work RVU of 11.25 for CPT code 61891 (*Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)*), and the RUC-recommended work RVU of 15.00 for CPT code 61892 (*Removal of*

skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed).

We proposed the RUC-recommended direct PE inputs for CPT codes 61889, 61891, and 61892 without refinement.

We did not receive comments on our proposals. We are finalizing as proposed the RUC-recommended work RVU and PE inputs for CPT codes 61889, 61891, and 61892 respectively.

(10) Spinal Neurostimulator Services (CPT Codes 63685, 63688, 64596, 64597, and 64598)

For CPT codes 63685 (*Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 63688 (*Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we proposed the RUC-recommended work RVUs of 5.19 and 4.35, respectively. We proposed the RUC-recommended direct PE inputs for CPT codes 63685 and 63688 without refinement.

We agreed with the RUC recommended contractor pricing for CPT codes 64596 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array*), 64597 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array*), and 64598 (*Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator*); and we proposed contractor pricing for these three codes.

Comment: One commenter disagreed with the proposed work RVU of 4.35 for CPT code 63688, stating that the current work RVU of 5.30 is more appropriate. This commenter stated, without further explanation, that the valuation of the revision code should be greater than the initial insertion, as it is more complex to revise or remove an existing implant than to insert a new implant.

Response: We appreciate the feedback, but we note that the RUC's Summary of Recommendations (SOR) for CPT code 63688 contained two key reference codes that appropriately support the proposed valuation. Without additional data provided by the commenter, we continue to believe that the RUC-reviewed survey 25th percentile work RVU of 4.35 accurately reflects the time and intensity of CPT code 63688.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended work RVUs and direct PE inputs for CPT codes 63685 and 63688. These commenters also supported our proposal to assign contractor pricing to CPT codes 64596, 64597, and 64598.

Response: We appreciate the support for our proposals from commenters.

After consideration of all comments on our proposals for CPT codes 63685 and 63688, we are finalizing the RUC-recommended work RVUs of 5.19 and 4.35, respectively. We are finalizing the RUC-recommended direct PE inputs for CPT codes 63685 and 63688 without refinement. We are also finalizing the RUC-recommended contractor pricing for CPT codes 64596, 64597, and 64598 as proposed.

(11) Neurostimulator Services-Bladder Dysfunction (CPT Codes 64590 and 64595)

For CPT codes 64590 (*Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 64595 (*Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we proposed the RUC-recommended work RVUs of 5.10 and 3.79, respectively.

We requested clarification on the direct PE inputs for CPT code 64590 in the non-facility setting. Specifically, we believed the RUC inadvertently proposed 56 minutes of equipment time for the EQ114 equipment (electrosurgical generator), instead of 48 minutes using the default formula for calculating equipment time. We believed that 48 minutes of equipment time for EQ114 was appropriate and matched the clinical labor time; therefore, we proposed 48 minutes for the EQ114 equipment for CPT code 64590. We also believed that the EQ209 equipment (*programmer, neurostimulator (w-printer)*) was intended to match the same 84 minutes of equipment time listed for the EF031 power table as both were indicated to be used during the follow-up office visit. Therefore, we proposed 84 minutes of equipment time for EQ209 for CPT code 64590.

We proposed the remaining RUC-recommended direct PE inputs for CPT code 64590 without refinement. We also proposed the RUC-recommended direct PE inputs for CPT code 64595 without refinement.

Comment: The RUC agreed with the proposed 48 minutes of equipment time for the EQ114 equipment, and 84 minutes of equipment time for EQ209 for CPT code 64590.

Response: We appreciate the additional information provided by the RUC to clarify the equipment time.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended work RVUs and direct PE inputs for CPT codes 64590 and 64595.

Response: We appreciate the support for our proposed work RVUs and direct PE inputs from the commenters.

After consideration of all comments on our proposals for CPT codes 64590 and 64595, we are finalizing the RUC-recommended work RVUs of 5.10 and 3.79, respectively. We are finalizing 48 minutes of equipment time for EQ114 and 84 minutes of equipment time for EQ209 for CPT code 64590. We are also finalizing the remaining RUC-recommended direct PE inputs for CPT codes 64590 and 64595 as proposed.

(12) Ocular Surface Amniotic Membrane Placement/Reconstruction (CPT Codes 65778, 65779, and 65780)

CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*) was identified by the Relativity Assessment Workgroup (RAW) via the high-volume growth screen for codes with Medicare utilization over 10,000 screen. During the September 2022 RAW meeting, the specialty societies stated that CPT codes 65778, 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*) would be surveyed for the January 2023 RUC meeting.

For CY 2024, we proposed the RUC-recommended work RVUs for all three CPT codes. We proposed a work RVU of 0.84 for CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*), a work RVU of 1.75 for CPT code 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and a work RVU of 7.03 for CPT code 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*). We also proposed the RUC-recommended direct PE inputs for CPT codes 65778, 65779, and 65780 without refinement.

Comment: Several commenters disagreed with the proposed work RVU of 0.84, stating that the amniotic membrane supply product, Prokera, has

a higher cost than the proposed rate. These commenters also stated that the proposed work RVU does not account for the time spent explaining the product at the time of insertion, and stated that the valuation should not decrease from the current work RVU of 1.00.

Response: We did not receive additional pricing data from these commenters to support a change in the pricing of the amniotic membrane supply. Additionally, we did not receive information supporting a change to the proposed work RVU. The RUC-recommended time values have remained unchanged since the code was last valued in 2015. However, the previous valuation was based on a crosswalk and marked not to use to validate physician work for other services in the RUC database. Therefore, the RUC determined that the survey 25th percentile work RVU of 0.84 appropriately accounts for the work required to perform this service. We continue to agree with the RUC-recommended work RVU for CPT code 65778.

Comment: A commenter disagreed with the proposed pricing of the human amniotic membrane allograft mounted on a non-absorbable self-retaining ring (SD248) supply. The commenter stated that the proposed pricing of $872.50 was not typical for the SD248 supply and submitted more than 100 invoices to support their recommendation of increased pricing.

Response: We appreciate the submission of such a large quantity of invoices for more accurate pricing of the human amniotic membrane allograft mounted on a non-absorbable self-retaining ring (SD248) supply. The submitted invoices all displayed the identical price of $1049 for the Prokera Plus item, and we agree with the commenter that this is the current market price for the Prokera Plus device. However, we disagree that using the Prokera Plus would necessarily be typical for use in CPT code 65778. We also received invoices in the RUC's recommended materials for this code family containing prices for the Prokera Slim ($850) and Prokera Classic ($895) devices which the RUC indicated would also be appropriate for use in CPT code 65778. The manufacturer's website described the Prokera Plus as an item that ''maximizes the therapeutic benefit,'' which is intended ''for patients who need intensive treatment.'' As a result, we do not believe it would be appropriate to use the pricing for the Prokera Plus item for the SD248 supply as we do not believe that it would be typical for providers to use the most intensive and expensive product as the standard of care. We are instead averaging together the invoice prices of the Prokera Slim, Prokera Classic, and Prokera Plus to price the SD248 supply at $931.33, which is an increase of $58.83 above our proposed price of $872.50. We believe that averaging these products' prices together will more accurately capture the market-based pricing of the devices currently used in CPT code 65778.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs of 0.84 for CPT code 65778, 1.75 for CPT code 65779, and 7.03 for CPT code 65780. We are finalizing $931.33 as the price for the SD248 supply item for CPT code 65778, and the remaining direct PE inputs for this code as proposed. We are also finalizing the RUC-recommended direct PE inputs for CPT codes 65779 and 65780 without refinement.

(13) Fractional Flow Reserve With CT (CPT Code 75580)

For CY 2018, the CPT Editorial Panel established four new Category III CPT codes for fractional flow reserve derived from computed tomography (FFRCT): CPT codes 0501T–0504T. Medicare began payment for CPT code 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model*) in the hospital outpatient department setting under the Outpatient Prospective Payment System (OPPS) in CY 2018 (82 FR 59284). We typically assign contractor pricing for Category III codes for the PFS since they are temporary codes assigned to emerging technology and services. However, we made an exception for FFRCT services, and we have since been trying to understand the costs of the PE resource inputs for CPT code 0503T in the physician's office setting. In the CY 2021 PFS final rule (85 FR 84630), we stated that we found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology; and that our recent reviews for the overall cost of CPT code 0503T had shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS (85 FR 84630). As such, we proposed to use the geometric mean costs under the OPPS as a proxy for CPT code 0503T and ultimately finalized national pricing for CPT code 0503T based on a valuation crosswalk to the technical component (TC) of CPT code 93457 in the CY 2022 PFS final rule (86 FR 65037–65042).

For CY 2024, the CPT Editorial Panel approved the replacement of Category III codes 0501T–0504T with a single new Category I code (75580) to report a non-invasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the dataset from a coronary computed tomography angiography. CPT code 75580 (*Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*) was reviewed at the January 2023 RUC meeting and valuation recommendations were submitted to CMS. These recommendations include a software analysis fee for FFRCT listed as a supply input which accounts for the overwhelming majority of the code's valuation.

We have long had concerns that the software algorithm in the analysis fee for CPT code 75580 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchasing the FFRCT software and its ongoing use. This was the rationale for our previous policy to use a crosswalk that reflected this service's overall relative resource costs. At the same time, we continued to consider potentially refining and updating our PE methodology. The RUC recommendations include the previously mentioned software analysis fee for FFRCT as a supply input. However, analysis fees are not well accounted for in our current PE methodology. Although we recognize that these fees are a cost for practitioners, we have not traditionally recognized these analysis fees as forms of direct PE in our methodology. We previously stated our belief that crosswalking the RVUs for CPT code 0503T to a code with similar resource costs (the TC for CPT code 93457) allowed CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 0503T, which would not typically be considered direct PE under our current methodology (86 FR 65038 and 65039).

Therefore, we proposed maintaining the previous valuation crosswalk to the technical component of CPT code 93457 for the new FFRCT code 75580. This new Category I code is intended as a direct replacement for Category III code 0503T, and maintaining the current crosswalk will allow the geometric mean costs under the OPPS to continue serving as a valuation proxy. We are specifically crosswalking the technical component of CPT code 75580 to the technical component of CPT code 93457; we proposed the RUC-recommended work RVU of 0.75 for the professional component of CPT code 75580, and the global component will be comprised of their sums as usual. We also noted that there was an error in the RUC's recommended equipment time for the Professional PACS Workstation (ED053), which was listed at 14.5 minutes instead of the correct 13.5 minutes based on the sum of the intraservice work time (11 minutes) plus half of the preservice work time (5 divided by 2 = 2.5 minutes).

Comment: Many commenters stated their approval of the CMS proposal of the RUC's recommended work RVU of 0.75 for the professional component of CPT code 75580 and the proposal to maintain the crosswalk from CPT code 75580's predecessor code to the technical component of CPT code 93457 for the technical component of the procedure. Commenters stated that given the predominance of the cost of the analysis fee for CPT code 75580, it was critical that CMS utilize something other than the current PE methodology when establishing the physician fee schedule rate for the procedure. Commenters stated that CMS' proposal to continue to use the crosswalking methodology, that has been in place since CY 2022, was an appropriate alternative for the valuation of the technical component of CPT code 75580 and should be finalized. Commenters stated that the proposed crosswalk to the technical component of CPT code 93457 was an appropriate method to account for the costs physicians incur to provide FFRCT. Many commenters detailed the clinical benefits of FFRCT services, such as leading to a 70% reduction in rates of heart attack, death, or unnecessary invasive catheterization in one study, and urged CMS to finalize their proposed policies.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: A commenter disagreed with the proposed crosswalk to the technical component of CPT code 93457 and objected to CMS using data from the OPPS in establishing relative values for the PFS. The commenter stated that any proposal to use the relativity of hospital charge data to determine the relativity of practice costs within a physician office is not consistent with statutory provisions under Section 4505 of the Balanced Budget Act of 1997.

Response: We disagree with the commenter and believe that we can use OPPS data in certain circumstances to inform payment under the PFS. As we stated in the proposed rule, our recent reviews for the overall cost of CPT code 0503T showed the costs in the physician office setting to be similar to those reflected in payment under the OPPS (85 FR 84630). As such, we proposed to use the geometric mean costs under the OPPS as a proxy for CPT code 0503T and ultimately finalized national pricing for CPT code 0503T based on a valuation crosswalk to the technical component (TC) of CPT code 93457 in the CY 2022 PFS final rule (86 FR 65037–65042). We then carried over this proposed policy to CPT code 75580, the direct replacement for CPT code 0503T. We believe this is a more accurate way to value the service due to the problems that this service's analysis fee poses for our PE methodology.

Comment: A commenter disagreed with the proposed crosswalk to the technical component of CPT code 93457 by stating that this crosswalk approach was not resource-based. The commenter stated that the software analysis fee was the only supply input and represented a per-patient, single-use item, and thus was appropriately included as a direct supply. The commenter recommended that CMS negate the need for a crosswalk by accepting this software as a direct practice expense input.

Response: As we stated in the proposed rule, we have long had concerns that the software algorithm in the analysis fee for CPT code 75580 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchasing the FFRCT software and its ongoing use. This was the rationale for our previous policy to use a crosswalk (86 FR 65037 through 65042) that reflected the overall relative resource costs for this service while we continued to consider potentially refining and updating our PE methodology. The RUC recommendations included the previously mentioned software analysis fee for FFRCT as a supply input. However, analysis fees are not well accounted for in our current PE methodology. Although we recognize that these fees are a cost for practitioners, we have not traditionally recognized these analysis fees as forms of direct PE in our methodology. We continue to believe that the software analysis fee would not be considered as a form of direct PE under our current methodology, and therefore, we proposed to maintain the previous valuation crosswalk to the technical component of CPT code 93457 to incorporate these costs.

Comment: Several commenters recommended that CMS separately identify and pay for high-cost disposable supplies. Commenters stated that creating separate high-cost supply codes would be a way to pay for the software analysis fee included in CPT code 75580.

Response: We have received a number of prior requests from interested parties, including the RUC, to implement separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. (For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251)).

After consideration of the public comments, we are finalizing our proposal of the RUC-recommended work RVU of 0.75 for the professional component of CPT code 75580. We are also finalizing our proposal to crosswalk the technical component of CPT code 75580 to the technical component of CPT code 93457, maintaining the previous crosswalk in place for CPT code 0503T, as well as finalizing our proposed equipment time for the Professional PACS Workstation (ED053), which was unmentioned by commenters.

(14) Ultrasound Guidance for Vascular Access (CPT Code 76937)

To specify the insertion of a peripherally inserted central venous catheter (PICC), the CPT Editorial Panel decided to create two new codes: CPT code 36572 and CPT code 36573, and revised CPT codes 36568, 36569 and 36584 in September of 2017. This revision of these codes created a scenario where these bundled services could be performed by a clinician that performs the procedure without imaging guidance or a radiologist that performs the procedure with imaging guidance. When this code family was surveyed again in January 2018, CPT code 76937 *(Ultrasound guidance for vascular*

access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure) was identified as part of this code family. Since it was expected that utilization of PICC procedures would decrease once CPT code 76937 was bundled with these services, the specialty societies that perform this service proposed to review CPT code 76937 after 2 years, once more data about these services became available. CPT code 76937 was reviewed at the October 2022 RUC meeting for CY 2024.

We proposed the RUC-recommended work RVU of 0.30 for CPT code 76937. We also proposed the RUC-recommended direct PE inputs for CPT code 76937.

Comment: Commenters were in support of the CMS proposal of the RUC-recommended values for CPT code 76937.

Response: We thank the commenters for their support.

After consideration of the comments, we are finalizing a work RVU of 0.30 for CPT code 76937 as proposed. We are also finalizing the direct PE inputs as proposed.

(15) Neuromuscular Ultrasound (CPT Codes 76881, 76882, and 76883)

Since their creation in 2011, CPT codes 76881 (*Ultrasound, complete joint (ie, joint space and peri-articular soft-tissue structures), real-time with image documentation*) and 76882 (*Ultrasound, limited, joint or other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation*) have been reviewed numerous times as New Technology/New Services by the Relativity Assessment Workgroup (RAW). In October 2016, the RAW reviewed these codes and agreed with the specialty societies that the dominant specialties providing the complete (CPT code 76881) versus the limited (CPT code 76882) ultrasound of extremity services were different than originally thought, causing variation in the typical PE inputs. The RAW recommended referral to the Practice Expense Subcommittee for review of the direct PE inputs and the CPT Editorial Panel to clarify the introductory language regarding the reference to one joint in the complete ultrasound. The PE Subcommittee reviewed the direct PE inputs for CPT codes 76881 and 76882 and adjusted the clinical staff time at the January 2017 RUC meeting, and the CPT Editorial Panel editorially revised CPT codes 76881 and 76882 to clarify the distinction between complete and limited studies and revised the introductory guidelines to clarify the reference to one joint in the complete ultrasound procedure in June 2017.

In October 2021, the CPT Editorial Panel approved the addition of CPT code 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*) for reporting real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity, and the revision of CPT code 76882 to add focal evaluation. CPT codes 76881 and 76882 were identified as part of the neuromuscular ultrasound code family with CPT code 76883 and surveyed for the January 2022 RUC meeting. We reviewed these recommendations for CY 2023 and discussed our concerns with the commenters' assertions regarding typical PE inputs for CPT code 76882 in the CY 2023 PFS final rule (87 FR 69506 through 69510). Specifically, given the changes in dominant specialty for these CPT codes from 2010 to 2017, and again from 2017 to 2022, we recommended that the RUC and interested parties reconsider the PE inputs for each code based on the dominant specialty for each CPT code, based on the most recent year's Medicare claims data, and consideration of survey responses submitted to CMS in response to the CY 2023 PFS proposed rule.

The PE inputs for CPT codes 76881, 76882, and 76883 were subsequently re-reviewed at the January 2023 RUC meeting and the RUC submitted refinements to the PE inputs for CPT code 76882 only. We proposed the RUC-recommended PE refinements for CPT code 76882 with the exception of the RUC-recommended 13.5 minutes for ED053 (Professional PACS workstation) and 23 minutes for EQ250 (ultrasound unit, portable). We noted that the old intraservice time of 11 minutes was used in error when calculating the standard equipment time for ED053. Therefore, we disagreed with the RUC-recommended equipment time of 13.5 minutes and proposed 17.5 minutes for ED053, which is calculated by using the standard equipment formula for ED053 established in the CY 2017 PFS final rule (81 FR 80182) with the updated intraservice time from the CY 2023 PFS final rule ((0.5*5)+15 = 17.5).

We disagreed with the RUC-recommended 23 minutes of equipment time for EQ250, which includes one minute of clinical labor time for CA014 (Confirm order, protocol exam) in the highly technical equipment formula, as discussed beginning in the CY 2013 PFS final rule (77 FR 69028), in error. Therefore, the correct equipment time for EQ250 using the highly technical equipment formula would be 22 minutes. However, because the Summary of Recommendations included in the RUC recommendations did not provide a rationale for the use of the highly technical equipment formula for EQ250, we proposed to maintain the 15 minutes of equipment time for EQ250 for CPT code 78882, which corresponds to the interservice time for this code and maintains consistency with how equipment time is allotted for EQ250 across the three codes in this family. We referred readers to the classification of highly technical equipment in the CY 2014 PFS final rule (79 FR 67639).

The RUC did not make recommendations on the work RVUs for CPT codes 76881, 76882, and 76883, and CMS did not propose any changes.

Comment: Some commenters thanked CMS for proposing the RUC recommended direct PE inputs for CPT code 76882. One commenter agreed with the CMS PE refinements for CPT code 76882, including the refinement for EQ250.

Response: We thank the commenters for their support.

Comment: Some commenters expressed continued concern about the PE inputs for CPT code 76881, and one commenter submitted several invoices for ultrasound machine technology used by rheumatologists for neuromuscular ultrasound services. The commenter stated that the clinical labor, which they believed was typically a diagnostic medical sonographer, and the dedicated ultrasound room and high-quality ultrasound machines utilized by rheumatologists were not appropriately accounted for in CPT code 76881. Some commenters requested that CMS utilize the invoices and informal survey data provided in response to last year's CY 2023 PFS proposed rule to raise the PE values for CPT code 76881 to match the proposed PE values of CPT code 76882 until a formal workforce survey of typical rheumatology practice expenses has been conducted to prevent a rank order anomaly. Multiple commenters stated that rheumatologists' typical practice expenses are not accounted for in the valuation of CPT code 76881, and many offered to provide more resources to capture these expenses. Some commenters asserted that rheumatologists were not surveyed on

their typical practice expense and requested a similar re-review for CPT code 76881 that was done for CPT code 76882.

Response: As stated in the CY 2023 PFS final rule, we appreciate the commenters' survey collection efforts to reflect rheumatologists' costs in performing neuromuscular ultrasound and the concern regarding the accounting of rheumatologists' typical clinical labor and equipment in the RUC recommendations. We encourage the commenters to coordinate with the RUC to provide their survey data to facilitate a reconsideration of PE inputs if the commenters believe certain specialties were not appropriately queried. Because the RUC has standardized procedures for PE and physician surveys, and the fact that the commenters' survey results differ so drastically from the January 2022 and 2023 RUC recommendations, we encourage the RUC and other interested parties to consider the commenters' survey efforts. We encourage collaboration with the RUC PE subcommittee and the submission of specific invoices to support the surveys' results and robust data to show the typicality of these PE inputs.

We note that the RUC submitted a letter in their January 2023 recommendations outlining the process for re-surveying these codes. The RUC noted that PE recommendations were formulated at the January 2022 meeting based on RUC database claims at the time, which showed Rheumatology as the highest single provider of CPT code 76881 and Radiology as the highest single specialty provider of CPT code 76882, although for both codes no single specialty has more than a plurality. For the January 2023 RUC meeting, there was a change in the dominant specialty for CPT code 76882 to Podiatry, rather than Radiology, in the non-facility setting; therefore, the PE recommendations were adjusted to reflect the more common hand-held ultrasound device, rather than the ultrasound room, sonographer, and PACS workstation that are typical in radiology practices. The RUC's letter stated that they reviewed the several hundred letters from rheumatologists submitted in response to the CY 2023 PFS proposed rule.

In response, the American College of Radiology, American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, American Academy of Physical Medicine and Rehabilitation, American College of Rheumatology, and American Podiatric Medical Association convened a panel that included experts familiar with these services and typical practice expense to reevaluate the direct practice expense inputs for neuromuscular ultrasound. At the time of the panel, rheumatology was the dominant specialty for CPT code 76881 at 26 percent, and radiology was the dominant specialty for CPT code 76882 at 27 percent. Because of the dominant specialty change back to radiology for CPT code 76882, which has been the historical standard and was temporarily changed to Podiatry based on COVID pandemic alterations of the utilization, the RUC-recommended inputs for CPT code 76882 submitted for the January 2023 meeting reflected updated clinical staff, clinical activities, supplies, and equipment (PACS) utilized when performed by Radiology. The letter also stated that the expert panel carefully considered the comments submitted to CMS regarding the practice expense for CPT code 76881. The letter stated the following: ''While the use of dedicated sonographers is increasing in Rheumatology, we did not believe it was yet the typical clinical staff in the non-facility setting and will re-evaluate the issue when the code family returns for review under the new technology process. The expert panel recognizes that many non-radiology specialties are increasingly adopting a ''picture archiving and communication system (PACS)'' for image storage and important patient care. However, the RUC has previously indicated that these are general practice expenses not typically allocated to a single patient/code and that only the specific use of the PACS workstation is acceptable under PE supplies. As many PACS vendors increasingly shift to a per-patient cost, the RUC may need to reconsider how these supplies are allocated in practice expense.''

We also remind interested parties that we have established an annual process for the public nomination of potentially misvalued codes. This process provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention, as detailed in section II.C. of this final rule. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. While this process is available to interested parties, we remind commenters that the RUC plans to review the practice expense for CPT codes 76881, 76882, and 76883 with additional data according to their new technology process at a future RUC meeting.

After consideration of the comments, we are finalizing the direct PE refinements as proposed for CPT codes 76881, 76882, and 76883. We did not propose and are not finalizing any changes to the work RVU for CPT codes 76881, 76882, and 76883.

(16) Intraoperative Ultrasound Services (CPT Codes 76998, 76984, 76987, 76988, and 76989)

In October 2018, the Relativity Assessment Workgroup (RAW) created a screen for CMS/Other codes with Medicare utilization of 20,000 or more, and CPT code 76998 (*Ultrasonic guidance, intraoperative*) was subsequently identified as part of that screen. When CPT code 76998 was identified in the CMS/Other screen, it was noted that many specialties were represented in the Medicare claims data. Specialties representing cardiothoracic surgery, general surgery, breast surgery, urology, interventional cardiology, interventional radiology and vascular surgery jointly submitted an action plan that the RAW reviewed in October 2019. Based on the variability of intraoperative ultrasound for each specialty with differences in the typical patient and physician work, it was decided that each society would submit applications for new code(s) as needed to carve out the work currently reported with CPT code 76998 until the code was no longer needed, or until it was clear what the final dominant use of CPT code 76998 was so that a survey could be conducted.

In October 2019, the RUC referred this issue to the CPT Editorial Panel to clarify correct coding and accurately differentiate physician work, as multiple specialties currently report CPT code 76998. The CPT Editorial Panel addressed CPT code 76998 in 2020 and 2021 by adding instructional parentheticals that restrict the use of imaging guidance with vein ablation procedures and adding new codes that bundled imaging guidance for urological procedures. In May 2022, the CPT Editorial Panel created four new codes to report intraoperative cardiac ultrasound services, thus carving out most of the prior reporting of CPT code 76998 by cardiothoracic surgeons and cardiologists.

After utilization was removed from CPT code 76998 for vein ablation procedures, most urological procedures, cardiac procedures, and intra-abdominal procedures through instructions and/or new or revised codes, it was determined that the dominant use of the code would be related to breast surgery, allowing for

CPT code 76998 to be surveyed. CPT codes 76984 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 76987 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report*), 76988 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 76989 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only*), and 76998 were surveyed by the specialty societies for the September 2022 RUC meeting.

We disagreed with the RUC-recommended work RVU of 1.20 for CPT code 76998 and proposed the total time ratio work RVU of 0.91. The RUC recommended a 7-minute total time decrease for CPT code 76998. We agreed with the RUC that the intensity of CPT code 76998 (real-time during an operation) is greater than the identically-timed CPT code 76641 (*Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete*), which represents a single ultrasound session typically performed by a technician, whereas CPT code 76998 includes multiple, separate ultrasound maneuvers during a surgical procedure that require a more intense, immediate interpretation in order to direct resection of the breast tissue and ensure a thorough and complete surgical excision of the abnormal breast tissue. The work RVU of 0.91 for CPT code 76998 adequately values the surgeon's 5 minutes of pre-service time, 12 minutes of intraservice time, and 5 minutes of immediate post-service time more than the same 5, 12, and 5 minutes of the technician's time for CPT code 76641, which has a work RVU of 0.73.

Additionally, the IWPUT of CPT code 76641 is appropriately less than the IWPUT of CPT code 76698, with IWPUTs of 0.0422 and 0.0572, respectively. We remind interested parties that we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, decreases in time should be reflected in decreases to work RVUs. We disagreed with the RUC-recommended maintenance of the current work RVU for CPT code 76998 for a few reasons: the RUC recommendations did not advocate for a change in intensity, and presumably some higher-intensity cardiac procedures will no longer be reported using CPT code 76998, as they can now be reported using CPT codes 76984 through 76989. Instead, we proposed an appropriately lower work RVU and associated IWPUT to account for the 7-minute decrease in total time and removal of higher-intensity cardiac procedures previously reported by CPT code 76998. We noted that the work RVU of 0.91 for CPT code 76998 is supported by the upper brackets of CPT codes 72125 (*Computed tomography, cervical spine; without contrast material*), 72128 (*Computed tomography, thoracic spine; without contrast material*), and 72131 (*Computed tomography, lumbar spine; without contrast material*), and a lower bracket of CPT code 76641. CPT codes 72125, 72128, and 72131 represent spinal computed tomography (CT) of the cervical, thoracic, and lumbar spine, respectively.

We proposed the RUC-recommended work RVU of 0.60 and work times of 5 minutes of pre-evaluation time, 10 minutes of intraservice time, and 3 minutes of immediate postservice time for total time of 18 minutes for CPT code 76984. We also proposed the RUC-recommended work times for CPT codes 76987 and 76988 of 10 minutes of pre-evaluation time and 20 minutes of intraservice time for both codes, and 5 and 10 minutes of immediate postservice time, for total times of 40 and 35 minutes, respectively. We proposed the RUC-recommended work times for CPT code 76989 with the exception of the intraservice time. We proposed the survey median intraservice time of 15 minutes rather than the RUC-recommended 75th percentile based on the assertion in the RUC's Summary of Recommendations that the cardiologist is typically in the operating room intraoperatively with the cardiothoracic surgeon prior to and after the cardiac repair. Based on this assertion, we do not believe the cardiologist spends the same amount of time in the operating room as the cardiothoracic surgeon in CPT codes 76987 and 76988. Therefore, we proposed 5 minutes of pre-evaluation time, 15 minutes of intraservice time, and 10 minutes of immediate postservice time for total time of 30 minutes for CPT code 76989.

Due to the CPT code descriptor for CPT code 76987, we believe that the appropriate work for this service is reflected in the combined work of CPT codes 76988 and 76989. We noted that in the CY 2015 PFS final rule (79 FR 67669), we reviewed a similarly constructed family of codes representing interventional transesophageal echocardiography (TEE) for congenital cardiac anomalies in the same way by proposing and finalizing a work RVU for CPT code 93315 (*Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report*) equal to the combined work RVUs of CPT codes 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*) and 93317 (*Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only*). We noted that the Summary of Recommendations for CPT codes 76987 through 76989 state that these intraoperative ultrasound services are expected to be very rare, as intraoperative TEE is considered the gold standard and can be performed for most patients instead, which could be reported using CPT codes 93315 through 93317. Because CPT codes 76987 through 76989 are an alternative to CPT codes 93315 through 93317 for congenital cardiac anomalies when intraoperative TEE is contraindicated, we believe we should maintain consistency and propose a work RVU for CPT code 76987 that equals the combined work RVUs of CPT codes 76988 and 76989.

Therefore, we disagreed with the RUC-recommended work RVUs of 1.90, 1.20, and 1.55 for CPT codes 76987, 76988, and 76989, respectively. We proposed a work RVU of 1.62 for CPT code 76987 based on a crosswalk to CPT codes 73219 (*Magnetic resonance (e.g., proton) imaging, upper extremity, other than joint; with contrast material(s)*) and 78452 (*Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection*). We noted that this crosswalk is supported by total time ratios between CPT code 76987 and reference CPT codes 93312 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report*) and 93315, which equal 1.66 and 1.67 respectively. We also noted that this is supported by a total time ratio to

the current time and work RVU for the code that cardiothoracic surgeons currently use to report this service before the creation of CPT code 76987, CPT code 76998 ((40/29)*1.20 = 1.66). Lastly, this is also supported by a total time ratio to the same CPT code 76998 after factoring in the updated total time of 22 minutes and our work RVU for CPT code 76998 of 0.91 ((40/22)*0.91 = 1.65). We noted that a work RVU of 1.62 for CPT code 76987 yields an IWPUT of 0.059, which is slightly higher than the IWPUTs of the intraoperative TEE CPT codes 93315 and 93312 that represent the complete procedure, which are 0.0532 and 0.0580, respectively.

Similar to how CPT code 76987 is broken down into service parts by CPT codes 76988 and 76989 to allow for multiple providers to perform different parts of the whole service done by one provider (represented by CPT code 76987), CPT codes 93312 through 93314 and 93315 through 93317 are broken down as well. According to the RUC Database, CPT code 93316 represents placement of transesophageal probe only, typically performed by a cardiac anesthesiologist. CPT code 93313 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only*) also represents placement of transesophageal probe only, when performed by a cardiac anesthesiologist. Similarly, CPT code 76988 represents placement and manipulation of transducer and image acquisition only, which is typically performed by a cardiothoracic surgeon according to the Summary of Recommendations.

According to the RUC Database, CPT code 93317 represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the cardiac anesthesiologist, represented by CPT code 93316. CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*) also represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the anesthesiologist, represented by CPT code 93313. Similarly, CPT code 76989 represents interpretation and report only, which is typically performed by a cardiologist according to the Summary of Recommendations.

Because this family is broken down into service parts in the same way CPT codes 93312 through 93314 and 93315 through 93317 are, we disagreed with the RUC's recommendation to assign work RVUs for CPT codes 76988 and 76989 that sum to more than the aggregate work RVU for CPT code 76987. Therefore, we proposed a work RVU of 1.08 for CPT code 76988 and a work RVU of 0.54 for CPT code 76989, which sum to the aggregate work RVU of 1.62 for CPT code 76987. The work RVUs for CPT code 76988 and 76989 were calculated by taking the aggregate work RVU of the whole service, represented by CPT code 76987, and dividing by three based on the number of discernable service parts: probe placement and manipulation, image acquisition, and interpretation and report. Because CPT code 76988 represents two of the three service parts performed by a cardiothoracic surgeon, we allotted 2/3rds of the aggregated work RVU for CPT code 76987, equaling 1.08 (1.62 * ⅔ = 1.08). Because CPT code 76989 represents one of the three service parts performed by a cardiologist, we allotted 1/3rd of the aggregated work RVU for CPT code 76987, equaling 0.54 (1.62 * ⅓ = 0.54). Because the Summary of Recommendations was unclear regarding the intensity of each part of the service as broken out, we invited comments on additional ways to break down the aggregate work RVU of CPT code 76987 to adequately account for the cardiothoracic surgeon and cardiologist's time and intensity to perform CPT codes 76988 and 76989, but we believe that the work RVUs should sum to no more than the aggregate work RVU for CPT code 76987 based on similarly broken down code families that represent the more widely used intraoperative TEE procedures.

The RUC did not recommend, and we did not propose any direct PE inputs for the five codes in the Intraoperative Ultrasound family.

Comment: Some commenters disagreed with CMS' proposed work RVU of 0.91 for CPT code 76998, stating that it is invalid to draw comparisons between the current work times and work RVUs to the newly surveyed work time and work RVUs as recommended by the RUC because they were ''Harvard'' times. One commenter disagreed with the use of total time ratios to account for changes in time and stated that the work RVU was reduced by CMS for CY 1993 and 1995 without the time being adjusted, rendering the originally assigned times and work RVUs untethered. The commenter also stated that the proposed work RVU of 0.91 for CPT code 76998 is only 1/3rd more intense than CPT code 76641, which describes a diagnostic ultrasound study that is typically performed by a technician, where the saved images are then reviewed, and an interpretation report is generated by a radiologist at a later time. In comparison, a surgeon uses an ultrasound probe periodically during the operation and interprets the images in real time to help direct the limits of surgical excision of a mass, images are saved, and a report is generated by the surgeon for CPT code 76998. The commenter stated that the intensity and complexity of CPT code 76998 (dynamic real-time ultrasound at operation) is significantly greater than CPT code 76641. The commenter also stated that CPT code 76641 represents a single ultrasound session typically performed by a technician, whereas CPT code 76998 includes multiple separate ultrasound maneuvers throughout an operative procedure by the surgeon, which require a more intense immediate interpretation in order to direct resection of the breast tissue to ensure a thorough and complete surgical excision of the abnormal breast tissue.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, so we apply various methodologies to identify several potential work values for individual codes. However, we

reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We also disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

With regards to the relativity of intensity and complexity of CPT code 76998 (dynamic real-time ultrasound at operation) compared to CPT code 76641, we continue to believe that the intensity of CPT code 76998 (real-time during an operation) is greater than the identically-timed CPT code 76641. The work RVU of 0.91 for CPT code 76998 adequately values the surgeon's 5 minutes of pre-service time, 12 minutes of intraservice time, and 5 minutes of immediate post-service time more than the same 5, 12, and 5 minutes for CPT code 76641, which has a work RVU of 0.73. Additionally, the IWPUT of CPT code 76641 is appropriately less than the IWPUT of CPT code 76698, with IWPUTs of 0.0422 and 0.0572, respectively.

Comment: Commenters disagreed with the comparison to intraoperative TEE and stated that the sum of the different components of work will not be the same as the combined work as it is for intraoperative TEE. The commenters stated that there would be time savings, as represented by the surveyed times, if the cardiothoracic surgeon provides the service alone, represented by CPT code 76987. Commenters also stated that CPT codes 73219 and 78452 are inappropriate comparator codes, as they are not intraoperative services and CPT code 78452 describes cardiac imaging performed on a patient before and after exercise in which a technologist typically handles the image acquisition. Commenters stated that CPT code 76987 is rarely performed and describes ultrasound image acquisition performed in the operating room through an open chest where the ultrasound probe is placed directly on the patient's beating heart and sterility must be maintained throughout. Commenters suggested that a work RVU of 1.90 was supported by comparison to CPT code 93317, with a work RVU of 1.84, intraservice time of 20 minutes, and total time of 40 minutes, which is the component code for the image acquisition, interpretation and report only of the congenital TEE codes.

Response: We agree with commenters that the proposed work RVU does not adequately account for the complexity of the intraoperative ultrasound image acquisition performed on a beating heart with abnormal heart structure, and that CPT code 93317 is a better comparator code with a work RVU of 1.84. Therefore, we are finalizing the RUC-recommended work RVU of 1.90 for CPT code 76987.

Comment: Some commenters disagreed with CMS' proposed work RVU of 1.08 for CPT code 76988. Commenters stated that CPT code 76988 describes ultrasound image acquisition performed in the operating room through an open chest in a sterile field where the ultrasound probe is placed directly on the patient's beating heart. Commenters stated that the cardiologist can provide guidance to the cardiothoracic surgeon to ensure capture of certain views and that work by the cardiologist is captured in CPT code 76989. The physician work involved in placing and manipulating the echo probe both before surgical repair and after repair with various suture lines requires careful manual manipulation and positioning by the cardiothoracic surgeon in order to obtain certain views. The commenters stated that, because of the abnormal structure of the heart and the surgical repair, the normal external landmarks for probe positioning are not present adding increased complexity to the procedure.

Response: We agree with commenters that the proposed work RVU does not adequately account for the complexity of the intraoperative ultrasound image acquisition performed on a beating heart with abnormal heart structure and are finalizing the RUC-recommended work RVU of 1.20 for CPT code 76987.

Comment: Some commenters disagreed that the combination of CPT codes 76988 and 76989 should equal the value for CPT code 76987, and stated that this methodology is flawed and inconsistent with how CMS pays for most services that are performed by multiple providers for which CMS provides payment that is greater than 100% to the two surgeons. The commenters stated that when there are co-surgeons (modifier 62), CMS's payment of 125 percent is split between the two surgeons. Similarly, when there is an assistant at surgery (modifier 80), CMS pays the primary surgeon 100 percent and the assistant at surgery 16 percent. Commenters also disagreed with the proposed median intraservice time of 15 minutes rather than the RUC-recommended 75th percentile intraservice time, stating that pediatric cardiologists completing the survey underestimated the amount of time they spent in the operating room and stated that the nature of the service where the cardiologist is not in the operating room during the entire procedure but rather in the operating room prior to the repair(s), leaves and then comes back at the completion of the repair(s) could have resulted in the survey respondent's underestimation of time. Therefore, the commenters stated that the 75th percentile intraservice time of 20 minutes is more appropriate for CPT code 76989.

Response: We continue to believe that, because this family is broken down into service parts in the same way CPT codes 93312 through 93314 and 93315 through 93317 are, the work RVUs for CPT codes 76988 and 76989 should not sum to more than the aggregate work RVU for CPT code 76987. We did not receive comments that clarified the intensity of each part of the service as broken out from the aggregate work RVU of CPT code 76987 to adequately account for the cardiothoracic surgeon and cardiologist's time and intensity to perform CPT codes 76988 and 76989. Commenters only stated that co-surgeons and assistants at surgery are paid more than 100 percent and commenters reiterated that the RUC recommended that CPT code 76989 to be valued higher than CPT code 76988. While this is true, these codes along with the intraoperative TEE codes for congenital cardiac anomalies are not structured to allow the billing of co-surgeons or assistants at surgery. Rather, the CPT Editorial Panel structured these codes to have clearly sanctioned, disaggregated service parts to allow for

multiple providers to perform different parts of the aggregate service represented by CPT codes 76987 and 93315.

As stated above, CPT code 93317 represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the cardiac anesthesiologist, represented by CPT code 93316. Similarly, CPT code 76989 represents interpretation and report only, which is typically performed by a cardiologist according to the Summary of Recommendations. We note that the services as described by the disaggregated component CPT codes 76988 and 76989 would likely be an assistant at surgery situation if the codes were structured to be billed this way because CPT code 76989 is described as the cardiologist assisting the cardiothoracic surgeon on probe placement and manipulation with real-time image interpretation, guidance, and discussion of the findings before and after the cardiac repair(s) to ensure accurate image acquisition and to determine if the repair(s) is adequate or additional procedures are needed after the cardiac repair is complete. In this case, where the cardiologist is acting as an assistant at surgery, the primary surgeon who is actually placing and manipulating the probe on the beating heart would be paid 100 percent and the assistant surgeon would be paid 16 percent. If this were the case, the cardiologist that performs the work described by CPT code 76989 would be valued at 0.30 work RVUs (based on 16 percent of the finalized work RVU of 1.90 for CPT code 96987). Similarly, CPT code 93315 cannot be billed with modifier 62 or 80, but rather the codes were structured to allow for multiple providers to perform different parts of the aggregate service represented by CPT code 93315 by cardiologists and cardiac anesthesiologists, yet the work RVUs of CPT codes 93317 and 93316 do not total more than the work RVU of CPT code 93315.

We continue to believe that the sum of the work RVUs for CPT codes 76988 and 76989 should not be more than the aggregate work RVU of CPT code 76987 and disagree with the RUC that CPT code 76989 should be valued higher than CPT code 76988 based on the code descriptions and breakdown of service parts. Therefore, we are finalizing a work RVU of 0.70 for CPT code 76989 based on the subtraction of the finalized work RVU of 1.20 for CPT code 76988 from finalized work RVU of 1.90 for CPT code 76987. We subtracted these final work RVUs from each other to calculate the work RVU for CPT code 76989 to maintain the relationship where the work RVUs for CPT codes 76988 and 76989 sum to the work RVU of CPT code 76987. We note that commenters did not respond to the request for additional information that clarified the intensity of each part of the service as broken out from the aggregate work RVU of CPT code 76987 to adequately account for the cardiothoracic surgeon and cardiologist's time and intensity to perform CPT codes 76988 and 76989. We note that this final work RVU is greater than the 0.30 work RVUs that the cardiologist would receive if the surgeons were able to bill CPT code 76987 with modifier 80, greater than the proposed work RVU of 0.54, and greater than the work RVU of 0.63 that would result if we maintained the proposed methodology for calculating a work RVU for CPT code 76989, in which it where it was based on ⅓ of the work RVU of CPT code 76987 (1.90 * ⅓ = 0.63).

With regards to the intraservice time for CPT code 76989, we agree with the commenters that it is possible that the survey respondents underestimated their intraservice time because they are in and out of the operating room throughout the procedure, and that it is typical that the cardiologist spends 20 minutes of intraservice time for CPT code 76989 rather than the proposed 15 minutes. Therefore, we are finalizing the RUC-recommended work times for CPT code 76989 as follows: 5 minutes of pre-evaluation time, 20 minutes of intraservice time, and 10 minutes of immediate postservice time for total time of 35 minutes.

After consideration of the public comments, we are finalizing the proposed work RVUs for CPT codes 76984 and 76998 of 0.60 and 0.91, respectively, the RUC-recommended work RVUs of 1.90 and 1.20 for CPT codes 76987 and 76988, respectively, and a work RVU of 0.70 for CPT code 76989.

(17) Percutaneous Coronary Interventions (CPT Code 92972)

In September 2022, the CPT Editorial Panel created one new Category I CPT code for percutaneous coronary lithotripsy. Sixteen other percutaneous coronary intervention (PCI) codes were considered part of the code family but were ultimately not reviewed by the RUC. New add-on CPT code 92972 was reviewed by the RUC on an interim basis for CY 2024 while the entire percutaneous coronary intervention code family was referred to the CPT Editorial Panel for restructuring for the CY 2025 cycle.

We proposed the RUC-recommended work RVU of 2.97 for CPT code 92972 (*Percutaneous transluminal coronary lithotripsy*). The RUC did not recommend and we did not propose any direct PE inputs for this facility-based add-on service.

Comment: Several commenters thanked CMS for our consideration and for proposing the RUC's recommended work RVU for this code.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVU and lack of direct PE inputs for CPT code 92972 as proposed.

(18) Auditory Osseointegrated Device Services (CPT Codes 92622 and 92623)

In February 2022, the CPT Editorial Panel created CPT code 92622 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes*) and 92623 *(Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (list separately in addition to code for primary procedure)* for CY 2024. CPT code 92623 serves as the add-on code for base CPT code 92622.

We proposed the RUC-recommended work RVU of 1.25 for CPT code 92622 and 0.33 for CPT code 92623. We also proposed the RUC-recommended direct PE inputs for both codes. Additionally, because audiologists provide these services, we proposed to add CPT codes 92622 and 92623 to the list of audiology services that can be billed with the AB modifier, that is personally provided by audiologists without a physician/NPP referral for non-acute hearing conditions—the list for CY 2023 is available at *https://www.cms.gov/audiology-services.*

Comment: A majority of commenters supported the CMS proposal of the RUC-recommended values for CPT codes 92622 and 92623, as well as the proposal to add the AB modifier.

Response: We thank the commenters for their support.

Comment: One commenter disagreed with the valuation of these codes and stated that the RVU work value of 1.25 for CPT code 92622 is lower than other, less technical timed audiology codes and as a result will cause financial problems for audiologists to continue providing these procedures. This commenter urged CMS to reconsider the valuation of these codes.

Response: We thank the commenter for their feedback but we continue to believe that the RUC-recommended

values for these codes are correct. The RUC's recommended work RVU was based on a survey of 45 audiologists and supported by two key reference service codes: CPT codes 92626 (Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour) (work RVU = 1.40, 7 minutes pre-service, 60 minutes intra-service and 10 minutes post-service time)) and 92603 (Diagnostic analysis of cochlear implant, age 7 years or older; with programming) (work RVU = 2.25, 20 minutes pre-service, 82 minutes intra-service and 20 minutes post-service time)). These codes are optimal comparators as both have similar intensity to the surveyed code and service period times that increase respectively as the RVU increases. These reference service codes demonstrate appropriate relativity within other XXX-global audiologic and hearing implant testing services.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92622 and 92623 as proposed.

(19) Venography Services (CPT Codes 93584, 93585, 93586, 93587, and 93588)

In February 2022, the CPT Editorial Panel created six new CPT add-on codes to describe Venography services that are performed during cardiac catheterization for congenital heart defects in the superior vena cava (SVC), the inferior vena cava (IVC), and in other congenital veins, that will be reported in conjunction with the main cardiac catheterization procedure codes (CPT codes 93593–93598). CPT codes 93584 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*) and CPT codes 9X001 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; inferior vena cava (List separately in addition to code for primary procedure)*) were to replace the two more general CPT codes 75827 (*Venography, caval, superior, with serialography, radiological supervision and interpretation*) and 75825 (*Venography, caval, inferior, with serialography, radiological supervision and interpretation*). CPT code 9X001 has since been rescinded, and all the remaining new add-on codes have been clarified to state in their descriptors that they are specifically for congenital heart defects.

For CPT code 93584 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*), the AMA RUC proposed a work RVU of 1.20 for 10 minutes of intra-service time and total time. We proposed the AMA RUC recommended work RVU of 1.20 with 10 minutes of intra-service time and total time for CPT code 93584.

For CPT code 93585 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure)*), the AMA RUC proposed a work RVU of 1.13 for 10 minutes of intra-service time and total time. We noted that this code has the same number of minutes as CPT code 93584, but with a lower recommended work RVU. We proposed the AMA RUC recommended work RVU of 1.13 with 10 minutes of intra-service time and total time for CPT code 93585.

For CPT code 93586 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)*) the AMA RUC proposed a work RVU of 1.43 for 12 minutes of intra-service time and total time. We noted that this code has two additional minutes than CPT code 93584 which is 20 percent more in physician time than the 10 minutes from CPT code 93584. We proposed the AMA RUC recommended work RVU of 1.43 with 12 minutes of intra-service time and total time for CPT code 93586.

For CPT code 93587 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)*), the AMA RUC proposed a work RVU of 2.11 for 16 minutes of intra-service time and total time. We noted that this code has six additional minutes more than CPT code 93584 (10 minutes), which is 60 percent more physician time. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 93587, we believe that it would be more accurate to propose a work RVU of 1.92 to account for this increase in the surveyed work time as compared with CPT code 93584. Therefore, we proposed a work RVU of 1.92 along with 16 minutes of intra-service time and total time for CPT code 93587.

For CPT code 93588 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition to code for primary procedure)*), the AMA RUC proposed a work RVU of 2.13 for 17 minutes of intra-service time and total time. We noted that this code has seven additional minutes more than CPT code 93584 (10 minutes), which is 70 percent more physician time than CPT code 93584. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 93588, we believe that it would be more accurate to propose a work RVU of 2.04 to account for this increase in the surveyed work time as compared with CPT code 993584. Therefore, we proposed a work RVU of 2.04 along with 17 minutes of intra-service time and total time for CPT code 93588.

The RUC did not recommend and we did not propose any direct PE inputs for the five codes in the Venography Services family.

Comment: We received a few comments concerning these five new add-on codes for Venography congenital heart defect(s). All commenters were in favor of CMS accepting the AMA RUC recommended work RVUs for CPT codes 93584, 93585, and 93586. All commenters were also not in favor of the CMS proposed work RVUs for CPT codes 93587 and 93588, and they urged CMS to withdraw our proposed values and accept the RUC recommended values. Additionally, commenters stated that CPT codes 93584, 93585, 93586, 93587 and 93588, which were introduced for review as a family of congenital heart catheter add-on codes, are actually more of a selectively unique group of codes that are distinct from one another, rather than a family of codes in

the usual sense, and CMS had mistakenly treated them as a usual family of codes.

Response: We agree with the commenters regarding the grouping of these congenital heart catheter add-on codes. We acknowledge that these codes are services that are selectively unique and distinct from one another, and that they are not a just family of codes that are a series of similar services, as in having a base code with successively increasing values of magnitude of similar iterations in a rank order. As a result, we are finalizing the AMA RUC recommended work RVUs of 2.11 for CPT code 93587, and 2.13 for 93588. We are also finalizing the AMA RUC recommended work RVUs for CPT codes 93584, 93585, and 93586, as proposed.

(20) Post Operative Low-Level Laser Therapy (CPT Code 97037)

In May 2022, the CPT Editorial Panel created CPT code 97037 (*Application of a modality to 1 or more areas; low-level laser therapy (i.e., non-thermal and non-ablative), for post operative pain reduction*) to describe the application of low-level laser therapy for post operative pain reduction. The RUC did not offer a recommendation on CPT code 97037 and we did not realize that this code would be added to the CPT code set for CY 2024 until after the publication of the proposed rule. Although we did not receive recommendations for CPT code 97037 and did not have the opportunity to solicit public comments on its valuation, we are finalizing non-covered status (Procedure Status ''N'') for CPT code 97037 because NCD 270.6 states: The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy, is non-covered for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues. Thus, it is noncovered by Medicare.

(21) General Behavioral Health Integration Care Management (CPT Code 99484, and HCPCS Code G0323)

We proposed to refine the work RVU of both CPT code 99484 and HCPCS code G0323, (see section II.J.1.c. of this final rule), by increasing the work RVU to 0.93 from the current 0.61 and increasing the work time to 21 minutes to match the results of the surveyed work time. For CPT code 99484 we proposed the direct PE inputs as recommended by the RUC without refinement. We also proposed the same PE inputs for HCPCS code G0323.

CMS created four behavioral health integration (BHI) HCPCS G-codes for CY 2017. In 2018 the codes were replaced by new CPT codes. At that time RUC specialty societies undertook a survey, but the RUC did not use the survey results to establish work RVUs, and instead adopted the valuations we had finalized in 2017. For CY 2017 we finalized a work RVU of 0.61 based on a direct crosswalk from CPT code 99490 (chronic care management services) (81 FR 80351). We recognized that the services described by CPT code 99490 are distinct from those furnished under BHI, but we stated that until we have more information about how the services described by HCPCS code G0507 (replaced in 2018 by CPT code 99484) are typically furnished, we believed valuation based on an estimate of the typical resources would be most appropriate (81 FR 80351). For CY 2022 we increased the value of CPT code 99490 from 0.61 to 1.00 (86 FR 65118).

In the CY 2023 PFS final rule (87 FR 69549), we finalized a new HCPCS code G0323 (care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month. (*These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*) (See section II.J.1.c. of this final rule, for final code descriptor refinement.) We valued HCPCS code G0323 based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, because we believed the services described by HCPCS code G0323 mirrored those described by CPT code 99484. We noted that we may consider changes in how this code is valued for future rulemaking.

We continue to be concerned about undervaluing care management services under the PFS given the variability of costs involved with these evolving models of care. The RUC has recommended revaluing CPT code 99484, following a survey of 63 respondents. The median survey work RVU was 1.30, and the median time was 21 minutes (all intra-service). The specialty societies recommend a value of 0.93 based on a crosswalk to code 99202. We believe the specialty societies are in a good position to understand the evolving practice models. The RUC has recommended the 25th percentile survey work RVU of 0.85. Consistent with our goals of ensuring continued and consistent access to these crucial care management services we are finalizing to increase the work RVU of CPT code 99484 to 0.93. This value reflects the work RVU of CPT code 99202, which has a similar work time.

We continue to believe that the services described by HCPCS code G0323 (section II.J.1.c. of this final rule) closely mirror those described by CPT code 99484. As we proposed to update the work RVU and one of the PE inputs for CPT code 99484, we continue to believe that a direct crosswalk to the work values and direct PE inputs for CPT code 99484, is an appropriate valuation of the level, time, and intensity of the services under HCPCS code G0323 (section II.J.1.c. of this final rule). As such we proposed to value HCPCS code G0323, (section II.J.1.c. of this final rule), based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, previously in this section.

We continue to believe that there is a systemic undervaluation of work estimates for behavioral health services. We proposed values for CY 2024 that we believe will more accurately value the work involved in delivering behavioral health services.

Comment: Nearly all commenters were supportive of our proposal to increase payment for general behavioral health integration services. Some also expressed their appreciation for our support for multiple evidence-based models of integrated care, as it allows psychologists the flexibility required to support the behavioral health needs of the broader community. Some requested that we increase the payment for CPT code 99484 and HCPCS code G0323 to, at a minimum, account for the lower reimbursement rate that nonphysician MH and SUD counselors receive for delivering these services (75 percent of the Physician Fee Schedule) and ensure that such providers receive an adequate rate. Other commenters urged us to ensure the reimbursement rates are adequate, accounting for the systemic undervaluation of work for behavioral health services and increase where appropriate.

Response: We thank commenters for their overwhelming support for our

proposal. We note that the statute requires that clinical social workers are paid 75 percent of the amount paid to clinical psychologists. We also note that we are refining the code descriptor for HCPCS code G0323 to allow two new provider types to bill HCPCS code G0323. We refer commenters to section II.J.1.c. of this final rule for discussion of these two new provider types and to section II.J.5. of this final rule discussion of steps we are taking to improve the accuracy of the valuation of behavioral health services. We are finalizing values for CPT code 99484 and HCPCS code G0323, as proposed.

Comment: Some commenters requested that CMS consider creating a code for 20 minutes of additional care management services for behavioral health conditions. One commenter requested that CMS also increase payment for the three Collaborative Care Model behavioral health integration codes. Another requested that CMS also increase payment for Screening, Brief Intervention, and Referral to Treatment (SBIRT) services (HCPCS codes G0396 and G0397) to encourage greater integration of SUD treatment in primary care and more widespread screening for SUDs.

Response: We may consider the development of a code for 20 additional minutes of care management services for behavioral health conditions in future rulemaking. We note that we have a process for potentially misvalued codes, whereby we adjust the codes' RVUs taking into account recommendations provided by interested parties. On an annual basis prior to developing the proposed rule, we seek nominations from the public and from interested parties for codes that they believe we should consider as potentially misvalued. We invite the commenters to make such nominations per the process outlined in section II.C. of this final rule.

Comment: One commenter encouraged us to ensure that non-Medicare eligible Addiction Counselors and peer support specialists be permitted to participate in furnishing BHI services, consistent with applicable requirements for auxiliary personnel.

Response: We thank the commenter for raising the contributions that addiction counselors and peer support specialists might be able to make in the delivery of general behavioral health integration services as auxiliary personnel. CPT code 99484 may be billed by a physician or nonphysician practitioner (NPP), referred to as a qualified health care professional in the AMA's CPT Editorial Panel CPT® codebook, whose State licensure and scope of practice includes evaluation & management (E/M) services and who is authorized under their Medicare statutory benefit category to bill Medicare independently for their services (See FAQs about billing Medicare for BHI services, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Behavioral-Health-Integration-FAQs.pdf*). Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner), under § 410.26. This regulation permits payment for services and supplies furnished by the physician or other practitioner with an incident to benefit or auxiliary personnel. Auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. As such, a physician or NPP would be able to bill for behavioral health integration services furnished by addiction counselors and peer support specialists as auxiliary personnel under their general supervision if the addiction counselors and peer support specialists meet all the requirements under § 410.26.

We created HCPCS code G0323 specifically for clinical psychologists and social workers (section II.J.1.c. of this final rule), whose scope of practice does not include evaluation & management (E/M) services, to bill general behavioral health integration services. Only clinical psychologists have an incident to benefit enabling them to bill for general behavioral health integration services furnished under their general supervision by auxiliary personnel.

Comment: One commenter expressed dissatisfaction with the adequacy of the behavioral health integration codes and on that basis stated there was no need to increase their payment rates at this time. On the other hand, the commenter did offer that over time CMS should review and increase payment for more mental health and substance use services and integrated care codes to incentivize more providers to participate in Medicare and support innovation.

Response: We thank the commenter for their perspective and feedback. As discussed in the proposal we agree with the RUC and specialty societies that an increase in work RVUs is appropriate at this time. We are finalizing as proposed the work RVUs for both CPT code 99484 and HCPCS code G0323, (see section II.J.1.c. of this final rule), by increasing the work RVU to 0.93 from the current 0.61 and increasing the work time to 21 minutes to match the results of the surveyed work time. For CPT code 99484, we are finalizing the direct PE inputs as recommended by the RUC without refinement. We are also finalizing the same PE inputs for HCPCS code G0323.

(22) Advance Care Planning (CPT Codes 99497 and 99498)

In January 2022, the Relativity Assessment Workgroup reviewed CPT codes 99497 and 99498. The Workgroup determined these advance care planning services should be examined given the recent changes in evaluation and management services. The RUC recommended that CPT codes 99497 and 99498 be surveyed for physician work and practice expense for the April 2022 RUC meeting. The RUC recommended no changes in physician time, work RVUs, or direct PE inputs for these services for CY 2024.

We proposed the RUC-recommended work RVU of 1.50 for CPT code 99497 and 1.40 for CPT code 99498, which are the current values for these codes. We proposed the RUC-recommended direct PE inputs for these codes without refinement.

Comment: Some commenters supported our proposal to value these services with the RUC-recommended work RVUs and direct PE inputs without refinement.

Response: We appreciate the support of commenters.

Comment: One commenter did not support our proposal and stated that we should instead finalize work RVUs based on the survey median values, stating that the fact that CPT code 99498 is valued at an interval between the 25th and the median work RVU is anomalous and that the proposed values do not reflect that primary care delivery has become significantly more complex for providers and patients.

Response: As the commenter noted, the RUC survey material states, ''When CPT code 99498 is reported, it is typically a much more difficult situation that requires extra time and effort beyond that required for the base code and usually includes the presence of family members. This add-on code is more intense than the first 30 minutes of advance care planning because the physician or qualified health care professional (QHP) is not just filling out forms but is working through contentious and difficult issues and educating the family members on all diagnoses to reach planning decisions.'' We believe this difference in intensity between the two codes is accurately reflected in the slightly higher intensity of CPT code 99498 that results from the RUC-recommended values.

After considering the comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for these codes without refinement, as proposed.

(23) Pelvic Exam (CPT Code 99459)

In September 2022, the CPT Editorial Panel created a new CPT code for reporting a pelvic exam—CPT code 99459. The specialty societies noted that reimbursement for the work would be captured with the problem-oriented E/M code billed for the visit. The CPT Editorial Panel agreed, thus the new code is a practice expense only code that captures the direct practice expenses associated with performing a pelvic exam in the non-facility setting. CPT code 99459 (*Pelvic Exam*) captures the 4 minutes of clinical staff time associated with chaperoning a pelvic exam.

We proposed the RUC-recommended direct-PE inputs for CPT code 99459 without refinement. As a PE-only service, the RUC did not recommend and we did not propose a work RVU for this code.

Comment: One commenter noted that they believe there was an error with Addendum B regarding the PE RVUs for CPT code 99459.

Response: We thank the commenter for their support. We do not believe there is an error in Addendum B for CPT code 99459. The PE RVUs are listed correctly with 0.68 RVUs for non-facility and ''NA'' for facility, as there are no direct-PE inputs for this code in the facility setting.

After consideration of the public comments, we are finalizing our direct PE inputs for CPT code 99459 as proposed.

(24) Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT Codes 96547 and 96548)

In September 2022, the CPT Editorial Panel created two time-based add-on Category I CPT codes 96547 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes*) and 96548 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes*). CPT codes 96547 and 96548 were surveyed for the January 2023 RUC meeting. While reviewing the survey data, it was noted by specialty societies that the instructions were not sufficient as the survey data reflected time estimates that exceeded the time specified in the new time-based code descriptors. The RUC has stated that the survey results for both CPT codes 96547 and 96548 are inaccurate and that the codes should be resurveyed for 2025. Therefore, the RUC recommended contractor pricing for CPT codes 96547 and 96548 and that they be referred to the CPT Editorial Panel for revision.

We proposed to contractor price CPT codes 96547 and 96548 for CY 2024.

Comment: We received comments in support of our proposed contractor pricing for Hyperthermic Intraperitoneal Chemotherapy (HIPEC).

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing contractor pricing for these codes as proposed.

(25) Hyperbaric Oxygen Under Pressure (HCPCS Code G0277)

In 2015, CMS created HCPCS code G0277 (*Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval*) to describe direct practice expense inputs associated with CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) (consistent with the Medicare Hospital Outpatient Prospective Payment System coding mechanism). At the September 2022 Relativity Assessment Workgroup meeting, HCPCS code G0277 was identified as a high-volume growth code with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2022 and was reviewed at the January 2023 RUC meeting. Hyperbaric oxygen therapy is typically administered to one patient in one hyperbaric chamber for 2 hours. Two hours is typical, and all inputs are prorated for four units being performed (each 30 minutes, totaling 2 hours). All medical supply and time inputs were divided into quarters.

There was a change in the dominant specialty providing this service, which is now primarily performed by family medicine. There was also a change in clinical staff type, and it is now typical for a single staff person to perform all activities (RN/Respiratory Therapist) as opposed to two staff (an RN/LPN/MA and an RN/respiratory therapist). This was primarily due to a 2016 change by the National Board of Diving and Hyperbaric Medical Technology to no longer allow certified nursing assistants and certified medical assistants to be eligible to take the certified hyperbaric technologist examination. The PE Subcommittee agreed with the specialty societies to update the clinical staff type to reflect solely L047C *RN/Respiratory Therapist.* We agreed with the specialties that the intra-service time is more appropriately labeled as clinical activity CA021 (*Perform procedure/service—NOT directly related to physician work time*) as opposed to CA018 due to the change in clinical staff type.

We proposed to refine the clinical labor time for the CA013 activity (*Prepare room, equipment, and supplies*) from 1.5 minutes to 0.5 minutes, as well as the clinical labor time for the CA016 activity (*Prepare, set-up and start IV, initial positioning and monitoring of patient*) from 1 minute to 0.5 minutes to align with the 2-minute standard for these clinical activities. We arrived at these refinements by dividing the standard 2-minutes of clinical labor times for CA013 and CA016 by four to account for all inputs being prorated for four units being performed for one typical 2-hour session. CA013 and CA016 would each be 0.5 minutes per 30-minute interval, which amounts to the standard 2 minutes for these clinical activities when four units are billed for the typical 2-hour session. The RUC recommended 30 minutes for clinical labor activity CA021 *(Perform procedure/service—Not directly related to physician work time (intra-service time)* based on a flawed assumption that the current 15 minutes for CA021 accounts for two patients receiving treatment simultaneously. We noted that it had been standard for one patient to receive treatment at a time, and the current 15 minutes for CA021 was based on a time ratio to the CY 2015 RUC-recommended direct PE inputs for CPT code 99183; therefore, we disagreed with this RUC recommendation and proposed to refine the recommended intra-service CA021 clinical labor time to maintain the current 15 minutes. This was to reflect the 2015 PFS final rule where ''we used the RUC recommended direct PE inputs for CPT code 99183 and adjusted them to align with the 30-minute treatment interval'' (79 FR 67677). Each PE input was prorated for four units of HCPS code G0277 being provided in one typical 2-hour session. Since CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) was a 120-minute code with 60-minute intra-service time, all PE inputs in HCPCS code G0277 were prorated for four units being performed.

To conform to these changes in clinical labor time, we also proposed to refine the equipment time for the EQ362 (*HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve)*) and

EQ131 (*hyperbaric chamber*) equipment items from the recommended 39.75 minutes to 23.25 minutes. This was a result of the 15-minute intra-service time, as opposed to the RUC recommendation of 30 minutes of intra-service time.

Comment: We received many public comments disagreeing with the proposed refinements to the intra-service time (CA021) for HCPCS code G0277. Many of these comments were based on a concern for patient safety and supervision. Commenters stated that the standard of practice for patient safety is attendance and availability of clinical staff for 100 percent of the time. In case of an adverse event that could occur at any point in treatment, the clinical staff must be present to notify the physician to alter or stop the treatment. One staff member per patient must be available to carry out emergency procedures. Commenters provided many scenarios where an adverse event may require clinical staff attendance and availability. Due to this standard of practice, commenters stated that it is necessary for the clinical staff time to align with the code descriptor (30 minutes). The 30-minute clinical staff time is required because the patient is at pressure for longer than the 15-minute proposed time during the treatment. In a standard 2-hour session, which would account for four units of HCPCS code G0277, patients are at pressure for 106–110 minutes. Having a clinical staff time for a total of 60-minutes would not meet the standard of practice in which the clinical staff is in attendance for the entire treatment. There were similar comments regarding the equipment times; commenters specified that the equipment is used the entire treatment time. Commenters also provided information about the rarity of multiple patients to receive treatment at the same time, so intra-service time must be 30 minutes.

Response: We agree with the commenters and are finalizing the RUC-recommended clinical labor time of 30 minutes for the CA021 clinical labor task. We acknowledge that this time is needed to meet the standard of practice for clinical staff supervision during the entire treatment to ensure patient safety and to align with the time that patients are at pressure. This will also affect the equipment times (EQ362 and EQ131), adjusting each to 38.25 minutes to align with the adjustment to clinical staff time. This is because clinical labor task CA021 is used in the formula to calculate EQ362 and EQ131, so any refinements to CA021 also changes those values. We are finalizing RUC proposed values for CA021, EQ362, and EQ131.

Comment: Many commenters pointed out that clinical staff must be supervised by a physician the entire time, so clinical staff time should not be separate from physician work.

Response: The change in designation of intra-service time from CA018 to CA021 was a RUC recommendation that CMS agreed with. We specify that clinical staff are supervised by physicians during the entirety of the treatment. Physician or QHP work is accounted for in CPT code 99183 (Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy), while HCPCS code G0277 solely accounts for practice expenses associated with hyperbaric oxygen therapy. The change from the CA018 to the CA021 clinical labor task is a clerical update to reflect the fact that HCPCS code G0277 does not have an intraservice work time by virtue of being a PE-only code. We are finalizing as proposed to change the intra-service time from CA018 to CA021, consistent with the RUC recommendations.

Comment: We received many public comments disagreeing with CMS' proposed refinements to the clinical staff time (CA013 and CA016) which CMS proposed at 0.5 minutes per 30-minute interval, which amounts for each of them to equal the standard 2 minutes for these clinical activities when four units are billed for the typical 2-hour session. Commenters stated that clinical activities must align with the same clinical labor values for CPT code 99183 (the code for this service that is associated with physician work), which exceed the 2-minute standard. One commenter stated that during this clinical activity time, clinical staff complete additional activities. Commenters specified that one reason for clinical activity time to be beyond the standard, is due to increased need for disinfecting and infection control for the next patient.

Response: We note that all input values for HCPCS code G0277 do not align with CPT code 99183, and therefore, clinical activity times do not need to have the same values. We do not agree that CA013 and CA016 exceed the 2-minute standard for those inputs. We calculated these times to align with these specific clinical activities (in this case CA013 and CA016). Each clinical activity has a separate time calculation; therefore, the 2 minutes total for CA013 only includes preparing the room, equipment, and supplies. The 2 minutes total for CA016 only includes preparing, setting up and starting the IV and initial positioning and monitoring of patient. We do not consider staff completing additional activities during these specified times . We note that we did not adjust any of the time requirements that involve post-service time, for example cleaning rooms and equipment. The refinements to CA013 and CA016 that we are finalizingdo not affect the time spent ensuring infection control. We would also like to note that CA013 and CA016 are not the only aspects of pre-service for the treatment, they are the only ones that had refinements in this rulemaking cycle. All other values for pre-service time are aligned with the RUC recommendations. We disagree with commenters and are finalizing the proposed time refinements for CA013 and CA016 to align with the standard 2 minutes for these clinical activities.

After consideration of the public comments, we are finalizing the proposed CA013 and CA016 direct PE inputs for HCPCS code G0277 and we are finalizing the RUC-recommended clinical labor time of 30 minutes for CA021 and equipment times (EQ362 and EQ131) of 38.25 minutes, as detailed above.

(26) Remote Interrogation Device Evaluation—Cardiovascular (HCPCS Code G2066, and CPT Codes 93297, and 93298)

CPT code 93299 *(Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisitions(s),* receipt of transmissions and technician review, technical support and distribution of results) was meant to serve as a catch-all for both base CPT codes 93297 and 93298, which are work-only codes. However, the CPT Editorial Panel determined that CPT code 93299 was no longer necessary if CPT codes 93297 and 93298 were assigned direct PE inputs and therefore recommended CMS to delete CPT code 93299 at the beginning of CY 2020 under the assumption that CPT codes 93297 and 93298 would be assigned direct PE inputs. Since CMS did not agree with the recommended values, CMS decided to not allocate direct PE inputs for CPT codes 93297 or 93298 and instead created contractor priced HCPCS code G2066 for CY 2020 to ensure these services could still be furnished that were previously described under CPT code 93299 (84 FR 62777 and 62778). Since the publication of the CY 2020 PFS final rule, HCPCS code G2066 has remained contractor priced and CPT codes 93297 and 93298 remain as work-only codes. CMS continues to work with MACs and

interested parties to address a lot of the payment concerns surrounding G2066 such as discrepancies in payment between jurisdictions. However, interested parties have indicated that a long-term solution is needed from CMS in order to help establish payment stability for these services.

Therefore, for CY 2024, we proposed to delete HCPCS code G2066 and proposed the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. Since CPT code 93298 is most commonly billed with G2066, the RUC recommended the same inputs for CPT code 93298 and HCPCS code G2066 in the event that no change would be made for HCPCS code G2066. Since CMS does agree with the RUC recommended values, we proposed to delete HCPCS code G2066 altogether and establish direct PE-inputs for CPT codes 93297 and 93298 based on the RUC recommendations.

The RUC did not make recommendations on, and we did not propose any changes to the work RVUs for CPT codes 93297 and 93298.

Comment: One commenter disagreed with the proposal to delete HCPCS code G2066 and establish direct PE inputs for CPT Codes 93297 and 93298 because they believed CMS did not establish an alternative billing mechanism to allow continued access to these services in the facility setting.

Response: We disagree with the commenter that access to these services will be altered with the coding change. We note that the services which were previously billed under HCPCS code G2066 will now be billed under CPT codes 93297 and 93298. This will only change how the services will be reported but access to these services will remain the same.

Comment: Several commenters disagreed with the CMS proposal of the RUC's recommended equipment times for the pacemaker follow-up system (incl software and hardware) (Paceart) (EQ198) for CPT codes 93297 and 93298. The commenters stated that the RUC's PE subcommittee decided that the EQ198 equipment is not used when the technician is educating or re-educating the patient and accordingly reduced the total equipment minutes per service assigned to the equipment system. The commenters stated that this is an inaccurate assumption as the equipment must be operational and accessible for the technician to train the patient on how to use and understand the monitor, to review clinical status with the patient, to verify connection status and to further educate the patient about how to initiate transmissions when needed. The commenters recommended that CMS update the equipment time assigned to CPT codes 93297 and 93298 to reflect the total clinical labor time assigned to these services, 33 and 69 minutes, respectively.

Response: We disagree with the commenters and continue to agree with the RUC's recommendation that the EQ198 equipment would not typically be in use when the technician is educating or re-educating the patient. We agree with the commenters that the equipment time would be needed for tasks such as initiating transmissions with the patient and verifying their connection status. However, this equipment time is already incorporated into CPT codes 93297 and 93298 under the 4 minutes allocated for troubleshooting activities, and as a result we continue to believe that EQ198 would not typically require additional equipment time above what the RUC recommended.

Comment: The same commenters stated that if CMS continued to apply fewer minutes of EQ198 equipment time than the total clinical labor time for CPT codes 93297 and 93298, then CMS needed to correct a clerical error in the time assigned to the equipment. The commenters stated that the RUC's recommendations included 4 minutes of clinical labor time for education/re-education tasks, however the equipment time assigned to these services was inadvertently reduced by 11 minutes, in what appeared to be a clerical error. The commenters stated that if CMS would not set the EQ198 equipment time equal to the total clinical labor time assigned to these services, then CMS must correct the equipment time to only remove the 4 minutes assigned to education/re-education and finalize 29 minutes of equipment time for CPT code 93297 and 65 minutes of equipment time for CPT code 93298.

Response: After reviewing this information from the commenters, along with the RUC's recommendations for CPT codes 93297 and 93298, we agree that there appears to be a clerical error in the equipment minutes for EQ198. The RUC provided a sum of clinical labor tasks in its recommendations listing 33 total minutes for CPT code 93297 and 69 total minutes for CPT code 93298. The RUC stated that it was recommending a removal of the 4 minutes of clinical labor time allotted for education/re-education tasks from the EQ198 equipment time, but instead recommended 22 minutes and 58 minutes respectively for the two codes, a decrease of 11 minutes instead of 4 minutes. This was mostly likely an inadvertent error since one of the other clinical labor tasks (Technician requested transmissions) was listed at 11 minutes. We are therefore finalizing an increase in the EQ198 equipment time, for both codes, to 29 minutes for CPT code 93297 and to 65 minutes for CPT code 93298. These refinements should correct the errors and align with what the RUC presumably intended to recommend.

After consideration of the public comments, we are finalizing our proposal to delete contractor priced code HCPCS code G2066 and establish direct PE inputs for CPT codes 93297 and 93298.

(27) Payment for Caregiver Training Services

a. Background

In CY 2022, we received AMA RUC recommendations for a new code family of two codes (CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*) and CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service)*) that described group caregiver training services for patient behavior management/modification (without the patient in attendance). In CY 2023 we received AMA RUC recommendations for a family of three new caregiver training codes (CPT code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 97551 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 97551 in conjunction with 97550)*), and 97552 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or*

community (eg, activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers). Historically, we have taken the position that codes describing services furnished to other individuals without the patient's presence are not covered services. As we noted in the CY 2023 PFS final rule (87 FR 69521), we have explained in previous rulemaking that we read section 1862(a)(1)(A) of the Act to limit Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an individual Medicare patient's illness or injury or that improve the functioning of an individual Medicare patient's malformed body member. For example, in the CY 2013 PFS final rule (77 FR 68979), when discussing payment for the non-face-to-face care management services that are part of E/M services, we stated that Medicare does not pay for services furnished to parties other than the patient. We listed, as an example, communication with caregivers. Because the codes for caregiver behavior management training described services furnished exclusively to caregivers rather than to the individual Medicare patient, we indicated that we did not review the RUC-recommended valuation of these codes or propose to establish RVUs for these codes for purposes of PFS payment. Although we did not establish payment for the new caregiver behavior management training codes in the CY 2023 PFS final rule, we indicated that there could be circumstances where separate payment for such services may be appropriate. We stated that we would continue to consider the status of these and similar services in rulemaking for CY 2024 (87 FR 69522 through 69523). We specifically requested public comment on how a patient may benefit in medical circumstances when a caregiver is trained to effectively modify the patient's behavior, how current Medicare policies regarding these caregiver training services (CTS) can impact a patient's health, and how the services described by these codes might currently be bundled into existing Medicare-covered services. (87 FR 69521). Public comments were generally in favor of CMS making payment for these codes, stating that there is extensive empirical support for training parents/guardians/caregivers in behavior management/modification as a component of the standard of care for the treatment of certain social determinants of health (SDOH) behavior issues and that this training promotes improved outcomes. Commenters also noted that there are several CPT codes paid under the PFS that describe services that do not include direct contact with the patient but are still considered integral to the patient's care, including, for example, separately billable care management services, interprofessional consultations, and caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient. In response to public comments, we acknowledged the important role caregivers could have in a patient's overall care.

As indicated in the CY 2023 PFS final rule, we have continued to consider whether the caregiver behavior management training and similar caregiver training services could be considered to fall within the scope of services that are reasonable and necessary under section 1862(a)(1)(A) of the Act, in alignment with the principles of the recent Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers (*https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/*), and as part of a HHS level review of our payment policies to identify opportunities to better account for patient-centered care (*https://acl.gov/programs/support-caregivers/raise-family-caregiving-advisory-council*), changes in medical practice that have led to more care coordination and team-based care, and to promote equitable access to reasonable and necessary medical services. We also believed it was important for practitioners furnishing patient-centered care to use various effective communication techniques when providing patient-centered care, in alignment with requirements under section 1557 of the Affordable Care Act. We stated that we believe that, in certain circumstances, caregivers can play a key role in developing and carrying out the treatment plan or, as applicable to physical, occupational, or speech-language therapy, the therapy plan of care (collectively referred to in this discussion as the ''treatment plan'') established for the patient by the treating practitioner (which for purposes of this discussion could include a physician; NPP such as a nurse practitioner, physician assistant, clinical nurse specialist, clinical psychologist; or a physical therapist, occupational therapist, or speech-language pathologist). In this context, we believed Caregiver Training Services (CTS) could be reasonable and necessary to treat the patient's illness or injury as required under section 1862 (a)(1)(A) of the Act. We had the opportunity to consider the best approach to establishing separate payment for the services described by the caregiver training codes, especially as it relates to a practitioner treating a patient and expending resources to train a caregiver who is assisting or acting as a proxy for the patient.

For CY 2024, we proposed to establish an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT codes 97550, 97551, and 97552 (caregiver training services under a therapy plan of care established by a PT, OT, SLP). These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. We believed that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example, when the patient cannot follow through with the treatment plan for themselves.

We solicited public comment on this definition of 'caregiver' for purposes of CTS and were interested if there were any additional elements of a caregiver that we considered incorporating in the proposed CTS caregiver definition. We believed that our definition would allow for holistic patient care with those who know and understand the patient, their condition, and their environment. We were interested in and solicited comment on how the clinician and caregiver interactions would typically occur, including when the practitioner is dealing with multiple caregivers and how often these services would be billed, considering the established treatment plan involving caregivers for the typical patient.

We proposed that payment may be made for CTS when the treating practitioner identified a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. We further proposed that because CTS are furnished outside the patient's presence,

the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. We further proposed that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record. In the following discussion, we detail the specific aspects of our proposal and the comments received.

Comment: Most commenters supported the proposals. Many commenters detailed their experiences as caregivers, while others explained how CTS would have benefited them in the past. Some commenters also expressed support for CMS' recognition of the efforts of caregivers in effectuating the treatment of beneficiaries.

Response: We thank commenters for their feedback and value commenters sharing their experiences on how Caregiver Training Services could be beneficial.

Comment: Some commenters opposed our CTS proposals and stated that the proposed services are currently provided by organizations better equipped to provide CTS, such as home health agencies, home and community-based services, and non-profit organizations. Some commenters expressed concern about the efficacy of the services if the patient is not required to be present, while another commenter stated that there was insufficient scientific evidence proving that caregiver training improves patient outcomes. Additionally, one commenter was worried that CTS would cause medical care to be provided by caregivers as opposed to medical providers. Overall, many commenters who opposed CTS suggested direct payment be made to caregivers.

Response: The CTS codes, developed through the AMA CPT Editorial Panel's process, describe training services furnished by a practitioner to effectuate the practitioner's treatment plan to improve treatment outcomes for a patient. We believe there are circumstances where involving the caregiver in the treating practitioner's treatment plan through CTS would improve outcomes for the patient. We also believe that the treating practitioner who develops the treatment plan is best situated to provide CTS to inform the caregiver on how to help effectuate the treatment plan they develop for the patient. The availability of these codes and the provision of these services should not prevent caregivers from seeking support, education, certifications, or assistance from other organizations. As with other established coding, we expect that the treating practitioner who furnishes and bills for CTS to furnish services as described by the codes. Additionally, we note that the codes specify that the patient is not present during the service. We believe this is in recognition that both the practitioner's and the caregiver's undivided attention should be focused on the training that is being furnished to help the caregiver carry out an established treatment plan. In response to comments about the effects on patient eligibility to receive care under other programs or by medical providers, we clarify that the provision of CTS to a patient's caregiver does not affect patient eligibility for other Medicare services when reasonable and necessary. We clarify for commenters that under the statute, Medicare makes payments under the PFS only to enrolled physicians and other practitioners, not to caregivers. We continue to believe that CTS services have their place in a reasonable and necessary treatment plan for some patients and can serve as an important supplement to other caregiver training and other resources that might be available.

Comment: The majority of commenters supported our proposal to require the patient's (or representative's) consent for the caregiver to receive CTS. One commenter stated that the patient's consent for the initial plan of care is sufficient, so further consent is not needed for CTS. One commenter suggested using the terms ''informed consent'' or ''supported decision making'' instead of consent. Another commenter requested that in cases of an Alzheimer's or dementia diagnosis, patient consent be obtained early in diagnosis. A few commenters expressed that they did not want CTS to be required for the caregiver to participate in. One commenter was concerned about patient privacy if beneficiary consent was not required.

Response: We proposed to specifically require the patient's (or their representative's) consent for CTS because, unlike most services, the patient would not be present for the service. We believed it would be important to make the patient aware, out of concern for patient privacy, that the service is furnished outside their presence and that any applicable cost-sharing would be their responsibility. We do not believe that the general consent to receive treatment would be sufficient to make a patient aware of the unique circumstances under which CTS are furnished. For these same reasons, we continue to believe it is appropriate to require a specific consent for CTS. We are using the term ''consent'' as opposed to other recommended terms to remain consistent across other codes with consent requirements across the PFS. In cases of an Alzheimer's or dementia diagnosis, we encourage providers to obtain consent from the patient or their representative for CTS as early as possible in the diagnosis. We want to emphasize that CTS are not required services but services that the treating practitioner may choose to furnish, with a patient's consent, in consideration of a patient's diagnosis. If caregivers do not want to participate in caregiver training, they are not required to do so. We are finalizing, as proposed, that the patient's (or representative's) consent is required for the caregiver to receive CTS and that the consent must be documented in the patient's medical record.

Comment: Commenters requested more guidance regarding CTS, including specifically asking for descriptions of training sessions, the requirement of post-training resources, materials, or referrals to social agencies to be provided to caregivers, and for CTS to be culturally competent (including being provided in languages other than English and at varying literacy levels). Commenters also requested caregiver assessments to assess burden, capacity, and understanding. Commenters also suggested that CMS require quality standards for CTS and suggested teaching methods. Additionally, one commenter requested that documentation of the caregiver's contact information be required in the patient's health record. Many commenters also provided input about the settings in which CTS are provided, suggesting that CTS could be furnished inside the beneficiary's home, or current residence. Commenters requested that CTS be provided upon discharge from hospitals, skilled nursing facilities, or home health outpatient services. One commenter requested that CTS be included in the definition of primary care services for purposes of beneficiary assignment in the Medicare Shared Savings Program.

Commenters also requested additional coding to describe CTS furnished, for example, when the patient is present for part of all of the training, to recognize reduced time thresholds, to allow auxiliary personnel to perform CTS, or when training is included for additional tasks. Commenters also requested that CTS be added to the Medicare telehealth services list.

Response: We appreciate all the information and considerations included in these comments, which will inform any policy development for CTS

in future rulemaking. We will not be adding these codes to the telehealth list at this time. Additionally, concerns not addressed in this proposed rule, such as quality standards, teaching methods, and additional requirements may be considered for future rulemaking.

In the CY 2024 PFS proposed rule, we proposed a definition of ''caregiver'' for purposes of CTS and discussed the circumstances under which patients may benefit from care involving caregivers. We proposed that CTS may meet the conditions for Medicare payment when the treating practitioner identifies a need to involve and train caregivers to assist the patient in carrying out a treatment plan established by the treating practitioner. We also proposed values for each of the CTS codes.

(1) Definition of a Caregiver

In the CY 2024 PFS proposed rule, we proposed to define ''caregiver'' for purposes of CTS. We stated that in our ongoing education and outreach work on the use of caregivers in assisting patients, we have broadly defined a caregiver as a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition (*https://www.cms.gov/outreach-and-education/outreach/partnerships/caregiver#:~:text=Caregivers%20are%20broadly%20defined%20as,chronic%20illness%20or%20disabling%20condition*). Further, in the context of our proposals for CTS, we believe a caregiver is an individual who is assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling); involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and helping to navigate the patient's transitions between care settings. For purposes of CTS, we also include a guardian in this definition when warranted. For CTS, when we note ''caregiver,'' we are also referring to guardians who for purposes of CTS, are the caregiver for minor children or other individuals who are not legally independent. In these circumstances, a caregiver is a layperson assisting the patient in carrying out a treatment plan that was established for the patient by the treating physician or practitioner and assisted the patient with aspects of their care, including interventions or other activities directly related to a treatment plan established for the patient to address a diagnosed illness or injury. In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, and adherence to treatment related to the patient's primary clinical diagnoses. Caregiver understanding and competence in assisting and implementing these interventions and activities from the treating practitioner is critical for patients with functional limitations resulting from various conditions.

The following is a summary of the comments we received and our responses.

Comment: Many commenters did not favor the proposal to define caregiver for purposes of CTS to include only unpaid individuals, stating that this would unfairly exclude nursing aides, direct service professionals, or individuals paid directly by the beneficiary.

An overwhelming number of commenters requested that CMS use the definition of ''family caregiver'' that was used in the Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act (Pub. L. 115–119). The definition of family caregiver in the RAISE Act is ''an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation.'' The RAISE Family Caregivers Act directs the Secretary of Health and Human Services to develop a national caregiving strategy to recognize and support family caregivers. Commenters requested the RAISE definition because it is more expansive and provides more detail about what a caregiver is than the CMS definition.

Commenters also requested that we remove the terms ''layperson,'' ''proxy'', and/or ''guardian'' from our definition. One commenter requested that we use the term ''care partner'' as opposed to ''caregiver.'' Additionally, we note that commenters generally supported our proposal that CTS could be furnished to more than one caregiver representing the same beneficiary, as someone could have multiple caregivers, or the primary caregiver could change.

Response: We agree that the definition of caregiver matters. For that reason, we agree with commenters that the definition of ''family caregiver'' used in the RAISE Family Caregivers Act does support our CTS proposal as an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation. We will use the RAISE definition and the CMS Outreach and Education definition (a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition). Since the definitions do not contradict each other, we will adopt both definitions of caregiver.

We note that even as we refine our definition of caregiver, we maintain that the caregiver population receiving these services on behalf of the patient should not also receive concurrent CTS under another Medicare benefit category or Federal program (88 FR 52323).

After considering the public comments, we are finalizing a revised definition of caregiver to be ''an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation'' and ''a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition''.

(2) Patients Who Benefit From Care Involving Caregivers

In the proposed rule, we discussed our expectation that a patient-centered treatment plan should appropriately account for clinical circumstances where the treating practitioner believes a caregiver's involvement is necessary to ensure a successful outcome for the patient and where, as appropriate, the patient agrees to caregiver involvement. There may be clinical circumstances when it might be appropriate for the physician or practitioner to directly involve the caregiver in developing and carrying out a treatment plan. Such clinical cases could include various physical and behavioral health conditions and circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. Conditions include, but are not limited to, stroke, traumatic brain injury (TBI), various forms of dementia, autism spectrum disorders, individuals with other intellectual or cognitive disabilities, physical mobility limitations, or necessary use of assisted devices or mobility aids. The previously mentioned clinical scenarios are circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. For example, patients with dementia, autism spectrum disorder, or individuals with other intellectual or cognitive disabilities may

require assistance with challenging behaviors to carry out a treatment plan, patients with mobility issues may need help with safe transfers in the home to avoid post-operative complications, patients with persistent delirium may require guidance with medication management, patients with certain degenerative conditions or those recovering from stroke may need assistance with feeding or swallowing. Separate from medical circumstances noted previously, we also seek to avoid potentially duplicative payment. We would not expect the caregiver population receiving these services on behalf of the patient to also receive CTS on behalf of the patient under another Medicare benefit category or Federal program. Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CTS will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we solicited public comment regarding whether States typically cover services similar to CTS under their Medicaid programs, and whether such coverage would be duplicative of the CTS codes. We solicited comment on this issue and whether payment is currently available for CTS through other Federal or other programs.

The following is a summary of the comments we received and our responses.

Comment: Many commenters suggested various physical and behavioral health conditions and circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. The examples provided include traumatic injury, use of mobility devices, cell therapy, stem cell transplants, cancer, ESRD, lymphedema, rare diseases, and/or chronic conditions.

Additionally, many commenters detailed how these services could overlap with State-funded Medicaid consumer-directed programs and sometimes with our Innovation Center model tests. These commenters also noted that due to variations in Medicaid and other State programs, overlap in payment may be difficult to identify.

Response: The examples we provided in the proposed rule of physical and behavioral health conditions for which CTS might be appropriate were not intended to be exhaustive. We acknowledge that there are many circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. Also, we do not believe participation in Medicaid consumer-directed programs for dually eligible beneficiaries, or our demonstration models would be duplicative of the CTS codes, given how the services are designed and how the consumer-directed programs work. Through the CTS codes, Medicare will pay the treating practitioner to train caregivers. Currently, this is not duplicative of the Medicaid consumer- directed programs due to the limited scope of the CTS. Further, when designing Innovation Center models, we include overlap policies, billing policies, and other model parameters that are specifically designed to avoid duplication.

(3) Reasonable and Necessary CTS

In the CY 2024 PFS proposed rule, we proposed that CTS could be reasonable and necessary when furnished based on an established individualized, patient-centered treatment plan or therapy plan of care accounting for the patient's specific medical needs.

As provided in the code descriptors, treating practitioners may train caregivers in a group setting with other caregivers involved in care for patients with similar needs for assistance to carry out a treatment plan. Training for all the caregivers for the patient could occur simultaneously, and the applicable CTS codes (CPT code 96202, 96203, and 97552) would be billed once per beneficiary. We solicited comment on this issue. We also inquired about whether payment is currently available for CTS through other Federal or other programs. We considered whether CTS would be reasonable and necessary when furnished to caregivers in more than one single session, or to (presumably the same) caregivers by the same practitioner for the same patient more than once per year and solicited comment on this. We want to note that the treating physician or NPP may provide training to more than one caregiver for a single patient.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters stated that CTS would be reasonable and necessary, when furnished to (presumably the same) caregivers (by the same practitioner for the same patient) in more than one single session, more than once per year. Many commenters requested that payment be made per caregiver, not per beneficiary. A few commenters requested that CTS be limited to practitioners who have a longitudinal relationship with the patient.

Response: We agree that the number of CTS sessions furnished to caregivers, by the same practitioner and for the same patient, may be based on the treatment plan, as well as changes in patient condition, the treatment plan, the patient's diagnosis, or the patient's caregivers. In other words, the medical necessity of CTS for the patient should determine the volume and frequency of the training. CTS could be considered reasonable and necessary when the treating practitioner determines a caregiver needs more training to ensure a successful patient treatment plan outcome. We require the treating practitioner to document the need for each occurrence of CTS in the medical record.

To bill for CTS, practitioners should select the appropriate group code (CPT code 96202, 96203, or 97552) if more than one caregiver is trained at the same time, or individual code (CPT code 97550, 97551) if one individual caregiver is trained. If caregivers are trained in a group, practitioners would not bill individually for each caregiver. More than one caregiver trained at the same time must be billed under the group code, as the treating practitioner's time and effort should not be counted multiple times.

After consideration of the public comments, for CY 2024, we are finalizing our proposal for CTS with the following clarifications: the volume and frequency of CTS sessions furnished to caregivers by the treating practitioner for the same patient may be based on the treatment plan, as well as changes in patient condition, the treatment plan, the patient's diagnosis, or the patient's caregivers.

(4) Service Coding and Valuation

Behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis (CPT Codes 96202 and 96203)

a. Coding

CPT code 96202 (*Multiple-family group behavior management/ modification training for parent(s)/ guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/ guardian(s)/caregiver(s); initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of*

patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service)), were two new codes created by the CPT Editorial Panel during its February 2021 meeting. The two codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group behavior management/modification training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at effectuating the practitioner's treatment plan through addressing challenging behaviors and other behaviors that may pose a risk to the person, and/or others. According to the Summary of Recommendations (which was submitted by the AMA RUC with the valuation of this code), during the face-to-face service time, caregivers are taught how to structure the patient's environment to support and reinforce desired patient behaviors, to reduce the negative impacts of the patient's diagnosis on patient's daily life, and to develop highly structured technical skills to manage the patient's challenging behavior.

Behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each behavior should be clearly identified and documented in the treatment plan, and the caregiver should be trained in positive behavior management strategies.

b. Valuation

The RUC recommended the survey median work value for both CPT codes 96202 and 96203. Three specialty societies sent surveys to a random sample of a subset of their members. Based on survey results and after discussion, the RUC recommended a work RVU of 0.43 for a specific patient who was represented in the group session being billed for CPT code 96202. The RUC noted that this recommendation was based upon a median group size of six caregivers and includes 10 minutes pre-time, 60 minutes intra-time, and 20 minutes post-time for a total time of 90 minutes. For CPT code 96203, the 15-minute add on code, the RUC recommended a work RVU of 0.12, which was also based upon a median group size of six. We proposed the RUC-recommended work RVU of 0.43 for CPT code 96202 and the RUC-recommended work RVU of 0.12 for CPT code 96203. We also proposed the RUC-recommended direct PE inputs for these codes. We proposed requiring the full 60 minutes of time to be performed to report CPT code 96202. The add on code, CPT code 96203, may be reported once 75 minutes of total time is performed.

Finally, we note that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon.

Comment: Commenters were generally supportive of the proposed valuations for these codes. A few commenters suggested that higher valuations would more accurately reflect the time and intensity of services provided. These commenters expressed concerns that the proposed values do not reflect the significant amount of planning and effort required by the practitioner who furnishes these services, and that undervaluation of CTS could lead to underutilization or access issues for patients who would benefit from these services.

Response: We believe that the RUC-recommended valuations that we have proposed to adopt reflect the typical inputs for the service. The RUC's recommendations were based on extensive surveys with psychologists, child and adolescent psychiatrists, and dieticians, and represent the best information that we have at present for these new codes. Additionally, the Caregiver Training Services CPT codes fall appropriately between the key reference services used by the RUC to compare the work RVU, total time, and related intensity of each service. We believe that this supports the recommended values as maintaining relativity with other similar services already listed on the PFS.

After consideration of the public comments, we are finalizing our proposed work RVUs and direct PE inputs for CPT codes 96202 and 96203.

Caregiver training in strategies and techniques to facilitate the patient's functional performance (CPT codes 97550, 97551, and 97552)

(a) Coding

CPT codes 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 97551 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 97551 in conjunction with 97550)*), and 97552 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*) were new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADL's). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

During the face-to-face service time, caregivers are taught by the treating practitioner how to facilitate the patient's activities of daily living, transfers, mobility, communication, and problem-solving to reduce the negative impacts of the patient's diagnosis on the patient's daily life and assist the patient in carrying out a treatment plan. These specific services are reasonable and necessary when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. As part of an individualized plan of care, the caregiver is trained in skills to assist the patient in completing daily life activities. These trainings to the caregiver include the development of skills such as safe activity completion, problem solving, environmental adaptation, training in the use of equipment or assistive devices, or interventions focusing on motor, process, and communication skills.

(b) Valuation

The RUC recommended work values for CPT codes 97550, 97551, and 97552 based on the survey median values and the key reference CPT codes 97535 and 97130. The surveyed codes fall appropriately between these key reference services compared to the work

RVU, total time, and related intensity of each service. Three specialty societies sent surveys to a random sample of a subset of their members. Based upon survey results and after discussion, the RUC recommended a work RVU 1.00 for CPT code 97550, a work RVU of 0.54 for 97551, and a work RVU of 0.23 per specific patient represented in the group service being billed for CPT code 97552.

We proposed the RUC-recommended work RVU 1.00 for CPT code 97550, the RUC-recommended work RVU of 0.54 for CPT code 97551, and the RUC-recommended work RVU of 0.23 per identified patient service for CPT code 97552. The RUC noted that the recommendation for 97552 is based on a median group size of five caregivers. We also proposed the RUC-recommended direct PE inputs for these codes.

Finally, we noted that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon. We proposed to designate 97550, 97551, and 97552 as ''sometimes therapy'' services. This means that the services described by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care, that is, where the services are not integral to a therapy plan of care, they can be furnished under a treatment plan by physicians and NPPs.

Comment: Commenters were generally supportive of the valuations of these codes. A few commenters expressed concerns that the proposed values do not reflect the significant amount of planning and effort required by the practitioner who furnishes these services, and that undervaluation of CTS could lead to underutilization or access issues for patients who would benefit from these services. Commenters were also supportive of CMS designating CPT codes 97550, 97551, and 97552 as ''sometimes therapy'' services.

Response: We believe that the RUC-recommended valuations that we proposed reflect the typical inputs for the service. The RUC's recommendations were based on extensive surveys with occupational therapists, physical therapists, and speech language pathologists, and represent the best information that we have at present for these new codes. Additionally, the Caregiver Training Services CPT codes fall appropriately between the key reference services used by the RUC to compare the work RVU, total time, and related intensity of each service. We believe that this supports the recommended values as maintaining relativity with other similar services already listed on the PFS. We also understand that the RUC may intend to review the valuation of these services again soon—we will take potential updates from the RUC into consideration in the future.

After consideration of the public comments, we are finalizing our proposed work RVUs and direct PE inputs for CPT codes 97550, 97551, and 97552. We are also finalizing the designation of CPT codes 97550, 97551, and 97552 as ''sometimes therapy'' services.

(28) Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

a. Background

In recent years, we have sought to recognize significant changes in health care practice and have been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS. See, for example, our CY 2013, 2015, and 2017 PFS final rules, where we finalized new coding to provide separate payment for transitional care management services, chronic care management services, and behavioral health care management services to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations (77 FR 68978, 79 FR 67715 and 82 FR 53163, respectively). To improve payment accuracy, we are exploring ways to better identify and value practitioners' work when they incur additional time and resources helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers interfering with the practitioner's ability to execute a medically necessary plan of care. Practitioners and their staff of auxiliary personnel sometimes obtain information about and help address social determinants of health (SDOH) that significantly impact the practitioner's ability to diagnose or treat a patient. Additionally, practitioners and their staff of auxiliary personnel sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, taking into account the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in payment for other services such as evaluation and management (E/M) visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe practitioners are performing them more often. However, this work is not explicitly identified in current coding, so we believe it is underutilized and undervalued. Accordingly, we proposed to create new coding to expressly identify and value these services for PFS payment, and distinguish them from current care management services. We expect that our new codes would also support the CMS pillars [9] for equity, inclusion, and access to care for the Medicare population and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care. They would also support the White House's National Strategy on Hunger, Nutrition and Health, and the White House's Cancer Moonshot Initiative.[10]

As part of this effort, in the CY 2023 PFS final rule (87 FR 69551 through 69551), we issued a Request for Information (RFI) related to Medicare Part B Payment for services involving community health workers (CHWs). For CY 2024, we considered how we could better recognize, through coding and payment policies, when members of an interdisciplinary team, including CHWs, are involved in treatment of Medicare beneficiaries. Currently, no separately enumerated statutory Medicare benefit category provides direct payment to CHWs for their services. Additionally, current HCPCS coding does not specifically identify services provided by CHWs, even though CHWs may facilitate access to healthcare through community-based services that are necessary to alleviate barriers to care that are interfering with a practitioner's ability to diagnosis or treat an illness or injury. In rulemaking for the CY 2023 PFS, to gain a broader perspective on

[9] CMS Strategic Plan | CMS.

[10] *White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf* (*whitehouse.gov*); Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It | The White House *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/*.

CHWs and how we could refine our coding and payment policies to better recognize their role in furnishing Medicare-covered services, we solicited comment through an RFI on how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute.

Commenters were supportive overall of potential, separate coding and payment for services involving CHWs. The public comments indicated that many physicians, practitioners, group practices, and other entities currently utilize the services of CHWs to bridge gaps in the continuum of their medical and behavioral healthcare furnished to Medicare patients. In public comments on our RFI, interested parties provided testimonials and evidence about the effectiveness of CHWs and the services they provide to patients in the community by monitoring, interpreting, clarifying, and supporting the plans of care that physicians and practitioners establish for delivering care to patients.

In addition, in 2021, the AMA CPT Editorial Panel recognized in the CPT E/M Guidelines that SDOH needs can increase complexity of a practitioner's medical decision making (MDM) for an E/M visit and increase risk to the patient, when diagnosis or treatment is significantly limited by SDOH.[11] Specifically, the CPT Editorial Panel included as an example of moderate level MDM for E/M visit coding and level selection, a situation where diagnosis or treatment is significantly limited by SDOH. This situation is listed as an example of moderate risk of morbidity from additional diagnostic testing or treatment. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity.'' [12] We adopted these revised CPT guidelines for MDM in E/M visits through notice and comment rulemaking, effective January 1, 2021 (84 FR 62844 through 62860, 87 FR 69587 through 69614).

Physicians and NPPs are generally trained to obtain a patient's social and family history, in support of patient-centered care, to aid in diagnosis, and to better understand and help address problem(s) addressed in a medical visit and associated risk factors.[13] For example, a practitioner who discovers that a patient's living situation does not permit reliable access to electricity may need to prescribe an inhaler rather than a power-operated nebulizer to treat asthma. Some practices and facilities employ social workers or other ancillary staff to help address SDOH needs that impact the ability to provide medically necessary care, such as appropriate treatment or diagnostic services after an office visit or discharge from a facility.

Practitioners are increasingly expending resources to obtain information from the patient about SDOH and risks and formulate diagnosis and treatment plans that consider these needs. We believe that social workers, CHWs, and other auxiliary personnel are currently performing some of these activities and that the resources involved in these activities are not consistently appropriately reflected in current coding and payment policies. As such, we believe it would be appropriate to create codes to separately identify and more accurately value this work. Accordingly, we proposed new coding to describe and separately value three types of services that may be provided by auxiliary personnel incident to the billing physician or practitioner's professional services, and under the billing practitioner's supervision, when reasonable and necessary to diagnose and treat the patient: community health integration services, SDOH risk assessment, and principal illness navigation. In our proposed rule, we discussed the proposed codes and their valuation. We described the circumstances under which we believe these services may be reasonable and necessary for the diagnosis or treatment of illness or injury such that Medicare payment may be made for them.

b. Community Heath Integration (CHI) Services

In light of the feedback we received from our RFI regarding CHWs, and increased recognition within the medical community of the role that social needs can play in patients' health (specifically, interfering with ability to diagnose and treat patients), we proposed to establish separate coding and payment for community health integration (CHI) services. We proposed to create two new G codes describing CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services, and under the general supervision of the billing practitioner. We proposed that CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit.

We proposed that the CHI initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner, who would also be furnishing the CHI services during the subsequent calendar month(s). The CHI initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for CHI services. We stated that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits, would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary CHI services in the subsequent month(s).

The CHI initiating visit would serve as a pre-requisite to billing for CHI services, during which the billing practitioner would assess and identify SDOH needs that significantly limit the practitioner's ability to diagnose or treat the patient's medical condition and establish an appropriate treatment plan. The subsequent CHI services would be performed by a CHW or other auxiliary personnel incident to the professional services of the practitioner who bills the CHI initiating visit. The same practitioner would furnish and bill for both the CHI initiating visit and the CHI services, and CHI services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that CHI services are billed, but only before commencing CHI services, to establish the treatment plan, specify how addressing the unmet SDOH need(s) would help accomplish that plan, and establish the CHI services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual, which provides, ''where a physician supervises auxiliary personnel to assist them in rendering services to patients

[11] 2021 CPT Codebook, p. 16.

[12] 2021 CPT Codebook, p. 14.

[13] See for example Patient-Centered Communication: Basic Skills | AAFP; *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html; https://doi.org/10.7326/M17-2441; .https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/; https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf; https://edhub.ama-assn.org/steps-forward/module/2702762.* The Origins of the History and Physical Examination—Clinical Methods—NCBI Bookshelf (*nih.gov*) *https://www.ncbi.nlm.nih.gov/books/NBK458/.*

and includes the charges for their services in their bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal, professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect their active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf* (*cms.gov*)).

We also solicited comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for CHI services, including, for example, an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner or by other types of health professionals whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example, a health educator. When the AWV is furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. Therefore, if we allowed an AWV to be furnished by a health care practitioner other than a physician or practitioner to serve as the initiating visit for CHI services, the CHI services would not necessarily be furnished consistent with our proposed application of the ''incident to'' regulations as a condition of payment. Further, we believe that practitioners would normally bill an E/M visit in addition to the AWV when medical problems are addressed in the course of an AWV encounter, in accordance with our manual policy providing that a medically necessary E/M visit may be billed when furnished on the same occasion as an AWV in those circumstances (Chapter 12, Section 30.6.1.1.H of the Medicare Claims Processing Manual (Pub, 100–04).

The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of our proposal to establish CHI services, including allowing monthly furnishing of CHI services, as medically necessary, following an initiating E/M visit (CHI initiating visit).

Response: We thank the commenters for their feedback.

Comment: One commenter disagreed with the proposal to create new G codes for CHI services and stated these codes may be duplicative of both work and practice expenses already accounted for in existing CPT codes. The commenter noted that the CPT Editorial Panel revised the E/M visit coding and level selection to include an example of moderate level medical decision making (MDM), accounting for clinical scenarios when SDOH significantly limits diagnosis or treatment.

Response: We thank the commenter for noting the changes made by CPT. However, we believe the new G codes will describe and account for integrated services supported by certified or trained auxiliary personnel, including CHWs, who will assist the practitioner in connecting the patient with helpful resources. This is separate from the work being furnished as part of the medical decision-making in an E/M visit and want to reiterate that CHI services are separate and different from an E/M service. These new services, further described in the code descriptors below, consist of activities to address social determinants of health (SDOH) need(s) that are significantly limiting the practitioner's ability to diagnose or treat problem(s) addressed in an initiating CHI visit. These services include a person-centered assessment, practitioner, home-, and community-based care coordination, health education, building patient self-advocacy skills, health care access/health system navigation, facilitating and providing social and emotional support, and leveraging lived experience when applicable. We recognize that CPT recently revised its evaluation and management (E/M) code set to include language that pertains to diagnosis or treatment significantly limited by social determinants of health as an element of medical decision making, however the CHI services to address the SDOH limitations are not captured in the revised E/M codes. It is for this reason that we proposed new coding to account for the services that are not accounted for in the E/M code set. We believe the services described by the CHI codes will help to resolve the patient's health related social needs that are impacting their care and the practitioner's ability to properly diagnose and treat the patient.

Comment: A few commenters requested that CMS clarify whether these services can be billed at safety-net clinics in academic medical centers. Commenters also raised concerns that academic medical centers and other facility-based providers could not furnish the services, given the reliance on incident to billing. Commenters requested that CMS clarify how such facilities may furnish these services to ensure that patients can benefit from the services regardless of where they receive their care.

Response: We thank the commenters for their feedback and acknowledge that there are aspects of the policy that we must consider further for possible future rulemaking. As proposed, these services can only be furnished and billed by physicians and practitioners who can bill for services performed by auxiliary personnel incident to their professional services.

Comment: Some commenters sought clarification on whether the full range of qualified health professionals permitted to bill E/M codes would also be permitted to bill HCPCS code G0019.

Response: Our final policy requires the individual billing for the initiating visit to be the same as the practitioner billing for CHI. In order to bill for these services, practitioners must have a statutory benefit and be able to enroll and bill Medicare as they would for other services on the fee schedule and specifically be able to bill an E/M service that would serve as the initiating visit.

Comment: Some commenters requested CMS allow CHWs to enroll in Medicare as a type of practitioner that can bill directly and be paid for their services, and that CBOs be able to bill Medicare directly for the CHI services if they have a NPI number.

Response: There is no statutory benefit category that would allow CBOs to bill the PFS directly. Therefore, we are not finalizing such a policy.

Comment: One commenter stated that CMS does not have the statutory authority to implement separate payment for CHW services as a new benefit category. Other commenters requested that CMS seek authority and funding from Congress before establishing a new Medicare social services benefit category.

Response: We note that CHI services will be furnished and billed incident to the professional services of the billing practitioner. As such, only physicians and other types of practitioners that are

authorized by statute to enroll and bill the PFS directly will be included among those who can bill for CHI services. We clarify that our final policy will not create a new Medicare benefit category but instead allow CHI services to be furnished incident to the professional services of a billing practitioner. When diagnosis or treatment of a patient's medical condition is significantly limited by social determinants of health, we believe that these services are within the scope of medically necessary physicians' services, and that payment for them is permitted when the services are reasonable and necessary under section 1862(a)(1)(A) of the Act. We clarify that CHI services are consistent with the ''incident to physicians' services'' benefit category under section 1861(s)(2)(A) of the Act.

Comment: Some commenters expressed concern with the CHI initiating visit being limited only to E/M visits and asserted that doing so would restrict access to the service as proposed. Commenters requested that the following services that are not E/M visits, be allowed to serve as an initiating visit: AWV, CPT codes 90791 (Psychiatric diagnostic evaluation) and 96156 ((*Health behavior assessment, or re-assessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*)

Response: Regarding whether the CHI initiating visit can be an AWV, we solicited comment on this topic and having considered the public comments, we are finalizing that the AWV can be a CHI initiating visit when the furnishing practitioner identifies an unmet SDOH need that will prevent the patient from carrying out the recommended personalized prevention plan. We believe that, in these cases, it could be reasonable and necessary for the practitioner furnishing the AWV to furnish CHI services. There may be instances where the identification of SDOH needs through an SDOH risk assessment conducted with the AWV could identify and produce the conditions for reasonable and necessary CHI services, for example, when the practitioner furnishing the AWV is assuming ongoing ''longitudinal'' care for the patient. However, when the AWV is provided by a type of health care professional who does not have an ''incident to'' benefit for their services under the Medicare program, including, for example, a health educator, a registered dietitian, or nutrition professional, the AWV would not serve as an initiating visit for CHI because the furnishing professional could not then furnish and bill for CHI services incident to their professional services. Even if we allow AWV to be the initiating visit, the AWV would still need to be furnished by a physician or practitioner, consistent with the incident to rules so that services for CHI can be billed by a practitioner incident to their own professional services.

We continue to believe that when an AWV involves diagnosis or treatment of injury or illness to the degree that would warrant subsequent furnishing and billing of CHI to remove barriers significantly limiting the treatment plan, in most cases, an E/M visit would be separately billed.

While we considered adding services provided by clinical psychologists, specifically CPT codes 90791 and 96156 to the list of services that could serve as an initiating visit for CHI services based on feedback received from commenters, we are not including these services as services that can serve as an initiating visit for CHI. We believe that these services would be better captured under the PIN services discussed below and would better serve the needs being addressed with the PIN service elements. However, we will continue to analyze the uptake of CHI services and will consider these comments for future rulemaking.

Comment: Commenters wanted CMS to allow emergency department E/M visits, inpatient/observation E/M visits, and transitional care management services to serve as initiating visits for CHI.

Response: In response to the commenters, we note that inpatient/observation visits and ED visits could not serve as CHI initiating visits, as conceptualized in this final rule and the proposed rule, because the practitioners furnishing the E/M services in those settings would not typically provide continuing care to the patient, including furnishing necessary CHI services in the subsequent month(s) following a potential initiating visit. Additionally, under our regulations at § 410.26(b), Medicare payment is only made for services and supplies incident to the service of a physician or other practitioner (such as the proposed CHI services) when those services and supplies are furnished in a noninstitutional setting to noninstitutional patients (all settings other than a hospital or SNF). So, under our current regulations and the CHI policies that we are finalizing in this rule, an E/M service furnished in the ED or SNF setting would not serve as the initiating visit for CHI services.

ED visits, as well as inpatient and observation visits would not be an initiating visit since these practitioners would not be following the patient longitudinally in the community or furnishing the CHI services.

Response: As discussed above, ED visits would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically provide continuing care to the patient, including furnishing necessary CHI services incident to their professional services in the month(s) subsequent to an ED visit. We agree with commenters that the E/M visit done as part of a Transitional Care Management (TCM) services could serve as an initiating visit for CHI services because it includes a high level office/outpatient E/M visit furnished by a physician or nonphysician practitioner managing the patient in the community after discharge.

Comment: Commenters also expressed concern with our proposal to allow only one practitioner to furnish a CHI initiating visit and requested that CMS allow more than one practitioner to furnish and bill the CHI initiating visit and services. Additionally, a few commenters requested that CMS clarify whether more than one initiating visit would be required when a subsequent need for CHI is identified during the initiating visits.

Response: We continue to be concerned that CHI services would be too fragmented if the patient has more than individual addressing their unmet SDOH need(s). Therefore, we are finalizing that only one practitioner will bill CHI and therefore there will only be one initiating visit. We acknowledge that practitioners may identify additional SDOH that are significantly limiting their ability to diagnose or treat the problem(s) address addressed in the initiating visit. We provide additional discussion with regard to the service elements below.

After consideration of the public comments, we are finalizing our proposal to establish separate coding and payment for CHI services. We are finalizing that a CHI initiating visit can be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who would also be furnishing the CHI services during the subsequent calendar month(s), including an E/M visit furnished as part of TCM, or an AWV. The CHI initiating visit would be separately billed (if all requirements to do so are met) and would be a pre-requisite to billing for CHI services.

In the proposed rule, for purposes of assigning a supervision level for these ''incident to'' services, we proposed to designate CHI services as care management services that may be

furnished under the general supervision of the billing practitioner in accordance with § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

In the proposal, we explained that the phrase or term ''problem addressed'' referred to the definition in the CPT E/M Guidelines that we adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified healthcare professional and may not be the cause of admission or continued stay'' (2023 CPT Codebook, p. 6–8).

For purposes of CHI services (and PIN services outlined later in this section), we proposed that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We proposed to adopt CPT's examples of SDOH, with additional examples. Specifically, we proposed that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the CHI initiating visit. Since Medicare payment is generally limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, the focus of CHI services would need to be on addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit.

We proposed the following specific codes and descriptors:

G0019—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).*

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation.*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

G0022—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to G0019).

By way of example, tailored support could be provided through CHI services to a patient experiencing homelessness with signs of potential cognitive impairment and a history of frequent ED admissions for uncontrolled diabetes. The patient's primary care practitioner (PCP) learns during a clinic visit after discharge from the ED, that the patient has been able to reliably fill their prescriptions for diabetes medication, but frequently loses the medication (or access to it) while transitioning between homeless shelters and a local friend's home. In the medical record, the PCP documents SDOH need(s) of housing insecurity and transportation insecurity contributing to medication noncompliance, resulting in inadequate

insulin control and a recent ED visit for hypoglycemia. The PCP's treatment plan is daily diabetes medication, with the goal of maintaining hemoglobin A1c within appropriate levels. To accomplish the treatment plan, the PCP orders CHI services to develop an individualized plan for daily medication adherence/access while applying for local housing assistance, and also orders a follow up visit for cognitive impairment assessment and care planning to further evaluate the potential contribution of cognitive impairment. The PCP's auxiliary personnel provide tailored support, comprised of facilitating communication between the patient, local shelters, and the friend, to help the patient identify a single location to reliably store their medication while applying for local housing assistance. The auxiliary personnel also help the patient identify a reliable means of transportation daily to that location for their medication and show the patient how to create a daily automated phone reminder to take the diabetes medication. The auxiliary personnel document these activities (including amount of time spent) in the medical record at the PCP's office, along with periodic updates regarding the status of the patient's housing assistance application.

To help inform whether our proposed descriptor times were appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we solicited comment on the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problem(s) addressed in an E/M visit. We also solicited comment to better understand the typical duration of CHI services, in terms of the number of months for which practitioners furnish the services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to allow general supervision for CHI services. However, some commenters asked a related question about whether auxiliary personnel providing CHI services under general supervision can identify additional unmet SDOH needs to address. When CHI services are being furnished, sometimes a patient is receiving CHI services to address one unmet SDOH need, and in the course of auxiliary personnel providing CHI services during the month, the auxiliary personnel identify additional unmet SDOH need(s). These commenters recommended that if the auxiliary personnel are regularly updating the billing practitioner on CHI services they provide, we should not require another initiating visit in order for the auxiliary personnel to address the additional unmet SDOH needs.

Response: We thank the commenters support of our proposal for general supervision. It would not be in the scope of practice of the auxiliary personnel for them to make a determination that a given SDOH need(s) is impacting ability of the billing practitioner to diagnose or treat problems addressed in an initiating visit. In addition, general supervision requires the CHI services to be furnished under the billing practitioner's direction and control. While we do not believe another initiating visit is necessary, the auxiliary personnel must review all unmet SDOH need(s) they find in order for them to be addressed by the billing practitioners in the CHI services.

Comment: Some commenters also stated that general supervision could inadvertently lead to the consolidation and integration of CHWs and other auxiliary personnel currently employed by CBOs to instead be employed by billing practitioners, where payment may be more robust,

Response: There is no statutory benefit that can allow CBOs to directly bill the PFS. In accordance with this final rule, CHI services must be provided incident to the professional service of a physician or other statutorily qualified practitioner who must bill for those services. Auxiliary personnel who provide these services must be under the supervision of the physician [or other practitioner] and the provided services must be reasonable and necessary for diagnosis and treatment of illness or injury. In the course of implementing our payment policy for chronic care management services, we became concerned about the number of care management companies that were contracted by the physician with potentially little oversight, clinical integration and communication with the billing practitioner, where the services might not be furnished under the direction and control of the billing practitioner. As discussed above, we were concerned that our incident to policy might not be met, which requires the billing practitioner to maintain active participation in and management of the course of treatment. We are allowing for the broadest level of supervision possible (general supervision) and contracting with third parties (such as CBOs) in accomplishing the furnishing of CHI services but this must be part of clinical care and treatment by the billing practitioner. Under our incident to regulations, we cannot prohibit physicians from directly hiring auxiliary personnel for furnishing CHI services.

Comment: Commenters were generally supportive of assigning general supervision for CHI services.

Response: We thank commenters for supporting our proposal to assign general supervision for the CHI codes. We believe that general supervision offers flexibility for the auxiliary personnel to provide the CHI services without the billing practitioner being physically present or immediately available, as would be required under direct or personal supervision (see § 410.26).

Comment: Another commenter recommended that the services provided by a CHW should be provided under the supervision of a qualified health professional providing care management activities, including, but not limited to registered nurses.

Response: No, our regulations require supervision by the practitioner who bills for the services.

Comment: Commenters were overall supportive of the valuation for HCPCS codes G0019 and G0022. Some commenters requested that CMS consider 20- or 30-minute increments for HCPCS code G0019, or other shorter increments, that could be billed individually, or as multiple units during the same encounter, with a maximum per calendar month of no less than 60 minutes total. One commenter also requested that HCPCS code G0019 be extended to 120 minutes and HCPCS code G0022 be extended up to 60 minutes per calendar month. A few commenters stated 30 minutes was sufficient, but the majority of commenters stated they spend 60 minutes up to 120 minutes, especially during the first few months.

Response: We asked commenters what they believe is the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problem(s) addressed. Commenters suggested a broad range of the time they expected to spend furnishing CHI services over a month. We are not finalizing a frequency limitation for the add on HCPCS code G0022 to allow for flexibility when practitioners do spend more than 60 minutes on CHI services in the month. Commenters expressed that for CHI services, especially during the first month, more time may be spent on providing services. We believe it is difficult to adequately address a

patient's social needs, consistent with the proposed elements of the CHI service, in less than an hour. As a result, we continue to believe that the 60 minutes of time spent by auxiliary personnel is most appropriate. For HCPCS code G0022, we continue to believe that 30 minutes of time spent by auxiliary personnel is most appropriate for the code descriptor. Therefore, we are finalizing 60 minutes for the base code and 30 minutes for the add-on code with no frequency limitation for the add-on code as long as the time spent is reasonable and necessary.

Comment: Several commenters requested that CMS include social workers and registered nurses in the code descriptors for HCPCS codes G0019 and G0022. Commenters also requested that these professionals be included as personnel who may conduct the initial CHI visit and oversee the provision of these services. Commenters also requested that CMS identify social workers, including a bachelor of social work (BSW), as eligible auxiliary workforce under CHI and PIN. Commenters expressed that including social workers is especially important as auxiliary personnel are employed by community care hubs (CCHs) and/or individual community-based organizations (CBOs) that may be contracting with a Medicare billing provider, and BSWs make up a significant part of this workforce. Another commenter stated that social workers provide services aligned with these proposed codes day in and day out across the country, yet they are not identified among lists of providers recognized for offering these proposed services.

Response: We note that our HCPCS G-code descriptors specify that auxiliary personnel may provide these services under general supervision. These codes were specifically designed to capture services commonly performed by community health workers, which are a type of auxiliary personnel. But the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1).

Comment: Some commenters supported our proposal to establish CHI services described by HCPCS code G0019 and stated the code should only be billed by one practitioner, to maintain longitudinal care. Other commenters did not agree with our proposed limitation for CHI and PIN services to one billing practitioner per patient per calendar month, and requested that we not impose such a limit. One commenter expressed that limiting CHI services to one practitioner per patient per month would impair the ability of auxiliary personnel to provide CHI services to the patient. Most commenters opposed our proposal that the add-on service, HCPCS code G0022, could be billed only once per month. Some commenters suggested that practitioners should be allowed to bill HCPCS code G0022 at least once a week. Another commenter expressed concern regarding frequency limits for the CHI add-on code and noted that spending adequate time with patients will be essential for high-quality CHI service provision. Another commenter requested not limiting the number of add-on services per month or the length of time a patient can continue to receive CHI or PIN services and expressed that if a patient needs services beyond six months, for example, a new order from the billing practitioner could be submitted. Several commenters recommended that CHI services have one in person interaction per month and expressed it was critical to allow the add on service (HCPCS code G0022) to be billed weekly.

One commenter noted that most beneficiaries screened for SDOH had two to five SDOH needs and to address those identified needs, it was conceivable that the CHI services would occur over multiple months (when more than one need was identified). The commenter noted that they would anticipate more intensity/time spent with the patient during the first month, while subsequent months may not have the same intensity or time spent, and that time spent delivering CHI services would be aggregated to determine the total time spent, per calendar month. Some commenters asserted that they could typically spend up to 120 minutes providing CHI services in the first month.

Response: We thank the commenters for their suggestions regarding frequency limitations for the CHI codes, specifically the add-on code, HCPCS code G0022. We are not finalizing to establish a frequency limitation for HCPCS code G0022. Considering the feedback from the commenters, we understand that it may be typical for practitioners and auxiliary staff to spend significant time supporting the activities described by the CHI codes during the first month. We believe as long as the time spent by auxiliary personnel is reasonable and necessary for the diagnosis and treatment of injury or illness, we should allow it to be billed. We agree with commenters that there could be situations where a patient requires more intensive CHI services over a month that would warrant billing more than one unit of the add-on HCPCS code G0022, perhaps especially in the first month and where multiple health related social needs impact the practitioner's ability to diagnose and treat the patient. We will monitor utilization in the claims data of the add-on code for medical necessity.

Comment: Several commenters recommended that we create a separate HCPCS code for CHI services performed in a group setting. These commenters expressed that certain service elements such as health education and facilitating behavior change, may be provided to patients as part of a group session with other patients. The commenter expressed that many patients benefit from services provided to a group of similar patients similar challenges.

Response: We did not propose a code describing services furnished to a group of patients. CHI services are highly individualized and focused on a person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating visit and subsequently by the CHW and/or auxiliary personnel in the community. Therefore, we continue to believe that the service should be tailored to address the individual patient's specific needs, and did not consider whether it would be appropriate for CHI services to be furnished in a group setting.

Comment: Many commenters asked whether the new G codes for CHI could be excluded from budget neutrality.

Response: We remind commenters that section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality. There is no statutory exception available for CHI services, so the expected spending associated with these services must be included in the CY 2024 BN adjustment.

Comment: Several commenters expressed concern regarding the medical record documentation requirements for CHI services and requested that CMS clarify that services must be documented by the billing practitioner and not necessarily by the

auxiliary staff delivering the services. This arrangement would allow a CBO to communicate with the billing practitioner about the services provided (including the time spent furnishing services and the social needs addressed), without requiring CBOs to have the technical capacity to directly input documentation into medical records. Other commenters stated that the billing practitioner or the auxiliary personnel should be responsible for documenting CHI and PIN services in the Electronic Medical Record (EMR).

Response: We thank the commenters for requesting clarification regarding documentation in the medical record, including an EMR, by the auxiliary personnel. We refer commenters to the finalized policies about medical record documentation in the CY 2020 PFS final rule (84 FR 62681 through 62684) and our later clarifications in the CY2021 PFS final rule (85 FR 84594 through 84596), which state that any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. Documentation, in the end, is the responsibility of the billing practitioner. CBOs may enter data following our general policy, as long as the biller reviews and verifies the documentation.

After consideration of the public comments, we are finalizing our proposal to designate CHI services as care management services that may be furnished under the general supervision of the billing practitioner in accordance with § 410.26(b)(5). We are also finalizing the proposed code descriptor for HCPCS code G0019, with a few minor changes. The final code descriptor for HCPCS code G0019, states that CHI services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner requires 60 minutes per calendar month to bill the service. We are also finalizing the valuation for HCPCS code G0019 as proposed. We are also finalizing the proposed code descriptor and 30 minutes per calendar month for HCPCS code G0022 as proposed. Additionally, we are not finalizing a frequency limitation for HCPCS code G0022. We will monitor utilization of the add-on HCPCS code G0022 and may re-evaluate these policies in future rulemaking.

With regard to changes in our final code descriptor, we are modifying the descriptor to reflect the policy we are finalizing in response to public comments received. We removed 'E/M' from the code descriptor since we are finalizing a policy to allow an E/M service, including an E/M service that is part of a TCM service, and an AWV service to serve as the initiating visit for CHI services. Additionally, we are adding a service element for the SDOH risk assessment to describe instances when a CHW or other auxiliary personnel performing CHI services identifies an SDOH need that the furnishing practitioner did not identify and needs to apprise the billing practitioner of that unmet SDOH need(s) they find for the need to be addressed by the billing practitioners and for the billing practitioner to identify if that need would impact the ability of the billing practitioner to diagnose and treat the problem addressed in the initiating visit .

We are finalizing the code descriptor for HCPCS code G0019 to read as follows:

Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting the ability to diagnose or treat problem(s) addressed in an initiating visit:

- Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating visit.

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- Practitioner, Home-, and Community-Based Care Coordination

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (*e.g.,* housing, utilities, transportation, food assistance) to address the SDOH need(s).

- Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.
- Health care access/health system navigation

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.
- Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

The commenters did not suggest any changes to the add-on code descriptor so for the add-on HCPCS code G0022 we are not finalizing any changes and the descriptor will read as follows: HCPCS code G0022—*Community health integration services, each additional 30*

minutes per calendar month (List separately in addition to G0019).

In the proposed rule, we proposed that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are being furnished. In States where there are no applicable licensure or other laws or regulations relating to individuals performing CHI services, we proposed to require auxiliary personnel providing CHI services to be trained to provide them. Training must include the competencies of patient and family communication, interpersonal and relationship-building skills, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local community-based resources. We proposed these competencies because they reflect professional consensus regarding appropriate core competencies for CHWs, applied to this context.[14] We solicited public comment on whether it would be appropriate to specify the number of hours of required training, as well as the training content and who should provide the training.

The following is a summary of the comments we received and our responses.

Comment: Most commenters generally agreed with our proposal. Some commenters expressed that a minimum number of training hours is needed to ensure basic skills and understanding related to the CHW scope of work. Other commenters noted that training should be development-oriented and not be a one-time certification. Some commenters expressed that CHWs, and the associations that represent them, are best positioned to determine the appropriate training requirements to balance patient safety and access to care. Commenters also expressed that there should be flexibility in training and certification requirements to support the development of a diverse CHI services workforce.

Several commenters noted they utilize the Community Health Worker Core Competency (C3) project. A few commenters agreed that training should not focus on clinical topics as CHWs are not trained clinicians or health educators. Other commenters also suggested and agreed that when there are no applicable licensure or State laws related to individuals performing CHI, services should align with the C3 Project competencies.

Response: We continue to believe that our rules for all incident to services should apply such that applicable State rules and requirements must be met and that training/certification must meet any applicable requirements to provide the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State.

Comment: Some commenters disagreed with our proposal to require auxiliary personnel providing CHI services to be trained. These commenters suggested that CMS offer a legacy certification option for CHWs with extensive lived experience.

Response: We thank commenters for their feedback. We do not understand what the commenters mean by legacy certification. We continue to believe that we should defer to States, as they have applicable standards for auxiliary personnel (as specified for all incident to services under § 410.26). For States without a standard for training or certification, that we believe that we should adopt the professional consensus regarding appropriate core competencies for CHI services, applied to this context.

Comment: While some commenters stated that requiring a specific number of training hours may be a deterrent for some individuals to actually obtain the required training, others suggested auxiliary personnel providing CHI services should participate in training programs with anywhere from 7 to 10 hours, 30 to 40 hours, and up to 140 hours before beginning work. Other commenters recommended an annual training requirement of 2 to 3 hours.

Response: We thank the commenters for their thoughts and suggestions on whether it would be appropriate to specify the number of hours of required training, as well as the training content and who should provide the training to be obtained by CHWs. We did not propose and do not plan to finalize a specific number of hours of training for auxiliary personnel providing CHI services.

After consideration of the public comments, we are finalizing our proposal that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations.

For CHI services, as with all incident to services, it is the billing practitioner's responsibility to ensure that all payment rules and applicable State requirements are met including licensure, certification, and/or training. This does not mean that the billing practitioners are required to provide the licensure, certification, and/or training themselves, but rather that they must ensure that the Medicare criteria for billing and payment of CHI services are met.

We continue to believe that the training required to provide CHI services must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local community-based resources.

Because we defer to applicable State rules, we are not requiring a set number of training hours or content in States that have applicable rules. For States that do not have applicable rules, we continue to believe that our proposed competencies as specified above are appropriate. Due to the wide range of training hours suggested by commenters, we are not specifying a required number of training hours that need to be obtained in States who do not have an applicable rule to specify the number of required hours.

Comment: One commenter suggested a national certification mechanism and to call these personnel certified Community Health Professionals (CCHPs). Some commenters expressed that there should be a program-level accreditation that recognizes community-based organizations that are employing community-health workers, and pointed to accrediting bodies that have plans in the works for such accreditations.

Response: We are not sure whether the commenter is recommending a national accreditation for CHI services, CHWs, or CBOs. PFS payment policy provides payment rules for services, in this case CHI services furnished by CHWs or other types of auxiliary personnel who may or may not be working in conjunction with a CBO. Above, we have finalized our policy for CHI services and if a national accreditation program trains or certifies and meets our requirements which includes applicable State requirements, then those auxiliary personnel would

[14] *https://chwtraining.org/c3-project-chw-skills/.*

meet requirements to provide CHI services (assuming all other billing requirements are met).

In our proposed rule, we proposed to require that time spent furnishing CHI services for purposes of billing HCPCS codes G0019 and G0022 must be documented in the patient's medical record in its relationship to the SDOH need(s) they are intended to address and the clinical problem(s) they are intended to help resolve. The activities performed by the auxiliary personnel would be described in the medical record, just as all clinical care is documented in the medical record. We proposed to require the SDOH need(s) to be recorded in the patient's medical record, and for data standardization purposes, stated that practitioners would be encouraged to record the associated ICD–10 Z-code (Z55–Z65) in the medical record and on the claim.

Since CHI services are community-based and involve connecting the patient with local resources in their community, and are highly personalized, for example, hearing and understanding a patient's life story and culture, we believe that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient, and that a substantial portion would be in-person, but recognized that a portion might be performed via two-way audio. We sought to confirm our understanding of where and how these services would be typically provided (for example, in-person, audio-video, two-way audio).

We solicited public comment regarding whether we should require patient consent for CHI services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may pose a barrier to receipt of needed services. We did not propose to require consent for CHI services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, we stated that if we heard from public commenters that CHI services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as multiple months), we would consider requiring patient consent to receive CHI services. We solicited comment regarding whether we should require patient consent for CHI services. The following is a summary of the comments we received and our responses.

Comment: Commenters confirmed that CHI services would most likely occur both in-person and virtually (via audio-video or via two-way audio) but noted that evidence shows that all services should include some in-person interaction. As a result, a few commenters requested that CMS provide a higher payment for services when they are delivered in person to incentivize these types of interactions. Additionally, one commenter recommended at least one in-person interaction each month, unless the patient is in an area designated as rural, frontier, tribal, or a geographically isolated territory.

Response: We acknowledge the commenters' suggestion that CHI services would be available either in person, virtually, or a mix of both. However, we continue to believe that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient. Thus, we do not plan to provide a higher payment for services when they are delivered in person, and we do not believe that we need to incentivize in-person interactions. We hope to engage with practitioners and other interested parties to inform any refinements to the services through future rulemaking, as our collective experience with these services grows.

Comment: Most commenters stated that patient consent should be obtained prior to initiating services for CHI, so the beneficiary can be counseled on the services being provided, in addition to potential co-insurance and/or cost sharing requirements. A few commenters stated that a patient should be allowed to give their consent verbally, documented in the medical record, that the auxiliary personnel may obtain consent, or virtually. Lastly, another commenter stated that including the CHW in the CHI initiating visit with the practitioner as part of the patient care team would avoid complications with consent since the patient's approval would be provided during the initial visit. The commenters stated that, considering that a variety of factors may prevent a patient from returning to the clinic, it is imperative that the CHW is introduced during the initial visit.

Comment: A few commenters disagreed consent should be required for several reasons. One commenter expressed that consent should not be required for CHI services because often times, patients do not understand CHI services at the time presented, therefore discussing consent would be difficult especially when there may be a lack of understanding or if there are literacy, language, culture and learning difficulties. Requiring consent is especially challenging given the short time spent with the practitioner, especially during long appointments where there are interpreter needs. Commenters generally agreed that if consent will be required, they ask CMS to consider verbal consent or consent as part of the annual consent for treatment.

Response: Having reviewed the public comments, we are persuaded by the opinions of the commenters that we should require consent. CHI services may not necessarily be in person, could be provided over many months, and the patient would not necessarily expect to incur cost sharing.

Comment: We received comments recommending on how consent should be obtained. Commenters recommended that we not require consent to obtained in person. Commenters stated that there may be circumstances where it may not be possible to obtain consent during the initiating visit. Commenters recommended that we not require written consent but rather allow the patient to provide a verbal consent.

Response: After considering public comments we agree with commenters that in order to reduce administrative burden that written or verbal consent may be obtained as long as it is documented in the medical record.

Comment: Several commenters asked about who would obtain consent. Commenters asked CMS if consent could be obtained by auxiliary personnel.

Response: While we believe it would be best for the billing practitioner to obtain consent, we agree with the commenters that we should allow auxiliary personnel to obtain the consent and that is what we are finalizing. As part of the consent process, it must be explained to the patient that cost sharing will apply and that only one practitioner per month can bill the services. Consent only has to be obtained once (rather than annually) and in cases where there is a change in the billing practitioner, a new patient consent would be required.

In summary, after consideration of public comments, we are finalizing that patient consent is required in advance of providing CHI services, but may be obtained either in writing or verbally, so long as the consent is documented in the patient's medical record. We are also finalizing that consent for CHI services may be obtained by auxiliary personnel and must be obtained if there is a change in the billing practitioner. The consent process must include explaining to the patient that cost sharing applies and that only one practitioner may furnish and bill the services in a given month.

In the proposed rule, we proposed that a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. Although we proposed to allow CHI services to be performed by auxiliary personnel under a contract with a third party, we stated, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for other care management services in the CY 2017 PFS final rule, if there was little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we did not believe services, as we proposed to define them, could be fully performed; and therefore, in such cases, services should not be billed (see 81 FR 80249). We stated that we would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier in this section, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. We stated that, generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide CHI services. We understood that many CBOs provide social services and do other work that is beyond the scope of CHI services, but we believed they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI services.

Because we were concerned about potential fragmentation that could occur in addressing specific SDOH, we proposed that only one practitioner per beneficiary per calendar month could bill for CHI services. This would allow the patient to have a single point of contact for all their CHI services during a given month.

We proposed that the practitioner could separately bill for other care management services during the same month as CHI services, if time and effort are not counted more than once, requirements to bill the other care management service are met, and the services are medically reasonable and necessary.

We proposed that CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B, since we believed there would be significant overlap between services furnished under a home health plan of care and CHI services, particularly in the home health services referred to as ''medical social services,'' and in comprehensive care coordination. For example, medical social services can be furnished to the patient's family member or caregiver on a short-term basis when the home health agency (HHAs) can demonstrate that a brief intervention by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to the patient's rate of recovery. Additionally, the home health agency (HHA) conditions of participation require that HHAs coordinate all aspects of the beneficiary's care while under a home health plan of care, such as integrating services, whether provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines; and involvement of the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Also, we noted that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CHI services will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we solicited public comment regarding whether States typically cover services similar to CHI under their Medicaid programs, and whether such coverage would be duplicative of the CHI service codes. We also solicited comment on whether there are other service elements not included in the proposed CHI service codes that should be included, or are important in addressing unmet SDOH need(s) that affect the diagnosis or treatment of medical problems, where CMS should consider coding and payment in the future.

The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS reconsider the exclusion of home health patients and urged CMS to allow for concurrent billing of CHI services and skilled home health plan of care because it is well established that the limited social work component of a home health plan of care is not adequate to address complex health related social needs and does not include the same intensity of support that is outlined in the CHI services benefit. Commenters expressed that not allowing CHI services to be billed for patients who are receiving the home health benefit and have a home health plan of care could result in patients losing the services provided by CHWs to meet their needs related to social determinants of health, healthcare translation, and patient advocacy. Commenters noted that home health services typically extend for 60 days or more, and if the patient is currently receiving home health benefits it would put the patient in a position of choosing between two important services, potentially negatively impacting health outcomes.

Response: We acknowledge the commenter's assertions that a home health plan of care is inadequate to address complex health-related social needs and does not include the same intensity of support that is outlined in the CHI services benefit. However, we believe that policy and payments accounted for under the home health prospective payment system already reflect much of the services described by the CHI codes, such that there would be significant overlap between CHI services and services furnished under a home health plan of care. Specifically, when a beneficiary is under a home health plan of care, medical social services are a covered home health service. Services of these professionals which may be covered include, but are not limited to: assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment and adjustment to care; assessment of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources and availability of community resources; appropriate action to obtain available community resources to assist in resolving the patient's problem; and counseling services that are required by the patient and medical social services for the patient's family member or caregiver on a short-term basis.

Comment: Some commenters stated that most State Medicaid programs do not directly cover CHI services at this time, and the States that do have Medicaid billing codes for CHW services have reimbursement rates that are insufficient and unsustainable. Other commenters stated that authorizing Medicare payments for the CHI services would be complementary to services currently provided under Medicaid. Additionally, commenters stated that the Medicare proposal takes a more effective holistic approach to identify and remedy all social determinants of health impacting a beneficiary's medical condition compared to Medicaid.

Response: We thank the commenters for their feedback. The CHI services are meant to resolve those specific concerns to facilitate the patient's medical care, which would distinguish CHI from other social services and programs that may be available through Medicaid State plans or other State or community programs.

After consideration of public comments, we are finalizing as proposed that a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met, and that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided. We are also finalizing as proposed that CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B. We want to emphasize the idea that CHI is covered and paid under the Medicare program when there are SDOH needs that are interfering with the billing clinician's diagnosis and treatment of the patient. These services are meant to resolve those specific concerns to facilitate the patient's medical care, which would distinguish CHI from other social services and programs that may be available through Medicaid State plans or other State or community programs.

c. CHI Services Valuation

For HCPCS code G0019, we proposed a work RVU of 1.00 based on a crosswalk to CPT code 99490 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as we believed these values most accurately reflected the resource costs incurred when the billing practitioner furnishes CHI services. CPT code 99490 has an intraservice time of 25 minutes and the work is of similar intensity to our proposed HCPCS code G0019. Therefore, we proposed a work time of 25 minutes for HCPCS code G0019, based on this same crosswalk to CPT code 99490. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0019.

For HCPCS code G0022, we proposed a crosswalk to the work RVU and direct PE inputs associated with CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*) as we believed these values reflected the resource costs incurred when the billing practitioner furnishes CHI services. Therefore, we proposed a work RVU of 0.70 and a work time of 20 minutes for HCPCS code G0022.

We received public comments on valuation. The following is a summary of the comments we received and our responses.

Comment: While most commenters were generally supportive of our proposed crosswalks and valuations for HCPCS codes G0019 and G0022, and our proposed work RVU of 1.00 and a work time of 25 minutes based on a crosswalk to CPT code 99490 for G0019 and proposed a work RVU of 0.70 and a work time of 20 minutes for HCPCS code G0022 based on a crosswalk to CPT code 99439. While some commenters agreed with HCPCS code G0019 and the crosswalk to CPT code 99490, they disagreed with the suggested time for the service and suggested that every subsequent 20 minutes of CHI services up to 60 minutes should have a separate HCPCS code that has an equivalent RVU crosswalk to CPT code 99490. Then, these commenters would agree with the RVU for HCPCS code G0022, as long as

there is recognition that the first hour can be billed in 20-minute increments up to a total of 60 minutes.

Additionally, several commenters noted that the chronic care management services codes are billed in 20-minute increments and questioned whether every subsequent twenty minutes of CHI, up to 60 minutes, should have a separate HCPCS code that has an equivalent RVU crosswalk to CPT codes 99490 and 99439, up to 60 minutes per calendar month.

Response: We thank the commenters for their feedback. It is our understanding that appropriately addressing patient needs that require CHI services would take longer than 20 minutes per month, and so to promote the comprehensiveness and integrity of the service elements we are finalizing as proposed for these services. We will monitor the utilization of CHI services and will consider changes over time for future rulemaking.

Comment: A few commenters were not in support of the proposed valuations and encouraged CMS to reevaluate as there is a significant amount of work the CHW provides to the patient, whether for SDOH support or coordination of care for chronic conditions, wellness, and prevention, educating the patient, and building patient self-advocacy skills. Another commenter requested the work RVU for HCPCS code G0019 be increased. An additional commenter suggested that the work RVU value of the 60-minute monthly CHI service should be equivalent to a CPT code 99214 E/M visit and the additional 30-minutes CHI service should be equivalent to a CPT code 99213 E/M visit.

Commenters recommended that CMS submit the CHI services codes and the PIN services codes to the RUC for their review.

Response: We thank commenters for their feedback and recommendation to have these new G codes for CHI services be reviewed by the RUC. While the RUC does not typically review G codes created by CMS, these codes could be potentially reviewed in a future rule cycle if the RUC chooses to do so. We remind readers that the RUC is an independent organization not administered by CMS that typically decides which codes will be reviewed based on its own internal criteria.

After consideration of public comments, we are finalizing the valuation of these codes as proposed. We will monitor the utilization of these new codes and consider any changes in possible future rulemaking.

d. Social Determinants of Health (SDOH)—Proposal To Establish a Stand-Alone G Code

i. Background

As previously discussed, there is increasing recognition within the health care system of the need to take SDOH into account when providing health care services, given that it is estimated [15] that around 50 percent of an individual's health is directly related to SDOH. Healthy People 2030 define the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context, which include factors like housing, food and nutrition access, and transportation needs. Many Federal agencies are also developing policies to better address the impact SDOH have on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity,[16] as well as the CMS Framework for Health Equity.[17]

ii. SDOH Risk Assessment Code

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients, including by recommending the assessment of SDOH through position or discussion papers,[18] [19] [20] organizational strategic plans,[21] and provider training modules.[22] In the proposed rule, we outlined how the practice of medicine currently includes assessment of SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally performed by physicians and practitioners in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. We believe the resources involved in these activities are not appropriately reflected in current coding and payment policies. As such, we proposed to establish a code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit.

We proposed a new stand-alone G code, now assigned as HCPCS code G0136, *Administration* of *a standardized,* evidence-based *Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months.* SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We proposed HCPCS code G0136 to identify and value the work involved in the administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs and enable comparisons across populations. For example, through administration of the SDOH risk assessment for a patient presenting for diabetes management, a practitioner might discover that a patient's living situation does not permit reliable access to electricity, impacting the patient's ability to keep insulin refrigerated. The practitioner may then prescribe a type of insulin that remains stable at room temperature or consider oral medication instead. In this example, the practitioner could furnish an SDOH risk assessment in conjunction with the E/M visit to gain a more thorough understanding of the patient's full social history and to determine whether other SDOH needs are also impacting medically necessary care.

We further proposed that the SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Required elements would include:

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[15] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[16] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[17] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[18] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[19] *https://doi.org/10.7326/M17-2441.*

[20] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[21] *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf.*

[22] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

• Administration of a standardized, evidence-based [23] SDOH risk assessment tool that has been tested and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.

++ Billing practitioners may choose to assess for additional domains beyond those listed above if there are other prevalent or culturally salient social determinants in the community being treated by the practitioner.

Possible evidence-based tools include the CMS Accountable Health Communities (AHC) [24] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) [25] tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[26]

Given the multifaceted nature of unmet SDOH needs appropriate follow-up is critical for mitigating the effects of the identified, unmet SDOH needs on a person's health. An SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose. As such, CMS solicited comment on whether we should require as a condition of payment for SDOH risk assessment that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations (CBO) to address identified SDOH needs.

The SDOH needs identified through the risk assessment must be documented in the medical record and may be documented using a set of ICD–10–CM codes known as ''Z codes'' [27] (Z55–Z65) which are used to document SDOH data to facilitate high-quality communication between providers. We proposed a duration of 5–15 minutes for HCPCS code G0136 for the administration of an SDOH risk assessment tool, billed no more often than once every 6 months. We proposed to limit the SDOH assessment service to once every six months, as we believe there are generally not significant, measurable changes to health outcomes impacted by a patient's SDOH in intervals shorter than 6 months.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overall supportive of our definition of SDOH. We received several comments requesting that CMS change the name to social drivers of health, drivers of health, or health-related social needs. Many of these commenters noted that other CMS programs use the term social drivers of health and requested that CMS use consistent naming conventions. Many commenters agreed that our proposal aligns with ongoing efforts to improve health equity and applauded our proposal for a new code. Other commenters discussed work that is already occurring in performing SDOH risk assessments and cited the benefits of adding payment in the PFS for these services, as they are currently under- or unpaid. Several commenters from rural and underserved areas noted that funding is scarce for resources like community-based organizations, and they were hopeful this code would increase funding and therefore access to such services.

One commenter suggested that this service was duplicative as the E/M coding structure allows practitioners to report a higher code to capture increased intensity services, such as when SDOH considerations are present. A few commenters strongly opposed the proposal, expressing concern that our proposal would divert dollars from medical care and would impose surveillance data gathering, which they considered intrusive on patients. A few other commenters recommended that the proposal should not be finalized and should be further studied before implementation. Another commenter recommended that we delay implementation until a more detailed analysis is available on the use of SDOH to improve patient outcomes. Several commenters recommended this code be exempted from budget neutrality, and a few other commenters suggested that CMS waive cost-sharing for this service.

Response: We note that there are many definitions and names for similar assessments, and we share the desire to align naming conventions across programs, especially within CMS. However, we note that there is not yet a universally accepted term for these types of factors. Many definitions have slight differences in their intent or meaning, which complicates standardization. SDOH is defined by the Current Procedural Terms (CPT) coding guidelines, which is why we used this term in the proposal. We will consider whether there could be greater alignment in terminology across CMS in the future. We acknowledge that the E/M coding structure does allow for a higher level of Medical Decision-Making when taking things like SDOH into consideration. For this reason, we continue to believe that this code represents work that is currently not accounted for.

With respect to budget neutrality, we remind commenters that section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. There is no statutory exception available for the SDOH risk assessment, so the expected spending associated with these services must be included in the CY 2024 BN adjustment. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have authority to waive cost sharing for care management or other services except as specified in statute, such as for certain preventive services. Rather, cost sharing remains applicable for the proposed SDOH risk assessment and other care management services. We note that the beneficiaries likely to benefit the most from this risk assessment may qualify or already be enrolled in programs to reduce or eliminate cost sharing, such as Medicaid or other supplemental insurances. We do not agree with commenters who stated this type of information will impose surveillance data gathering in a way that is intrusive to patients. We acknowledge that the information collected as part of an SDOH risk assessment could be sensitive in nature, and we understand that discussing SDOH-related topics may be perceived as intrusive to some beneficiaries. However, as we discussed in the introduction, this information is already being collected by practitioners in medical settings, as many across the medical community agree that this type of information is important to the health care patients receive. We are not proposing new forms of data collection, but rather are seeking to acknowledge this work through payment, which was supported by other commenters.

Comment: We received many comments related to the proposed requirement that SDOH risk assessment be furnished the same date as an E/M visit. Many commenters requested clarification on the same date requirement, citing operational difficulty in performing the assessment during the visit and requested that we

[23] *https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidence-based-resources.*

[24] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[25] *https://www.nachc.org/research-and-data/prapare/.*

[26] CMS–10825.

[27] *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

allow for the risk assessment to be performed 7–10 days prior to the appointment, given that many practitioners utilize a ''pre-check-in'' system via an online portal. We also received many comments discussing the furnishing of the SDOH risk assessment in conjunction with E/M visits. Some commenters requested that clinical psychologists be allowed to furnish SDOH risk assessment and specified that the SDOH risk assessment should be billable with CPT code 90791 and HBAI codes in addition to E/M visits, noting that patients with mental health conditions often have unmet social needs and may not see another health care practitioner routinely beyond a clinical psychologist. We received many comments requesting clinical social workers be added explicitly to the list of practitioners able to furnish SDOH risk assessments, citing that assessment of SDOH needs falls within their competencies and training. Other commenters recommended including all practitioners who can bill Medicare directly, such as marriage and family therapists (MFTs), mental health counselors (MHCs), and physical and occupational therapists.

Response: We understand that many practitioners use online portals for the collection of demographic and insurance information prior to the visit for operational ease. However, we emphasize that this is a SDOH risk assessment, not a screening. The SDOH risk assessment is intended to be used when a practitioner has reason to believe there are unmet SDOH needs that are interfering with the practitioner's diagnosis and treatment of a condition or illness. As such, there are limited scenarios in which we envision a practitioner would know ahead of a visit that an SDOH risk assessment would be appropriate, such as a patient who has a history of unmet SDOH needs, or the patient disclosed such information before the visit. Examples could include the patient requesting an appointment at a specific time or on a specific date due to the limited availability of transportation to or from the visit, or the patient requests a refill of refrigerated medication that went bad when the electricity was terminated at their home. Given this, we do not agree with commenters that it would be typically appropriate to have a patient fill out an SDOH risk assessment 7–10 days in advance of an appointment. We understand that in limited scenarios, such as described above, a clinician may wish to get an SDOH risk assessment during pre-check-in paperwork. We are also sensitive to commenters' feedback about the operational difficulties in getting an SDOH risk assessment during an associated appointment, especially in circumstances discussed by the commenters where it is already part of the check-in process practitioners have in place. We agree with commenters that SDOH risk assessment is relevant to the diagnosis and treatment of conditions furnished by practitioners such as clinical psychologists for patients with behavioral health conditions. We do not agree with commenters that all practitioners who can bill for Medicare should qualify to perform the SDOH risk assessment under statute as reasonable and necessary, as we believe that practitioners who can bill E/M or similar behavioral health visits such as CPT code 90791 and HBAI codes are best positioned to provide follow-up and ongoing assessment in a longitudinal way. These codes are used by clinical psychologists to diagnose and treat behavioral health conditions as analogous codes to E/M services given State law and scope of practice. We acknowledge that other practitioners such as clinical social workers may benefit from an understanding of the patient's SDOH considerations to furnish their services. However, we believe that this information should be shared when possible or applicable with the care team by the furnishing practitioner of the associated E/M or behavioral health visit.

After consideration of the public comments, we are finalizing the title, ''Social Determinants of Health'' (SDOH) risk assessment for HCPCS code G0136 as proposed. As discussed in response to public comments, this is to align with the language used by CPT. Given that we are focused on payment for physicians' services, most of which are billed using CPT codes, we believe that aligning our terminology with CPT makes the most sense. We are not finalizing the requirement that the SDOH risk assessment must be performed on the same date as the associated E/M or behavioral health visit (such as CPT code 90791 or HBAI codes), for the operational ease of practitioners. This is also in alignment with when HCPCS code G0136 is performed in conjunction with an AWV, as the AWV may be split over two visits (see section III.S. of this final rule for this discussion). We continue to believe that in most cases, HCPCS code G0136 would not be performed in advance of the associated E/M or behavioral health visit. We reiterate that the SDOH risk assessment code, HCPCS code G0136, when performed in conjunction with an E/M or behavioral health visit is not designed to be a screening, but rather tied to one or more known or suspected SDOH needs that may interfere with the practitioners' diagnosis or treatment of the patient.

Regarding the types of associated visits that can be performed with HCPCS code G0136, our aim is to allow behavioral health practitioners to furnish the SDOH risk assessment in conjunction with the behavioral health office visits they use to diagnose and treat mental illness and substance use disorders. We are finalizing that in addition to an outpatient E/M visit (other than a level 1 visit by clinical staff) as proposed, SDOH risk assessment can also be furnished with CPT code 90791 (*Psychiatric diagnostic evaluation*) and the Health Behavior Assessment and Intervention (HBAI) services, described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168. We are also finalizing that HCPCS code G0136 may also be performed in conjunction with an Annual Wellness Visit. This is discussed in more detail in section III.S. of this final rule.

Comment: We received several comments requesting clarification on the types of settings in which a SDOH risk assessment can occur, and several commenters asked whether this service could be furnished in the emergency department, observation unit, or during the perioperative period. These commenters noted that beneficiaries with unmet social needs are often seen more frequently in the emergency department setting, and these beneficiaries may lack access to primary care. Other commenters asked whether HCPCS code G0136 could be performed in conjunction with the E/M that is part of TCM. These commenters discussed that a patient's SDOH needs may have changed during the time of a hospitalization, citing examples such as new financial or housing instability due to being out of work for a prolonged time. Another commenter discussed that if a patient was going to be going home in a wheelchair for the first time, they may have new transportation issues if they do not have access to wheelchair-accessible transportation. Commenters also asked about the use of HCPCS code G0136 in conjunction with hospital discharge visits.

Response: We thank the commenters for their feedback. We recognize that unmet SDOH needs may be relevant to the care received in facility settings such as emergency departments and observation units, and it may be appropriate for practitioners to adjust the treatment plan in these settings

based on known SDOH needs. When we created HCPCS code G0136, we envisioned it being used in outpatient office settings, in which a patient is interacting with a practitioner with whom they have a long-standing care relationship. We acknowledge that patients may have long-standing care relationships with practitioners they see in settings such as during the operative period, but we believe this to be atypical. Additionally, we are generally wary of paying for SDOH risk assessment upon every interaction with the health care system, since this could be burdensome for the patient and have less utility if the unmet SDOH needs are never addressed or followed up with in a longitudinal way. We agree with commenters that it makes sense to permit the use of HCPCS code G0136 in conjunction with hospital discharge visits. We note that this is consistent with other CMS policies since SDOH are present in the Hospital Inpatient Quality Reporting Program measures, and that SDOH have been identified as key factors related to safe discharge planning. Even so, our expectation is that patients that have identified unmet SDOH needs will continue to follow up as an outpatient either through TCM or E/M visits.

We also believe that SDOH risk assessment is especially important during transitions in care, which was pointed out by commenters when asking if hospital discharges and TCM would count as an applicable associated visit. For TCM visits, we clarify that individuals who are discharged from a hospital, observation unit, or post-acute care, would also be able to receive the SDOH risk assessment during the TCM E/M visit, to ensure that SDOH needs have been taken into consideration as the patient transitioned back into the community. The use of HCPCS code G1036 in conjunction with the TCM E/M visit has the added benefit that it is likely that the practitioner furnishing TCM will be following the patient longitudinally in an outpatient setting and can assess for changes in unmet SDOH needs over time.

After consideration of public comments, we are finalizing that HCPCS code G0136 may be furnished with hospital discharge visits, to remain consistent with other CMS policies promoting assessment of SDOH as an indicator of quality care and to promote safe discharge planning. We are also finalizing that HCPCS code G0136 can be billed in outpatient settings. We are interested in learning more about the ideal settings for HCPCS code G0136 as we work with interested parties about how HCPCS code G0136 is used, and we will continue to examine this issue in future rulemaking.

Comment: Commenters were generally supportive of the proposed requirements for the use of a standardized, evidence-based SDOH risk assessment tool. Commenters generally appreciated the operational flexibility of CMS not requiring a specific tool, especially if they are already utilizing an SDOH risk assessment tool. A few commenters requested that CMS specify one specific tool or publish a list of approved tools to improve standardization and interoperability. Other commenters requested that CMS clarify that the list of tools is not exhaustive, and tools beyond those listed can be used if they meet the criteria. A few commenters requested that CMS only accept tools that meet the Office of the National Coordinator (ONC) for Health Information IT's interoperability standards. Others recommended that CMS limit to a specific list of industry-approved tools. Several commenters also noted that some quality standards allow for practitioners to combine questions from validated instruments and suggested CMS adopt similar standards.

Response: We agree with commenters that interoperability and standardization are important, and we understand that specifying a list of tools or limiting to one tool would work towards those aims. As such, we note that in the proposed rule, we discussed that possible evidence-based tools include the CMS Accountable Health Communities tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment. However, we are also interested in ensuring that practitioners are able to select tools and questions beyond the specified tools, that are relevant to the beneficiaries they serve. There is not a national consensus around one specific tool for the assessment of SDOH needs. Currently, practitioners and researchers choose the tool (or tools) that fit their needs, and we have no desire to limit or restrict this current work, so long as it meets the parameters specified in this rule. We remain committed to finding a balance between the benefits of allowing maximum operational flexibility and encouraging evidence-based standardization and interoperability.

Comment: Commenters were in favor of requiring the use of a tool which includes the specified domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. Several commenters discussed food insecurity as a foundational or key domain to be assessed, citing the dietary aspects to the treatment of conditions such as diabetes and hypertension. A few commenters expressed appreciation for the option to add additional domains, as relevant to their patient population. Several commenters also requested that the tool used be required to include the domain of interpersonal safety, citing CMS quality programs that require inclusion of interpersonal safety, and evidence that this is an important SDOH need. Another commenter recommended CMS explore including domains related to climate change.

Response: We agree with commenters who discussed the importance of food insecurity, and we believe the inclusion of this domain is in line with efforts across the government to tackle food insecurity, such as the White House Conference and Strategy on Hunger, Nutrition, and Health.[28] We agree that interpersonal safety is an important dimension of potential SDOH needs, and we also recognize the potential difficulty of collecting, storing, and acting on such sensitive information in a clinical setting. We note that practitioners may add additional domains if they believe those domains are relevant to their patient population, in which case they could utilize a tool that includes interpersonal safety.

After consideration of public comments, we are finalizing as proposed, that any standardized, evidence-based SDOH risk assessment tool that has been tested and validated through research, may be used to conduct the SDOH risk assessment. The tool must include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.

We solicited comments regarding whether we should require as a condition of payment for SDOH risk assessment, that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations (CBO) to address identified SDOH needs.

Comment: Commenters were mixed on this potential required condition of payment. Most commenters agreed with our assessment that follow-up is critical to mitigating the impacts of unmet SDOH needs. However, commenters differed on how CMS should potentially handle this. Many commenters agreed

[28] *https://health.gov/our-work/nutrition-physical-activity/white-house-conference-hunger-nutrition-and-health.*

that furnishing CHI, PIN, other care management services, or having partnerships with CBOs would address identified SDOH needs and was a reasonable requirement to furnish this service. Some commenters stated that we should only finalize this proposal with some requirement for follow-up. A few commenters stated that there is no need to perform an SDOH risk assessment if the practitioner does not have the ability to provide adequate follow up in place. Some commenters agreed that ideally, a practitioner would have an established relationship with a CBO, but noted that in some areas, particularly those that are rural and underserved, there are a limited supply of CBOs to address SDOH needs. Other commenters asked us to clarify if we were expecting practitioners to solve long-standing barriers for patients, or if we were focused on immediate actions that practitioners could take based on a positive risk assessment. A few other commenters agreed with the importance of follow-up but noted that this requirement is too burdensome for practitioners to have in place before they understand the SDOH needs of their patients and the communities in which their patients live.

Response: We continue to believe that follow-up or referral is an important aspect of following up on findings from an SDOH risk assessment. We acknowledge that practitioners may not be ideally suited to solve long-standing SDOH concerns, but we also agree with commenters that follow up or referral after an SDOH risk assessment is an important element to addressing the issues that impact a patient's health and can help the patient connect with services and individuals that can address more of the patient's SDOH needs. We are clarifying that we are focused on SDOH risk assessment to identify issues that impact the practitioner's ability to diagnose and treat the patient. We thank the commenters for noting supply issues with CBOs in some places, and we understand that this will likely be an ongoing issue for some time, particularly in rural and underserved areas as many practitioners do not currently have relationships with CBOs. We are also sensitive to the operational needs of practitioners who do not yet have these resources in place, but who may wish to develop these relationships with the advent of this new coding. We are attempting to strike a balance between these two needs. We expect to monitor utilization of these codes, and we leave open the opportunity to reevaluate this decision on an ongoing basis.

Comment: Many commenters supported the use of the ICD–10–CM codes known as Z codes (Z55–Z65) for documentation of SDOH data. A few commenters recommended CMS require the use of Z codes for standardization and interoperability across platforms. Other commenters recommended CMS mention or require the utilization of other systems for documenting social needs. Commenters who discussed the duration of 5–15 minutes agreed that this seemed appropriate.

Response: As stated previously, we understand and recognize the importance of data standardization and interoperability. We are requiring that the SDOH needs identified through the risk assessment be documented in the medical record, and we are actively encouraging Z-code reporting to improve our data and understanding of how SDOH affect the patient populations enrolled in CMS programs. For example, recently CMS identified that when the Z code for homelessness was encoded during an inpatient admission, there is an increase in resource usage by the hospital, and as such, CMS underwent rulemaking to incorporate the Z code for homelessness as a comorbidity or complication that would increase the severity level in the MS–DRG [29] system.

Comment: Many commenters discussed the proposed frequency limitation of once per 6 months, requesting that CMS clarify if the limitation was per beneficiary, or per practitioner per beneficiary. Many commenters noted operational difficulty if the frequency limitation was per beneficiary, as beneficiaries often have practitioners across different health systems, and interoperability constraints with EHRs would make it difficult to verify if the patient had received an SDOH risk assessment in the last 6 months. Other commenters noted that a new diagnosis may cause a rapid shift in SDOH needs, with sudden onset of mobility and transportation difficulty, or a disability that limited a beneficiary's ability to work. Many commenters discussed alternative frequency limitations, understanding that 6 months may be appropriate for those without previous SDOH needs, but more frequent risk assessment may be necessary for those with a history of unmet SDOH needs. Commenters also noted that the SDOH risk assessment would be especially salient during care transitions such as discharge from a facility such as a hospital or SNF, or a beneficiary who was seen several times in the emergency department recently.

Response: We appreciate the commenters for their thoughtful and thorough comments. We agree that with new services, the appropriate frequency limitation is often difficult to ascertain. We also appreciate the operational difficulty of knowing when a beneficiary last received an SDOH risk assessment, given that many beneficiaries seek care with several practitioners or in different health systems. We acknowledge that SDOH needs may change quickly, especially in beneficiaries with a history of unmet social needs. We also agree with the comments discussing that care transitions are especially important moments for potential SDOH risk assessment and note that the Transitional Care Management (TCM) (CPT codes 99495 and 99496) are E/M visits and qualify as an associated visit. We aim to strike a balance between what is best for the patient and what is operationally best for the practitioner, as well as considering the patient's cost sharing responsibilities for each time HCPCS code G0136 is furnished separately from the AWV. We also note that if a patient requires frequent SDOH reassessments, this patient may benefit from CHI or PIN to manage these concerns on an ongoing basis. We will continue to engage with interested parties and may consider policy changes in future rulemaking cycles based on our review of claims data or feedback from interested parties.

In light of comments we received in response to the proposed rule, we are not finalizing the requirement that the practitioner who furnishes the SDOH risk assessment must also have the capacity to furnish CHI, PIN, other care management services, or have partnerships with CBOs. We do expect that the practitioner furnishing an SDOH risk assessment would, at a minimum, refer the patient to relevant resources and take into account the results of the assessment in their medical decision making, or diagnosis and treatment plan for the visit.

We are finalizing as proposed that any SDOH need identified during HCPCS code G0136 must be documented in the medical record. We are clarifying that we are not requiring the use of the Z code for documentation, though we are confirming that use of Z codes would be appropriate to document SDOH needs in the medical record. We encourage the use of Z codes across CMS programs to better understand the needs of our beneficiaries. We are finalizing a limitation on payment for the SDOH

[29] 88 FR 58640.

risk assessment service of once every 6 months per practitioner per beneficiary.

iii. Valuation for SDOH Risk Assessment (HCPCS Code G0136)

We proposed a direct crosswalk to HCPCS code G0444 (*Screening for depression in adults, 5–15 minutes*), with a work RVU of 0.18, as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0136. HCPCS code G0444 has an intraservice time of 15 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0136. Therefore, we proposed a work time of 15 minutes for HCPCS code G0136 based on this same crosswalk to HCPCS code G0444. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0136.

We believe these services would largely involve direct patient contact between the billing practitioner or billing practitioner's auxiliary personnel and the patient through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we proposed to add this code to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner (or their auxiliary personnel incident to the practitioner's services) completes the risk assessment in an interview format, if appropriate. We believe it is important that when furnishing this service, all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We solicited comment on where and how these services would be typically provided, along with other aspects of the SDOH assessment service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters agreed with our proposed crosswalk to HCPCS code G0444 for similar time, intensity, and direct PE inputs. Commenters were overwhelmingly supportive of our proposal to add HCPCS code G0136 to the Medicare Telehealth Services List. Commenters also supported CMS' belief that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. A few commenters noted that SDOH risk assessments are typically provided in an outpatient setting on a tablet or paper document by auxiliary personnel. A few commenters noted that they are performing routine SDOH ''screening'' at standard intervals, with one commenter noting they screen patients at every visit. We also received a few comments requesting that CMS provide more clarity on the intersection between HCPCS code G0136 and PIN services. These commenters asked if HCPCS code G0136 should be used to reassess when SDOH needs are present while the patient is also receiving PIN services, or if SDOH reassessment can be counted towards time spent performing PIN services.

Response: We appreciate the comments providing more context around how similar services are currently being furnished. See section II.D. of this rule for more comments on the addition of the SDOH risk assessment service, HCPCS code G0136, to the Medicare Telehealth List. We reiterate that HCPCS code G0136 is not intended to be a routine screening for SDOH at standard intervals or every visit. We agree with commenters that SDOH risk assessment is related to CHI and PIN services, and we believe that time spent performing HCPCS code G0136 should count towards the 60 minutes per month spent in the performance of PIN services.

After consideration of public comments, we are finalizing, as proposed, a direct crosswalk for HCPCS code G0136 to HCPCS code G0444, with a work RVU of 0.18, intraservice time of 15 minutes, and matching direct PE inputs from HCPCS code G0444 to HCPCS code G0136.

e. Principal Illness Navigation (PIN) Services

i. Background

Experts on navigation of treatment for cancer and other high-risk, serious illnesses have demonstrated the benefits of navigation services for patients experiencing these conditions.[30] Experts have noted the importance of these services for all affected patients, but especially those with socioeconomic disadvantages or barriers to care. Navigation generally means the process or activity of ascertaining one's position and planning and following a route; the act of directing from one place to another; the skill or process of plotting a route and directing; the act, activity, or process of finding the way to get to a place you are traveling. In the context of healthcare, it refers to providing individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the landscape is complex and delaying care can be deadly. It is often referred to in the context of patients diagnosed with cancer or another severe, debilitating illness, and includes identifying or referring to appropriate supportive services. It is perhaps most critical when a patient is first undergoing treatment for such conditions, due to the extensive need to access and coordinate care from a number of different specialties or service-providers for different aspects of the diagnosis or treatment, and in some cases, related social services (for example, surgery, imaging and radiation therapy, chemotherapy for cancer; psychiatry, psychology, vocational rehabilitation for severe mental illness; psychiatry, psychology, vocational rehabilitation, rehabilitation and recovery programs for substance use disorder; infectious disease, neurology and immunology for human immunodeficiency virus (HIV)-associated neurocognitive disorders). For some conditions, patients are best able to engage with the healthcare system and access care if they have assistance from a single, dedicated individual who has ''lived experience'' (meaning they have personally experienced the same illness or condition the patient is facing). Although we currently make separate payment under the PFS for a number of care management and other services that may include aspects of navigation services, those care management services are focused heavily on clinical aspects of care rather than social aspects and are generally performed by auxiliary personnel who may not have lived experience or training in the specific illness being addressed. We sought to better understand whether there are gaps in coding for patient navigation services for treatment of serious illness, that are not already included in current care management services such as advance care planning services (CPT codes 99497–99498), chronic care management services (CPT codes 99490, 99439, 99491, 99437, 99487 and 99489), general behavioral health integration care management services (CPT code 99484), home health and hospice supervision (HCPCS codes G0181–G0182), monthly ESRD-related services (CPT codes 90951–90970), principal care management services (CPT codes 99424–99427), psychiatric collaborative care management services (CPT codes 99492–99494), and transitional care management services (CPT codes 99495–99496). See

[30] See for example, *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide.*

additional information on our PFS Care Management Services web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

For CY 2024, we proposed to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. Examples of serious, high-risk diseases for which patient navigation services could be reasonable and necessary could include cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder (SUD). We proposed new coding for Principal Illness Navigation (PIN) services. In considering the appropriate patient population, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[31] Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years.[32] Some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[33] The navigation services such patients need are similar to CHI services (as outlined previously in this section), but SDOH need(s) may be fewer or not present; and there are specific service elements that are more relevant for the subset of patients with serious illness. Accordingly, we proposed for PIN services a parallel set of services to the CHI services, but focused on patients with a serious, high-risk illness who may not necessarily have SDOH needs; and adding service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed.

Note about definitions: we are finalizing an additional subset of PIN codes below. For purposes of this section, where we refer to PIN, we mean all associated PIN codes (HCPCS codes G0023, G0024, G0140, and G0146). If there are items that do not apply to all, that is noted.

ii. Proposed Principal Illness Navigation (PIN) Service Definition

We proposed that PIN services could be furnished following an initiating E/M visit addressing a serious high-risk condition/illness/disease, with the following characteristics:

- One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death;
- The condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

Examples of a serious, high-risk condition/illness/disease include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder (SUD).

We proposed that the PIN initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the PIN services during the subsequent calendar month(s). The PIN initiating visit would be separately billed (if all requirements to do so are met) and would be a pre-requisite to billing for PIN services. We believe that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as PIN initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary PIN services in the subsequent month(s).

The PIN initiating visit would serve as a pre-requisite to billing for PIN services, during which the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. The subsequent PIN services would be performed by auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit. The same practitioner would furnish and bill for both the PIN initiating visit and the PIN services, and PIN services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that PIN services are billed, but only prior to commencing PIN services, to establish the treatment plan, specify how PIN services would help accomplish that plan, and establish the PIN services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual which provides, ''where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.*

We also solicited comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for PIN services, including, for example, an AWV that may or may not include the optional SDOH risk assessment. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner, or by other types of health professionals whose scope of practice does not include the diagnosis and

[31] *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[32] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

[33] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

treatment involved in E/M services, for example a health educator.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported this proposed code. Several commenters expressed support for PIN services but requested that CMS exempt PIN services from budget neutrality. Many commenters discussed the wide range of benefits navigation services can have on a variety of conditions. Some commenters discussed the important health equity implications for such a proposal, citing research showing that members of historically disadvantaged communities and communities of color often receive lower rates of patient navigation, are often diagnosed with serious, high-risk illnesses like cancer at later stages, and have longer times between suspicion and definitive diagnosis for conditions like cancer. Many of these inequities are tied to access issues, and commenters suggested that PIN services would fill a critical gap in navigation services, noting that many navigation programs are currently grant-funded and unable to serve all patients that might benefit. Commenters also opined on the benefits of condition-specific navigation, discussing the value of navigators with targeted training or lived experience in the conditions for which they are providing navigation services.

We received many comments requesting that CMS clarify the definition of a serious, high-risk condition, the expected duration of the illness, and whether conditions beyond those we listed are appropriate. Commenters stated that CMS should not limit the timeframe to an expected duration of 3 months, discussing that there are many conditions that meet all requirements listed by CMS of a serious, high-risk condition, but that may be treated with the patient being cured or in remission within a 3-month period. Many commenters applauded our inclusion of severe mental illness and substance use disorder (SUD) as serious, high-risk conditions and noted that PIN services could be very impactful for these beneficiaries. Other commenters requested clarification on conditions such as chronic liver disease, chronic kidney disease, stroke, diabetes, and conditions with treatments that require stem cell transplantation.

Response: With respect to budget neutrality, we remind commenters that section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. There is no statutory exception available for PIN services, so the expected spending associated with these services must be included in the CY 2024 BN adjustment.

As we noted in the proposed rule, the definition of a serious, high-risk condition is dependent on clinical judgement. The list of conditions we provided is not exhaustive, and we will monitor utilization across beneficiaries and specialties to ascertain where and how PIN services are best utilized going forward. We agree with the commenters that additional conditions such as chronic liver disease, chronic kidney disease, stroke, and conditions that require stem cell transplantation could all meet the outlined definition depending on the specific severity of the illness in individuals with these conditions. We disagree with commenters who requested the inclusion of conditions that can be treated fully within the 3-month timeframe, as we do not believe a condition of this limited duration would require the extent of navigation services provided by PIN. We believe that an expected 3-month period is a reasonable benchmark for the use of PIN services, as we envision PIN services as necessary to treat serious, high-risk conditions that require navigation over the course of several months.

Comment: Many commenters recommended that CMS should not restrict PIN initiating visits to only E/M visits. Commenters noted that for many beneficiaries with severe mental illness or substance use disorder (SUD), a clinical psychologist may be the only health care practitioner they see regularly. Since clinical psychologists do not furnish E/M services, these beneficiaries would be unable to benefit from PIN services. Several commenters recommended including Behavioral Health Integration (BHI) and bundled office-based substance use disorder codes as initiating visits. Other commenters noted that inpatient/observation E/M visits and ED visits should count as initiating visits. Some commenters requested that CMS address whether TCM services would count as an initiating visit, further commenting that some serious, high-risk conditions are diagnosed in the hospital or similar setting, and PIN services would be beneficial upon discharge from such a facility. Many commenters also requested that the AWV count as an initiating visit for PIN. We received comments from dementia practitioners stating that the AWV includes a cognitive decline assessment, and positive results would likely prompt a practitioner to order PIN services. Commenters also requested clarification regarding the requirement that the initiating visit be completed by the practitioner who will be furnishing PIN services during the subsequent calendar months, with commenters discussing the burden of supervision for ongoing PIN services if one practitioner was covering for another practitioner, had the initiating visit for PIN, and would then transition care back to the returning practitioner after PIN services had started.

Response: We appreciate the commenters' views and specific examples of how PIN services may be furnished. We thank the commenters for pointing out that clinical psychologists may be the practitioner type that primarily interfaces with beneficiaries with severe mental illness and SUD, and that they would be unable to furnish PIN given the proposed requirement for an E/M initiating visit. We agree with commenters that clinical psychologists should be able to bill PIN codes, especially for those with behavioral health conditions. We note that clinical psychologists have an incident to benefit under § 410.26, and clinical psychologists most commonly use CPT code 90791 (*Psychiatric diagnostic evaluation*) and the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 to diagnose and treat behavioral health conditions as analogous codes to E/M, based on the services clinical psychologists are allowed to furnish under State law and scope of practice. We note that the BHI codes and office-based substance use disorder bundled codes also describe care management services. We believe considering those codes as an initiating visit for PIN would be duplicative, as they also require an initiating visit, but that is specified for those services. Therefore, we believe they would not serve the purpose of an initiating visit, which is meant to establish the beneficiary's relationship with the furnishing practitioner, ensure the practitioner assesses the beneficiary and identifies a clinical need for services prior to initiating care management, and provide an opportunity to inform the beneficiary about the services and obtain beneficiary consent (if applicable).

We agree with commenters that the E/M visit done as part of a Transitional Care Management (TCM) services could

serve as an initiating visit for PIN services because it includes a high-level office/outpatient E/M visit furnished by a physician or nonphysician practitioner managing the patient in the community after discharge.

We appreciate the commenters' suggestions about including the AWV as a type of initiating visit, and the comments from dementia practitioners who discussed that the cognitive decline assessment in the AWV may be a flag for initiating PIN services. In these circumstances the personalized prevention plan services may include elements for further diagnosis and treatment of cognitive impairment and dementia, which may count as a high-risk condition in certain clinical scenarios based on clinical judgement. We acknowledge that an AWV may be provided by health care practitioners who do not have the authority to diagnose or treat medical conditions. To this end, we believe it would be inconsistent with our proposed application of the ''incident to'' regulations, as a condition of payment, to allow an AWV furnished by a health care practitioner, other than a physician or qualified health care practitioner, to serve as the initiating visit for PIN services. Given that the AWV is a preventative service, there may be instances where the patient sees a medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician where an SDOH need may be identified. Additionally, the Personalized Prevention Plan that is part of AWV may also help a patient who has identified in the AWV a high-risk condition(s) that meets the standard for PIN, and the high-risk condition may be part of the focus of the recommended Personalized Prevention Plan.

There is no benefit under the PFS for facility settings in accordance with the ''incident to'' regulation at § 410.26. Since PIN services are provided under incident to regulations, inpatient/observation E/M visits and ED visits cannot serve as initiating visits for the purpose of PIN. We also continue to believe that the furnishing practitioner should have continuity from initiating visit through the supervision of PIN services, given the medical necessity of PIN services, and the formation of the appropriate treatment plan specific to that patient. This framework is similar to the current requirements for billing care management services, and the requirements for billing CHI services that we are finalizing in this rule. PIN services are furnished over the course of a month, and we note that patients do not stay in inpatient, observation, or ED settings for one month, making practitioners in this setting unable to furnish PIN services for the duration of the month, as required under incident to requirements.

After consideration of public comments, we are finalizing CPT code 90791 (*Psychiatric diagnostic evaluation*) and the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 as initiating visits for PIN services, as we believe these are the most analogous codes to E/M codes that are utilized by clinical psychologists.

We are also finalizing that the AWV may serve as an initiating visit for PIN services when the AWV is furnished by a practitioner who has identified in the AWV a high-risk condition(s) that would qualify for PIN services under this rule.

For purposes of assigning a supervision level for payment, we proposed to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

We proposed the following codes for PIN services. As described previously, and in our proposed PIN code descriptors, the term ''SDOH need(s)'' means an SDOH need(s) that is identified by the billing practitioner as significantly limiting the practitioner's ability to diagnose or treat the serious, high-risk condition/illness/disease addressed in the initiating visit. We note that SDOH needs are not required for use PIN services but may be applicable. ''Addressed'' means the definition in the CPT E/M Guidelines that we have adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service.

For purposes of PIN services, we proposed that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We proposed to adopt CPT's examples of SDOH, with additional examples. Specifically, we proposed that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the serious, high-risk illness/condition/disease.

G0023—Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and establishing an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- Practitioner, Home, and Community-Based Care Coordination

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs,*

functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

G0024—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to G0023).

To help inform whether our descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we solicited comment on the typical amount of time practitioners spend per month furnishing PIN services. We also solicited comment to better understand the typical duration of PIN services, in terms of the number of months for which practitioners furnish PIN services following an initiating visit.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of including PIN as a care management service that may be furnished under general supervision. Commenters were overwhelmingly supportive of our inclusion of patient navigators in the code description, with many comments focusing on the breadth of types of patient navigators in relation to the treatment of serious, high-risk conditions. These commenters were supportive of the required service element activities outlined in the proposal. Commenters were generally not in favor of limiting the frequency of the add-on code, and many commenters stated that navigation time spent per month is greatly dependent on the condition or illness for which it is being provided and the needs of the beneficiary being served. A few commenters discussed that CMS could add flexibility in for those patients who require a lot of navigation time per month by not limiting the frequency of the add-on code. Commenters working in the cancer/oncology space estimated an average duration of 6 months of navigation, and commenters from the dementia care community suggested navigation of 3–6 months duration. Comments related to the amount of time per month varied widely, with many commenters in general discussing the difficulty and burden in trying to capture every minute of service time.

Response: We appreciate the varying nature of requirements for navigation across conditions. We strive to strike a balance, and we will monitor utilization and feedback from interested parties going forward to determine if changes need to be made. We appreciate the comments regarding a duration of 3–6 months across different conditions, as this aligns with our vision that PIN services will likely be needed for several months. We appreciate the difficulty named by commenters in estimating an ''average'' amount of time per month, as conditions and circumstances vary widely. We agree that the add-on code offers flexibility to provide more time if needed to patients, and we understand that if we limited the use of the add-on codes, we would be limiting the amount of time spent per month on navigation around an average that not every patient fits into.

Comment: Several commenters suggested that HCPCS code G0023 be broken into 20-minute increments, with 3 increments making up the first code, and HCPCS code G0024 describing an additional 30 minutes. One commenter suggested increasing HCPCS code G0023 to 120 minutes and another commenter suggested that months 1 and 2 of PIN services should be 120 minutes, then subsequent months decreased to 60 minutes per month as intensity of navigation decreases after the initial diagnosis and treatment period. A few commenters suggested no limit on the duration of PIN services, while another commenter suggested that another initiating visit be required every 6 months. Some commenters suggested that a timed code was not the best for this type of service and suggested CMS adopt a per member per month flat fee. Lastly, several commenters requested clarification on whether PIN services could start before definitive diagnosis, noting that for some types of cancer, there is not a definitive diagnosis until a surgical intervention has been performed, but that there are many steps leading up to that, and current navigation programs often start with practitioner suspicion of such a diagnosis, for example after a positive screening test such as a mammogram. Commenters noted that this impacts the duration of expected PIN services, as it can often be a month or more between suspicion and definitive diagnosis. These commenters also cited research outlining health equity impacts, as many underserved communities have higher rates of late diagnosis due to delayed follow-up. These commenters stated that early navigation is currently being used to get patients, especially those in underserved communities, to a definitive diagnosis faster.

Response: We understand the variability in the time that can be spent providing navigation services, given the diverse nature of what we have defined as a ''serious, high-risk illness.'' We continue to believe that PIN services should reflect a substantial amount of time spent per month in the navigation of the principal illness. We believe that if a patient requires less than 60 minutes per month for PIN services, then their needs may be best suited to other types of care management services. We thank the commenters for discussing the expected duration of PIN services in the context of how frequently the initiating visit should be performed. We disagree that a new initiating visit should be required every 6 months, but we do believe that requiring one every year

would be an appropriate middle ground between every 6 months and not requiring one as long as the serious, high-risk condition persists. We agree with commenters that the length of time between suspicion (such as a positive screening test) and definitive diagnosis can stretch into weeks for some conditions, and navigation services may be medically necessary to ensure full diagnosis and treatment of that condition. We note that our definition of a ''high risk condition'' does not exclude conditions without a definitive diagnosis. For example, a patient may have a mass in the colon identified on a CT scan of the abdomen. Regardless of the definitive diagnosis of the mass, presence of a colonic mass for that patient may be a serious high-risk condition that could, for example, cause obstruction and lead the patient to present to the emergency department, as well as be potentially indicative of an underlying life-threatening illness such as colon cancer. As such, a practitioner could exercise clinical judgement and determine that the mass represents a serious high-risk condition for that patient, and that PIN services should be furnished as part of the early treatment plan. Therefore, we are clarifying that a definitive diagnosis is not required before the practitioner makes a clinical determination that the patient has a serious high-risk condition.

Comment: We received several comments about our proposals for PIN and the SDOH risk assessment requesting that CMS clarify the requirements surrounding the reassessment of unmet social needs and proposed frequency limitations. Commenters also noted that there was no defined activity within the proposed PIN elements of service to perform an SDOH risk assessment and sought clarification on the intersection between PIN and the SDOH risk assessment code.

Response: We agree with commenters that the reassessment of known SDOH needs is interrelated to PIN services, especially within the presence of a serious, high-risk condition. We also agree that this reassessment should not be confined to the frequency limitations described for HCPCS code G0136.

Comment: We received many comments from the peer support community applauding our inclusion of certified peer support specialists in the code descriptor for PIN services. Commenters were effusive in their support for the use and benefits of peer support specialists for beneficiaries with behavioral health conditions like severe mental illness and SUD. Peer support specialists also appreciated the inclusion of lived experience as a key element to PIN services and noted that this lived experience is a particular strength and benefit that peer support specialists bring to their patients. These commenters discussed the fear and mistrust that commonly exists within the medical community regarding behavioral health conditions, and these commenters noted that peer support specialists help bridge that gap, as their lived experience enables them to be a trusted and safe member of the care team. Many of these commenters stated that, while they are certified and trained to perform many of the activities listed in the code descriptor, care coordination activities fall outside the scope of certified peer support specialists. We required in our proposal that auxiliary personnel performing PIN services be certified or trained to perform all activities, and these commenters stated that this requirement would effectively exclude peer support specialists from performing PIN services. These commenters discussed that beneficiaries with severe mental illness and SUD would benefit from the significant set of activities described for PIN services that peer specialists are qualified to perform and urged CMS to create unique coding for PIN performed by peer support specialists, removing the requirements that fall outside of peer support specialist expertise.

Several commenters discussed that, given low reimbursement rates throughout the health care industry for peer support services, many clinicians do not have experience working with peer support specialists, and misinformation about the role abounds. Commenters acknowledged that one way to include peer support specialists in HCPCS codes G0023 and G0024 would be to remove the requirement as proposed for all PIN auxiliary staff to be trained and certified in all service elements of PIN. However, these commenters described that peer support specialists are often asked to perform tasks outside of their competency and role. These commenters discussed the difficulty they face in clinical settings when the expectations placed on them by clinical practitioners do not align with what peer support specialists understand to be their scope and role on the treatment team. These commenters stated concern that having care management activities listed in the service descriptor but not required would further misunderstanding about the peer support specialist role and would lead to peer support specialists being asked to complete those tasks. Commenters also suggested that CMS remove the care coordination elements in the PIN code descriptors altogether to align these services with peer support competencies. We also received many comments recommending that CMS should align the PIN activities with SAMHSA's National Model Standards for Certification [34] for peer support workers.

Commenters were generally aligned on the specific items they noted were outside of the scope of peer support specialists but differed on how to handle these items. Below is a list of the items in the PIN descriptor on which we received comment.

One commenter recommended removing • *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.* The same commenter recommended changing ++ *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors, and including unmet SDOH needs (that is not separately billed)* to ++ *Conducting a person-centered interview.* Most commenters recommended changing ++ *Providing tailored support as needed to accomplish the practitioner's treatment plan* to ++ *Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan,* while another commenter removed this item.

Response: We thank the commenters for their feedback. The peer support community has told us through public comment that they have issues with scope of work, and they are frequently asked to perform tasks outside of their scope of practice. We defer to the peer support community with their suggestion of changing the word assessment to interview to make the language more consistent with peer support competencies and scope of practice. We also believe it is important to explicitly state items to be included in the interview. We agree with the commenters who suggested modifying this bullet to ''person-centered goals'' in the treatment plan, as this is in alignment with both peer support values as stated by the commenters and maintains the intention of the descriptor.

Comment: All commenters recommended either renaming • *Practitioner, Home, and Community-Based Care Coordination* to • *Practitioner, Home, and Community-*

[34] *https://www.samhsa.gov/about-us/who-we-are/offices-centers/or/model-standards.*

Based Care Communication or removing this bullet. All commenters recommended removing ++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).*

Commenters either recommended removing this bullet or renaming ++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors* to ++ *Assisting the patient in communicating with their practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

All commenters recommended removing ++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

Response: We largely defer to the commenters' judgements about these word choices, but we agree that ''assisting the patient in communicating'' with practitioners is largely analogous to communicating on behalf of patients, and we appreciate the intention to leave this important facet of all navigation services in the PIN code. Given that all commenters were in favor of removing some bullets, we again defer to the peer support community.

All commenters recommended removing • *Health care access/health system navigation.*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.*

++ *Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.*

Response: We thank the commenters for their feedback. Given that commenters were unanimous in removing these items from the descriptor, we support removing them from the PIN–PS descriptor.

Comment: Commenters were split on the descriptor • *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.* Some commenters suggested removal of this bullet, whereas others recommended rewriting to • *Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals.*

Response: We believe the inclusion of strategizing with a patient to help them meet their treatment goals is an important element of PIN services. We support the revision of this bullet to emphasize the person-centered approach to treatment goals and assisting the patient in using individualized strategies towards this aim.

Comment: Commenters also differed on • *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.* A few commenters suggested the addition of *person-centered* to meet the diagnosis and treatment goals, whereas others removed everything after *daily routines.* One commenter recommended editing • *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals* to end after inspiration, removing mention of meeting treatment goals.

Response: We continue to believe that the intersection of the diagnosis and treatment goals with the support provided to the patient is essential to the success of PIN services. We also support the revision throughout these code descriptors to emphasize the ''person-centeredness'' of diagnosis and treatment goals.

We are sympathetic to the nuances of the interactions between peer support specialists and clinicians, and we appreciate the peer support community for bringing these issues to our attention. We agree with the value and benefit of having peer support specialists as part of the treatment team for those with severe mental illness and SUD. We are clarifying that our intention in creating the PIN service elements was to include a navigation role for certified peer support specialists in the treatment of severe mental illness and SUD. We believe that it is important to preserve the care management elements of PIN that can be performed by other types of health care professionals, and which are important to PIN for many serious, high-risk conditions. We also recognize the role that peer support specialists can serve in providing navigation for patients with severe mental illness and SUD through PIN services. We thank the commenters for their efforts in specifically describing the items in the PIN service descriptor that they believe fall outside of the scope of a peer support specialist. We understand that, given the misalignment that can occur between clinical practitioners and peer support specialists regarding their role on the treatment team outlined in the peer support specialists' comments, it is important to be as specific when possible to avoid misunderstanding about the types of auxiliary personnel we envision performing these services. We believe that further defining the role of peer support specialists within PIN codes will help alleviate this misalignment. We note that the comments were generally unified around the removal or modification of some items, and we believe that the overall nature and value PIN services provide to behavioral health patients is unchanged from the original PIN descriptor.

As described by the commenters, the conducting of a person-centered assessment or interview to understand the patient's life remains critical to the medical benefit of navigation for serious, high-risk conditions including behavioral health conditions. Discussing goal setting, establishing an action plan, and identifying or referring the patient to appropriate supportive services is important to ensuring behavioral health patients stay engaged in the treatment of their principal illness. As discussed previously, we heard from commenters that many patients with behavioral health conditions have unmet SDOH needs, and service elements such as facilitating access to community-based social services, health education, and building patient self-advocacy skills all help patients better understand their condition, contextualize their principal illness within their lives, and advocate for themselves both in and out of health care settings with the aim of improving their diagnosis and treatment of said condition.

After consideration of public comments, we are finalizing the service elements, descriptors, and time per month for HCPCS codes G0023 and G0024 generally as proposed, with the addition of ''*and including unmet SDOH needs (that are not separately billed)*'' as part of the person-centered assessment. This addition is in response

to comments made in both the HCPCS code G0136 and PIN sections regarding the intersection of the SDOH risk assessment code. This service element describes the need to reassess SDOH needs within both CHI and PIN and allows for time spent performing SDOH reassessment that is not otherwise billed to count towards CHI and PIN services. We clarify that this time cannot be duplicated by HCPCS code G0136 or any other service. Below are the final code descriptors for HCPCS codes G0023 and G0024.

G0023—Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the practitioner's treatment plan.

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

G0024—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to G0023).

For certified peer support specialists, we continue to believe the work provided by peer support specialists is crucial to the treatment of some patients with behavioral health conditions. We attempted to recognize this work with our proposed PIN code, but given the public comments we received, we are also finalizing two new codes, HCPCS code G0140 and HCPCS code G0146 for Principal Illness Navigation—Peer Support (PIN–PS). Given the nature of work typically performed by peer support specialists, we are limiting these codes to the treatment of behavioral health conditions that otherwise satisfy our definition of a high-risk condition(s). Patients with behavioral health conditions can still receive HCPCS code G0023 and HCPCS code G0024 services, so long as the auxiliary staff providing them is trained and certified in all parts of those code descriptors. We understand that behavioral health patients are not a monolith, and some patients may be best suited to traditional PIN services.

G0140—Principal Illness Navigation—Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered interview, performed to better understand the individual context of the serious, high-risk condition.*

++ Conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors, and including unmet SDOH needs (that are not billed separately).

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan.

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Communication*

++ Assist the patient in communicating with their practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in*

using chosen strategies to reach person-centered treatment goals.

- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

G0146—Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month (List separately in addition to G0140).

We are not finalizing a frequency limitation for the services described by HCPCS codes G0024 or G0146, and we will monitor utilization of these codes going forward to ascertain the time spent per month per PIN service. We are not limiting the duration PIN services, but we are finalizing a requirement that a new initiating visit be conducted once per year. We proposed that all auxiliary personnel who provide PIN services must be certified or trained to provide all elements in the corresponding service and be authorized to perform them under applicable State law and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. Many States have applicable rules and certifications, and there are existing certification programs for navigators working in certain settings of care or with specified conditions, such as cancer navigators, diabetes navigators, cardiovascular navigators, mental health navigators, geriatric care navigators, pediatric navigators, social worker navigators, primary care navigators, general patient advocate navigators, and nurse navigators in ambulatory settings.[35]

For peer support specialists, approximately 48 States have professional certification programs for those providing services to patients with substance use or mental health conditions. States may include qualified peer support specialist in their Medicaid programs. In 2007, the Center for Medicaid and CHIP Services published guidance outlining minimum requirements for peer support specialist participating in Medicaid as follows: peer support specialists must be self-identified consumers who are in recovery from mental illness and/or substance use disorders, supervised by a competent mental health professional, and complete training that provides peer support specialists with a basic set of competencies necessary to perform the peer support function, including demonstrating the ability to support the recovery of others from mental illness and/or substance use disorders and ongoing continual educational requirements.[36] In States with professional certification programs, training and certification requirements vary, with an average of 40 and 46 hours of initial approved education, with almost all States requiring either a written or written and oral exam. A little less than half of States also require supervised work or volunteer hours to obtain certification.[37]

In States that do not have applicable licensure, certification, or other laws or regulations governing the certification or training of auxiliary personnel, we proposed to require auxiliary personnel providing PIN services be trained to provide all service elements. Training must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit. We proposed these competencies because we believe they reflect professional consensus regarding appropriate core competencies, adjusted to this context.[38] We solicited public comment on the number of hours of training to require, as well as the training content and who should provide the training.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments, outside of the peer support specialist community, regarding training and certification for auxiliary personnel providing PIN service elements. One commenter emphasized the importance of training and/or lived experience with the relevant condition to the PIN services being provided, and this commenter suggested training for all auxiliary personnel should require case studies for each condition for which the auxiliary personnel will be providing navigation. Commenters were split on whether a standard amount of training hours should be required, with one commenter suggesting 8 hours per year, and another commenter suggesting a requirement of 225 hours for the initial training. Another commenter suggested all navigators be trained in oncology navigation, given the prevalence of cancer in many communities, regardless of what population they will primarily serve. Another commenter discussed the importance of providing training on how to help patients access clinical trials. One commenter recommended CMS require all auxiliary personnel performing PIN services to have a bachelor's degree. Another commenter recommended CMS require training in trauma-informed care, implicit bias, empathetic inquiry, and motivational interviewing.

Response: We appreciate the suggestion of case studies and condition-specific training, as we outlined in the proposed rule. While we agree that PIN services are well-suited for oncology navigation, we disagree with the idea that all auxiliary personnel providing PIN services should be trained in oncology navigation, given that we expect PIN services to be focused on the principal illness for which PIN services are being furnished. We note that since we are finalizing PIN services as ''per condition,'' rather than the patient only being able to have one PIN service at a time, this crossover in navigation is unnecessary, as a patient receiving PIN for one condition that gets diagnosed with cancer would likely qualify for a second, oncology-specific PIN navigator. Given the wide variety of suggestions we received from commenters regarding the number of specific hours to require, we believe that it is important for PIN services to allow for many types of auxiliary personnel to furnish PIN, making potential standardization of training and education requirements, such as a set number of hours of training, difficult.

After consideration of public comments, we are not finalizing a required number of hours of training for auxiliary personnel to provide PIN services. We defer to State requirements

[35] *https://resumecat.com/blog/patient-navigator-certifications.*

[36] *https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/smd081507a.pdf.*

[37] *https://peerrecoverynow.org/wp-content/uploads/2023-FEB-07-prcoe-comp-analysis.pdf.*

[38] *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide; https://chwtraining.org/c3-project-chw-skills/;* and *https://peerrecoverynow.org/wp-content/uploads/Comparative-Analysis_Jan.31.2022-003.pdf; https://www.samhsa.gov/sites/default/files/national-model-standards-for-peer-support-certification.pdf?utm_source=SAMHSA&utm_campaign=4b88ba3e51-EMAIL_CAMPAIGN_2023_06_05_02_41&utm_medium=email&utm_term=0_-4b88ba3e51-%5BLIST_EMAIL_ID%5D.*

where applicable for all types of auxiliary personnel. For States with no applicable State requirements, we are finalizing as proposed that the training and certification for auxiliary personnel providing HCPCS codes G0023 and G0024 include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit.

Comment: Regarding certified peer support specialists, we received many comments regarding their training and certification requirements. A few commenters stated that training and certification is required at the State level in 49 States and that these requirements are sufficient for Medicaid payment by states. Several commenters requested that CMS not require any additional training for peer support specialists beyond State certification, as that would be a burden on the workforce and the agencies that employ them. A few commenters recommended that CMS mandate training alignment with the SAMHSA National Model Standards for the training of all peer support specialists, stating that these standards were developed with direct input and feedback from peer support workers themselves. These commenters discussed that it is important for those who are doing peer support work to have input into the training and certification standards for their profession.

Response: We note that a 2023 review of State requirements done in partnership with SAMHSA cited that two States remain without current peer support specialist certification or licensing requirements. One of the remaining States is currently working on developing a certification.[39] We thank the commenters for the mention of the National Model Standards, and we agree that we should aim to align across the Federal government where possible.

After consideration of public comments, for PIN–PS (HCPCS codes G0140 and G0146), if no applicable State requirements exist, we are finalizing that training must be consistent with the National Model Standards for Peer Support Certification published by SAMHSA. This is the most universally recognized standard for peer support specialists in the country and was developed and is maintained by SAMHSA, who has an expertise in this area.

We proposed that time spent furnishing PIN services for purposes of billing HCPCS codes G0023–4 must be documented in the medical record in its relationship to the serious, high-risk illness. The activities performed by the auxiliary personnel, and how they are related to the treatment plan for the serious, high-risk condition, would be described in the medical record, just as all clinical care is documented in the medical record. We would require identified SDOH need(s), if present, to be recorded in the medical record, and for data standardization, practitioners would be encouraged to record the associated ICD–10 Z-code (Z55–Z65) in the medical record and on the claim.

Similar to CHI services, we believe that many of the elements of PIN services would involve direct contact between the auxiliary personnel and the patient but may not necessarily be in-person and a portion might be performed via two-way audio. We sought to confirm our understanding of where and how PIN services would be typically provided (for example, with or without direct patient contact, in-person, using audio-video, using two-way audio; and whether navigators are typically local to the patient).

We solicited public comment regarding whether we should require patient consent for PIN services. For care management services that could generally be performed without any direct patient contact, we have required advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits, in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable, except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may unnecessarily prevent patient receipt of needed services. We did not propose to require consent for PIN services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, in the proposed rule we stated that if we heard from public commenters that PIN services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as several months), we would consider requiring patient consent to receive PIN services in our final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments regarding the use of two-way audio or audio-video technology in the current practice of navigation services. One commenter noted that the time required to provide navigation services for each patient had dropped during the pandemic when most of the communication switched to two-way audio or audio-visual. Other commenters discussed that for patients in rural areas, not requiring face-to-face contact in person reduced patient burden, given that the individuals providing navigation services may not be located in the exact community in which the patient live. This commenter noted that in rural areas, navigators often cover a large geographic area, but are still aware of community resources and all the appropriate services throughout their catchment area. Several commenters also discussed the importance of virtual communication for patients who are immunocompromised. A few commenters requested that PIN services be placed on the Medicare Telehealth Services List.

Response: We note that we did not receive comments directly discussing the current amount of time spent each month furnishing navigation services in person versus the amount of time spent using telecommunications. We did not receive comments discussing the

[39] *https://peerrecoverynow.org/wp-content/uploads/2023-FEB-07-prcoe-comp-analysis.pdf.*

amount of time navigators spend performing activities on behalf of the patient without the patient being present. We also did not receive much information regarding if there are elements of the navigation service that are best served face-to-face or pieces that are just as impactful if done via telecommunications technology. We agree with commenters generally that PIN services will likely benefit from the use of two-way audio or audio-visual technology as a key part of the service, but based on the comments received, we do not believe that we have a complete understanding of how technology is being used to furnish navigation services currently. We also acknowledge that PIN services (HCPCS codes G0023 and G0024) and PIN-Peer Support (HCPCS codes G0140 and G0146) may look different when they are being furnished. For example, the wording on the service elements for PIN–PS is slightly different, discussing that the navigator in PIN–PS ''assists the patient in communicating'' with health care practitioners, rather than communicating with the practitioners on behalf of the patient through coordination activities. This may mean that the navigator for PIN–PS is in direct contact with the patient more, as they are assisting the patient in performing a task, rather than performing that task on behalf of the patient. Given these intricacies and the lack of specificity in the comments we received, we do not believe we can make a determination at this time regarding whether or not PIN services meet the standards of services that are inherently in-person services that are instead furnished using an interactive telecommunications system as described in § 410.78(a)(3). Given these factors, we are not finalizing the inclusion of PIN services (HCPCS codes G0023, G0024, G0140, G0146) on the Medicare Telehealth Services List at this time. We will continue to consider this issue for potential rulemaking in the future.

Comment: In response to our comment solicitation, commenters were overwhelmingly in favor of requiring patient consent for PIN services. Many commenters cited patient cost sharing obligations, discussing both the expected duration of PIN services over several months, as well as the fact that some parts of the service may be provided without the patient present. Several commenters encouraged CMS to require consent, but noted potential burdens depending on how the consent is obtained, especially when advance consent is required. Commenters urged CMS to allow verbal consent to be documented in the medical record and to allow auxiliary personnel to document it. One commenter that was not in favor of requiring consent was concerned that a patient might not have a clear understanding of their condition and expected course of treatment at the beginning of a principal illness and is likely to be overwhelmed with information. This commenter further clarified that without adequate information, as well as potentially having concerns regarding their financial responsibility for both their course of treatment and any applicable cost-sharing for PIN, would decline PIN services without fully understanding the costs and benefits of navigation.

Response: We appreciate the commenters' thoughts about this issue. We acknowledge that beneficiaries are dealing with a lot at the time they are diagnosed with a principal illness, but we also acknowledge that navigation services are a key part of helping beneficiaries manage this difficult time. While we do not always require consent for all medically necessary services, we have required consent on occasion when services are being provided for a prolonged period of time and when some of the service may be performed without the patient's presence. In addition, the vast majority of commenters strongly supported the requirement of consent to provide improved patient awareness of cost-sharing responsibilities, especially given that these navigation services may be expected to last several months.

After consideration of public comments, we are finalizing that patient consent is required for PIN services, and that consent can be written or verbal, so long as it is documented in the patient's medical record. We believe that the commenters' feedback regarding the potential duration of PIN services over multiple months, in addition to the fact that PIN services may not be furnished with the patient present is convincing evidence that patients should be aware of their cost-sharing obligations over time for PIN services. We are finalizing that consent must be obtained annually and may be obtained by the auxiliary personnel either before or at the same time that they begin performing PIN services for the patient.

We proposed that a practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs or other auxiliary personnel, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. Although we proposed to allow PIN services to be performed by auxiliary personnel under a contract with a third party, we clarify, as we have in our regulations for other care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe PIN services, as we proposed to define them, could be fully performed; and therefore, in such cases, PIN services should not be billed (81 FR 80249). We would expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition.

In the CY 2023 PFS final rule (87 FR 69790) and as explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve and may have the infrastructure or systems in place to assist practitioners to provide PIN

services. We understand that many CBOs provide social services and do other work that is beyond the scope of PIN services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary PIN services.

We proposed that only one practitioner per beneficiary per calendar month could bill for PIN services for a given serious, high-risk condition, because we are concerned about potential care fragmentation if the patient has more than one navigator for their condition during a given month. Our proposal would allow the patient to have a single point of contact for navigation of their condition.

We proposed that the practitioner could bill separately for other care management services during the same month as PIN, if time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary.

Similar to CHI services discussed previously in this final rule, there are aspects of PIN services, or PIN services for certain conditions, that may be covered under a Medicaid State plan. When Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. We sought public comment regarding whether States typically cover services similar to PIN under their Medicaid programs, and whether such coverage would be duplicative of the PIN service codes. We also solicited comment on whether there are other service elements not included in the PIN service codes that are part of associated care that should be included in the PIN service codes, or are important in navigation for high-risk conditions, where CMS should consider coding and payment in the future. For example, are there circumstances when clinical navigators, under the supervision of another professional, typically spend time face-to-face with patients that the PIN services codes, as currently described, may not fully account for?

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters appreciated our mention of CBOs, and these commenters outlined the benefits of external partnerships to increase the capacity of practitioners to furnish services such as PIN. A few commenters noted that there are geographic areas with a limited presence of CBOs, and they were hopeful that increased reimbursement opportunities through PIN would increase the supply of CBOs able to work in this space. A few commenters requested clarification on what ''sufficient clinical integration'' means in this context, while a few other commenters discussed that CBOs often lack the funding to be integrated with electronic health records that may be used by practitioners in their area.

Response: We reiterate that regular communication between the patient, auxiliary personnel, and billing practitioner is essential to ensure that everyone is involved in the patient's ongoing care. Documentation of the PIN services furnished in relation to the serious, high-risk condition in the medical record is required to track a patient's progress through the diagnosis and treatment of their principal illness, describe the interventions and PIN service elements performed, and to describe the medical necessity of PIN services to the principal illness. Documentation is also required to describe the ongoing need or changes to the treatment plan that allow for the cessation of PIN services; we appreciate that CBOs may not have access to the electronic health record in which the furnishing practitioner is documenting the patient's care in the medical record. To reduce administrative burden, we are not requiring that all auxiliary personnel performing PIN services must document the services in the medical record themselves. Rather, the billing practitioner is responsible for ensuring appropriate documentation of the PIN services provided to the patient is included in the medical record.

Comment: Many commenters requested clarity on our proposed requirement that PIN services can be furnished by one practitioner per beneficiary per month for a serious, high-risk condition. These commenters asked if the limit was by practitioner, meaning beneficiaries could get one PIN service per practitioner or if each beneficiary could only get one PIN service for all conditions. Commenters noted that a patient may be receiving PIN for one condition and while receiving PIN services, get diagnosed with another illness or condition that also meets PIN criteria. A few commenters discussed that some types of navigation services, like oncology navigation, are highly condition-specific, and suggested that if a patient could only get PIN services from one practitioner for one condition per month, oncology navigators may not believe it within their skills and training to provide PIN services for other conditions. Other commenters mentioned that the enhanced value of navigation services in which the auxiliary personnel have lived experience or training specific to the serious high-risk condition and suggested that having the same navigators perform PIN services for conditions other than those in which they have training or lived experience would likely be detrimental to the treatment of those conditions. Commenters also discussed the operational difficulties of knowing whether the patient is receiving PIN services for another condition.

Lastly, commenters were overwhelmingly in favor of our proposal to allow PIN services to be billed in conjunction with other care management codes. Commenters noted that patients who are likely to receive PIN may also have comorbidities that are best managed through care management codes, and practitioners should not have to choose between PIN and other care management activities.

Response: Our intention in the proposed rule was to limit PIN services to one per month per beneficiary, as we were concerned about care fragmentation. We do not believe that having multiple navigators for each condition is conducive to the patient's experience, and we believe that the patient should generally have a single point of contact when navigating a principal illness. However, we understand that patients can have multiple principal illnesses at a time. We also understand that some types of navigation, such as peer support and oncology navigation are very condition-specific, which we continue to believe is a benefit of PIN services. Also, as discussed previously in this rule, we are not requiring auxiliary personnel furnishing PIN services to be versed in every principal illness for which a patient needs PIN services. However, we are also concerned about the duplication of time and effort if the same practitioner bills two kinds of PIN services for the same beneficiary. For example, a primary care physician might be providing PIN services to a patient for one serious, high-risk condition, and then the patient gets diagnosed with another high-risk condition that is also being managed by the same primary care physician. In this instance, the same navigator working incident to this primary care physician would be unable to fully perform the PIN service elements without duplicating time and effort, and therefore, the primary care physician can only provide PIN services once per month for this beneficiary.

We appreciate the commenters' support for our proposal to allow PIN

services to be billed with other care management codes. We aimed to provide maximum flexibility to practitioners to choose the right type of service for each of their patient's needs, and we agree with commenters that if a patient has chronic or comorbid conditions that are well-managed with a care management code and is then diagnosed with a principal illness, it makes the most sense to provide that patient with care management plus PIN.

After consideration of public comments, we are finalizing that PIN services can be provided more than once per practitioner per month for any single serious high-risk condition, to avoid duplication of PIN service elements when utilizing the same navigator or billing practitioner. We are also clarifying that PIN and PIN–PS should not be billed concurrently for the same serious, high-risk condition. However, practitioners furnishing PIN services may bill care management services as appropriate for managing and treating a patient's illness. We remain concerned about care fragmentation should patients receive multiple PIN services for different high-risk conditions. We believe that PIN is best suited for situations in which the navigator can serve as a point of contact for the patient. Given this, we do not expect a patient to require multiple PIN services for a prolonged period of time, except in circumstances in which a patient is receiving PIN services for highly specialized navigation, such as behavioral health or oncology. Lastly, we are finalizing, as proposed, that PIN services can be furnished in addition to other care management services as long as time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary.

iii. PIN Services Valuation

For HCPCS code G0023, we proposed a work RVU of 1.00 based on a crosswalk to CPT code 99490 (Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month) as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PIN services. CPT code 99490 has an intraservice time of 25 minutes and the physician work is of similar intensity to our proposed HCPCS code G0023. Therefore, we proposed a work time of 25 minutes for HCPCS code G0023 based on this same crosswalk to CPT code 99490. We proposed using this crosswalk to establish the direct PE inputs for HCPCS code G0023.

For HCPCS code G0024, we proposed a crosswalk to the work RVU and direct PE inputs associated with CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PIN services. Therefore, we proposed a work RVU of 0.70 and a work time of 20 minutes for HCPCS code G0024.

Comment: Commenters generally supported the proposed crosswalk to the Chronic Care Management services and our proposed valuation. Commenters agreed that the RVU for HCPCS code G0023 should have a work RVU of 1.00 based on the crosswalk to CPT code 99490 but the RVU crosswalk should not be limited to the first 20 minutes of PIN services and each subsequent 20 minutes should have its own code. We did not receive any comments regarding the proposed crosswalk for HCPCS code G0024.

Response: We thank the commenters for their feedback. We believe the commenters have misunderstood our crosswalk. While CPT code 99490 is broken down into 20-minute blocks of time, we do not believe that 20 minutes is sufficient per month to be spent on PIN services, as discussed above. We clarify that the RVU crosswalk for 60 minutes per month of CPT code 99490 has an intraservice time of 25 minutes, and has a work RVU of 1.00, so the valuation for 60 minutes per month of time is equal between CPT codes 99490 and G0023.

After consideration of public comments, we are finalizing the crosswalks for HCPCS codes G0023 and G0024 as proposed, with HCPCS code G0023 being directly crosswalked with CPT code 99490 at work RVU of 1.00, 25 minutes of intraservice time and matching direct PE inputs. We are also finalizing a direct crosswalk between HCPCS code G0024 and CPT code 99439, with a work RVU of 0.70, a work time of 20 minutes, and matching direct PE inputs. While we note that PIN–PS does not contain all descriptor elements to the original PIN service, we believe that the core elements of PIN are preserved in PIN–PS, and that the activities and service elements described in PIN–PS represent equal time and intensity to the PIN codes and CPT codes 99490 and 99439, respectively. The PIN–PS codes are targeted for specific work performed by auxiliary staff such as peer support specialists, and since this is a timed code, we believe that 60 minutes of time spent per month by auxiliary staff, including 25 minutes of intraservice time for the physician or billing practitioner is unchanged, even if the code descriptors vary slightly. Therefore, we are finalizing the crosswalk to CPT code 99490 for HCPCS code G0140 and CPT code 99439 for HCPCS code G0146.

(29) Maternity Services (CPT Codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622)

In the CY 2021 PFS final rule with comment period (85 FR 84554 and 84555), we finalized our proposal to revalue the bundled maternity codes used to bill for delivery, antepartum, and postpartum maternity care services to account for increases in the values of office/outpatient E/M services. These codes are all designated with a unique global period indicator ''MMM.'' There are 11 MMM codes that include E/M visits as part of their valuation.

For CY 2024, we proposed to update the work RVUs and work times of these MMM codes to reflect any relevant E/M updates associated with their global periods that were finalized in CY 2023. Table 13 contains a list of these codes and the proposed work RVUs for CY 2024. MMM codes are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, which include a relatively large number of E/M visits performed along with delivery services and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method.

TABLE 13: Current and Final Value for Each Maternity Services Code

CPT code	Current Work RVU value	2023 E/M adjustment value	New Work RVU Value
59400	36.58	0.42	**37.00**
59410	18.34	0.42	**18.76**
59425	7.80	0.00	**7.80**
59426	14.30	0.00	**14.30**
59430	3.22	0.00	**3.22**
59510	40.39	0.66	**41.05**
59515	22.13	0.66	**22.79**
59610	38.29	0.42	**38.71**
59614	20.06	0.42	**20.48**
59618	40.91	0.66	**41.57**
59622	22.66	0.66	**23.32**

Comment: Several commenters stated that they supported CMS' proposal to update the maternity codes to account for the increases in the office and hospital visits bundled into their global period and agreed that the work RVU increases were correct. However, the commenters stated that the total work times incorporating both the increases in office visits and hospital visits into the global periods for these maternity services were not correct; the commenters recommended that CMS fix this technical error when calculating the time increases in the global periods for the maternity services and submitted a spreadsheet detailing the correct work times.

Response: We appreciate the support for our proposed policies from the commenters, as well as alerting us to this potential technical error in the updated work times for the maternity services codes. After reviewing the additional information provided by the commenters, we discovered that the incorrect work time values for the maternity services codes were used in calculating the payment rates due to a technical error. We will correct these codes with their updated work times for the final rule.

After consideration of the public comments, we are finalizing our proposal to update the work RVUs and work times of these MMM codes to reflect any relevant E/M updates associated with their global periods that were finalized in CY 2023, as detailed in Table 13.

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TABLE 14: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	NEW	32.00	32.00	No
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	NEW	35.50	35.50	No
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	NEW	36.00	36.00	No
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	27.13	27.13	27.13	No
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	C	6.88	6.88	No
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device	NEW	7.86	7.86	No
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach	3.26	3.91	3.91	No
30118	Excision or destruction (eg, laser), intranasal lesion; external approach (lateral rhinotomy)	9.92	7.75	7.75	No
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	NEW	2.70	2.70	No
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve	NEW	2.70	2.70	No
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed	NEW	9.50	9.50	No
33277	Insertion of phrenic nerve stimulator transvenous sensing lead	NEW	5.43	5.43	No
33278	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)	NEW	9.55	9.55	No
33279	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only	NEW	5.42	5.42	No
33280	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only	NEW	3.04	3.04	No
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)	NEW	6.00	6.00	No
33287	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator	NEW	6.05	6.05	No
33288	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance,	NEW	8.51	8.51	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	and interrogation and programming when performed; transvenous stimulation or sensing lead				
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed	NEW	3.10	3.10	No
58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	NEW	7.21	7.21	No
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	36.58	37.00	37.00	Yes
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.34	18.76	18.76	Yes
59425	Antepartum care only; 4-6 visits	7.80	7.80	7.80	No
59426	Antepartum care only; 7 or more visits	14.30	14.30	14.30	No
59430	Postpartum care only (separate procedure)	3.22	3.22	3.22	No
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	40.39	41.05	41.05	Yes
59515	Cesarean delivery only; including postpartum care	22.13	22.79	22.79	Yes
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	38.29	38.71	38.71	Yes
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	20.06	20.48	20.48	Yes
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	40.91	41.57	41.57	Yes
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.66	23.32	23.32	Yes
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	NEW	25.75	25.75	No
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	NEW	11.25	11.25	No
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	NEW	15.00	15.00	No
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver	5.19	5.19	5.19	No
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array, with detachable connection to	5.30	4.35	4.35	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver direct or inductive coupling, requiring pocket creation and connection between electrode array and pulse generator or receiver	2.45	5.10	5.10	No
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array	1.78	3.79	3.79	No
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array	NEW	C	C	No
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array	NEW	C	C	No
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NEW	C	C	No
65778	Placement of amniotic membrane on the ocular surface; without sutures	1.00	0.84	0.84	No
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	2.50	1.75	1.75	No
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	7.81	7.03	7.03	No
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NEW	1.53	1.53	No
75580	Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	NEW	0.75	0.75	No
76881	Ultrasound, complete joint (ie, joint space and periarticular soft-tissue structures), real-time with image documentation	0.90	0.90	0.90	No
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft tissue mass[es]), real-time with image documentation	0.69	0.69	0.69	No
76883	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	1.21	1.21	1.21	No
76937	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting	0.30	0.30	0.30	No
76984	Ultrasound, intraoperative thoracic aorta (eg, epiaortic), diagnostic	NEW	0.60	0.60	No
76987	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	NEW	1.62	1.90	No
76988	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic;	NEW	1.08	1.20	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	placement, manipulation of transducer, and image acquisition only				
76989	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only	NEW	0.54	0.70	No
76998	Ultrasonic guidance, intraoperative	1.20	0.91	0.91	No
90832	Psychotherapy, 30 minutes with patient	1.70	1.78	1.78	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.50	1.50	1.57	No
90834	Psychotherapy, 45 minutes with patient	2.24	2.35	2.35	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	1.90	1.90	1.99	No
90837	Psychotherapy, 60 minutes with patient	3.31	3.47	3.47	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.50	2.50	2.62	No
90839	Psychotherapy for crisis; first 60 minutes	3.13	3.28	3.28	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.50	1.57	1.57	No
90845	Psychoanalysis	2.10	2.20	2.20	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.40	2.51	2.51	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.50	2.62	2.62	No
90849	Multiple-family group psychotherapy	0.59	0.62	0.62	No
90853	Group psychotherapy (other than of a multiple-family group)	0.59	0.62	0.62	No
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	NEW	1.25	1.25	No
92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes	NEW	0.33	0.33	No
92972	Percutaneous transluminal coronary lithotripsy	NEW	2.97	2.97	No
93150	Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming	NEW	0.85	0.85	No
93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system	NEW	0.80	0.80	No
93152	Interrogation and programming of implanted phrenic nerve stimulator system during a polysomnography	NEW	1.82	1.82	No
93153	Interrogation, without programming of implanted phrenic nerve stimulator system	NEW	0.43	0.43	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93584	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava	NEW	1.20	1.20	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	when it exists as a second contralateral superior vena cava, with native drainage to heart				
93585	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system	NEW	1.13	1.13	No
93586	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus	NEW	1.43	1.43	No
93587	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (eg, from innominate vein)	NEW	1.92	2.11	No
93588	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (eg, from the inferior vena cava)	NEW	2.04	2.13	No
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	2.10	2.10	2.20	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.45	1.45	1.52	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.50	0.50	0.52	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.21	0.21	0.22	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.10	0.10	0.10	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.55	1.55	1.62	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.55	0.55	0.58	No
96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	B	0.43	0.43	No
96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes	B	0.12	0.12	No
96547	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes	NEW	C	C	No
96548	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes	NEW	C	C	No
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, non-thermal and non-ablative), for post operative pain reduction	-	-	N	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
97550	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes	NEW	1.00	1.00	No
97551	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; each additional 15 minutes	NEW	0.54	0.54	No
97552	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers	NEW	0.23	0.23	No
99459	Pelvic examination	NEW	0.00	0.00	No
99484	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team.	0.61	0.93	0.93	No
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate	1.50	1.50	1.50	No
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes	1.40	1.40	1.40	No
G0017	Psychotherapy for crisis furnished in an applicable site of service; first 60 minutes	NEW	4.70	4.70	No
G0018	Psychotherapy for crisis furnished in an applicable site of service; each additional 30 minutes	NEW	2.25	2.25	No
G0019	Community health integration (CHI) services by certified or trained auxiliary personnel under the direction of the physician/other Qualified Healthcare Professional (QHP), including a community health worker located in the patient's community; 60 minutes per calendar month, in the following activities:	NEW	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	• Holistic personal assessment, performed in order to better understand the individualized context of the intersection between the identified social determinants of health (SDOH(s)) and problem(s) addressed in the CHI initiating visit (required only during the first month CHI services are provided). o Conducting a holistic personal assessment to understand patient's life story, needs, goals and preferences, including understanding cultural and linguistic factors. o Setting personalized goals and creating action plans o Providing tailored support as needed to accomplish the billing practitioner's treatment plan. o Periodic administration of SDOH survey tools and monitoring of related SDOH, that is not separately billed. As new SDOH that may affect the diagnosis and treatment of problem(s) in the initiating visit are identified, these SDOH may be focused on for CHI services. • Practitioner, Home, and Community-Based Care Coordination o Coordination with practitioner, home, and community-based services. o Communication to and from practitioners, home and community-based services, and hospital, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial needs, functional deficits, goals, and preferences, including cultural and linguistic factors. o Coordination of care transitions between and among health care practitioners and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. o Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH that the billing practitioner identifies as significantly limiting their ability to diagnose or treat the problem(s)identified in the CHI initiating visit • Health education- Helping patients contextualize health education provided by the patient's treatment team with their individual needs, goals, and preferences, and SDOH that affect problem(s) identified during the initiating visit, and educating the patient on how to best participate in medical decision-making • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing SDOH, in ways that are more likely to promote personalized and effective treatment of their problem(s) identified during the initiating visit. • Health care access / health system navigation Helping the patient arrange access to medical care, including securing medical or community-based appointments, identifying appropriate providers for care needs, identifying appropriate community-based				

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	resources for SDOH related to problem(s) identified during the initiating visit, and for accessing all clinical care services necessary • Facilitating behavioral change necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach treatment goals for the problem(s) addressed in the CHI initiating visit. • Facilitating and providing social and emotional support for the patient related to coping with the problem(s) addressing during the CHI initiating visit, related SDOH, and adjusting daily routines to better meet diagnosis and treatment goals for those problem(s).				
G0022	Community health integration services, each additional 30 minutes per calendar month	NEW	0.70	0.70	No
G0023	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator; 60 minutes per calendar month, in the following activities: ● Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition. ++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. ++ Facilitating patient-driven goal setting and establishing an action plan. ++ Providing tailored support as needed to accomplish the practitioner's treatment plan. ● Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. ● Practitioner, Home, and Community-Based Care Coordination ++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable). ++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. ++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s). ● Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences,	NEW	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. ● Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. ● Health care access / health system navigation. ++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them. ++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable. ● Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. ++ Periodic administration of SDOH survey tools and monitoring of related SDOH, that is not separately billed. PIN services may address newly discovered SDOH if the practitioner determines they are significantly impacting the practitioner's ability to diagnose or treat the high-risk condition(s). ● Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals. ● Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.				
G0024	Principal Illness Navigation services, additional 30 minutes per calendar month	NEW	0.70	0.70	No
G0136	Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes	NEW	0.18	0.18	No
G0140	Principal Illness Navigation – Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities: • Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition. ++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. ++ Facilitating patient-driven goal setting and establishing an action plan. ++ Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan. • Identifying or referring patient (and caregiver or family,	NEW	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	if applicable) to appropriate supportive services. • Practitioner, Home, and Community-Based Care Communication ++ Assist the patient in communicating with their practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s). • Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. • Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals. ++ Periodic administration of SDOH survey tools and monitoring of related SDOH, that is not separately billed. PIN services may address newly discovered SDOH if the practitioner determines they are significantly impacting the practitioner's ability to diagnose or treat the high-risk condition(s). • Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals. • Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.				
G0146	Principal Illness Navigation – Peer Support, additional 30 minutes per calendar month	NEW	0.70	0.70	No
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	0.00	0.00	0.00	No
G0323	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, clinical professional counselor, professional counselor, or marriage and family therapist time, per calendar month.	0.61	0.93	0.93	Yes
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and	0.00	D	D	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	technician review, technical support and distribution of results				
G2086	Office-based opioid treatment, monthly bundle including development of the treatment plan, care coordination, substance use counseling, individual therapy, and group therapy; initial month	7.06	8.14	8.36	Yes
G2087	Office-based opioid treatment, monthly bundle including care coordination, substance use counseling, individual therapy, and group therapy; subsequent month	6.89	7.97	8.19	Yes
G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.	B	0.33	0.33	No

TABLE 15: CY 2024 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	NF	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
30118	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
31242	Nsl/sinus ndsc rf abltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	32	E19: Refined equipment time to conform to established policies for scope accessories	-1.87
31242	Nsl/sinus ndsc rf abltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
31243	Nsl/sinus ndsc cryoabltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	34	E19: Refined equipment time to conform to established policies for scope accessories	-1.34
31243	Nsl/sinus ndsc cryoabltj pnn	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		39	41	E4: Refined equipment time to conform to established policies for scopes	0.02
31243	Nsl/sinus ndsc cryoabltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
33287	Rmv&rplcmt phrnc nrv stim pg	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	53	L9: Refined clinical labor to align with number of post-operative visits	8.47

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
58580	Transcrv abltj utrn fibrd rf	EQ138	instrument pack, medium ($1500 and up)	NF		65	77	E5: Refined equipment time to conform to established policies for surgical instrument packs	0.08
64590	Ins/rpl prph sac/gstr npgr	EQ114	electrosurgical generator, up to 120 watts	NF		56	48	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.14
64590	Ins/rpl prph sac/gstr npgr	EQ209	programmer, neurostimulator (w-printer)	NF		56	84	E7: Refined equipment time to conform to office visit duration	0.18
75580	N-invas est c ffr sw aly cta	ED053	Professional PACS Workstation	NF		14.5	13.5	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.06
76882	Us lmtd jt/fcl evl nvasc xtr	ED053	Professional PACS Workstation	NF		14	17.5	E18: Refined equipment time to conform to established policies for PACS Workstations	0.21
76882	Us lmtd jt/fcl evl nvasc xtr	EQ250	ultrasound unit, portable	NF		23	15	E11: Refined equipment time to conform with other codes in the family	-1.29
93297	Icm device interrogat remote	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		22	29	G1: See preamble text	5.98
93298	Ilr device interrogat remote	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		58	65	G1: See preamble text	5.98
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare room, equipment and supplies	1.5	0.5	G1: See preamble text	-0.64
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare, set-up and start IV, initial	1	0.5	G1: See preamble text	-0.32

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					positioning and monitoring of patient				

TABLE 16: CY 2024 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
33287	Rmv&rplcmt phrnc nrv stim pg	EF023	table, exam	F		36	53	E15: Refined equipment time to conform to changes in clinical labor time	0.18
G0277	Hbot, full body chamber, 30m	EQ131	hyperbaric chamber	NF		40	38.25	E15: Refined equipment time to conform to changes in clinical labor time	-0.41
G0277	Hbot, full body chamber, 30m	EQ362	HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve)	NF		40	38.25	E15: Refined equipment time to conform to changes in clinical labor time	0.00

TABLE 17: CY 2024 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
36514	tubing set, plasma exchange	SC085	$186.12	$277.20	49%	39	328
36514, 36516	tubing set, blood warmer	SC084	$8.01	$16.27	103%	53	911
36836	Ellipsys Vascular Access Catheter	SD351	$6,000.00	$7,378.75	23%	72	214
43754, 43755, 43756, 43757, 88120, 88121, 91065	biohazard specimen transport bag	SM008	$0.080	$0.087	9%	1	101,558
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring	SD248	$1,097.91	$931.33	-15%	102	48,005
65779	human amniotic membrane allograft	SD247	$771.33	$835.00	8%	1	106
88104, 88106, 88108, 88112, 88160, 88161, 88162	stain, PAP OG-6	SL491	$0.010	$0.020	100%	1	444,216
88302, 88304, 88305, 88307, 88309, 88312, 88313, 88319, 88323, 88325, 88355, 88358, G0416	slide dryer	EP034	$962.50	$1,785.49	86%	1	13,423,336
88302, 88304, 88305, 88307, 88309, 88341, 88342, 88344, 88360, 88361, G0416	Automated Casette Labeler	EP111	$26,700.26	$31,658.81	19%	1	14,100,742
88313	Congo Red kits	SA110	$6.16	$6.80	10%	1	799,406
88313, 88314	hematoxylin reagent	SL077	$0.0200	$0.0375	88%	1	815,572

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
88341	Anti CD45 Monoclonal Antibody	SL495	$4.48	$5.15	15%	3	982,692
88341, 88342, 88344, 88360, 88361	E-bar labels (Ventana 1358501)	SL475	$0.72	$1.104	53%	1	2,422,030
88341, 88342, 88344, 88360, 88361	UltraView Universal DAB Detection Kit	SL488	$9.70	$12.28	27%	3	2,422,030
88342	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	SL474	$3.82	$4.90	28%	1	1,061,368
88344, 88360, 88361	250 Test Prep Kit # 78 (Ventana 786-3034)	SL486	$0.290	$0.309	7%	2	377,970
92230, 92235, 92242, 92287	fluorescein inj (5ml uou)	SH033	$49.13	$72.00	47%	7	305,201
95145, 95146, 95148, 95149	antigen, venom	SH009	$30.93	$35.58	15%	18	49,334
95147, 95148, 95149	antigen, venom, tri-vespid	SH010	$60.24	$69.21	15%	9	38,269

TABLE 18: CY 2024 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
27278	Dorsal SI Joint Arthrodesis Implant	SD356	11,500.00	1	0
31242	Radiofrequency Stylus / wand	SD357	1,950.00	4	3,728
31242	Radiofrequency console	EQ407	4,972.50	4	3,728
31243	Cryoablation handpiece and 2 canisters (one per side)	SD358	1,882.80	7	7,501
52284	Optilume DCB, guidewire, and inflation device	SD359	2,245.00	22	0
58580	Dispersive electrode (Sonata)	SD360	30.00	1	0
58580	RFA Handpiece, sterile (Sonata)	SD361	2,500.00	1	0
58580	RFA Generator System, including probe, cables and sterilization tray (Sonata)	EQ408	118,250.00	2	0
93150, 93151, 93152, 93153	phrenic nerve stimulator programmer with wand	EQ406	3,008.00	2	156
none	WatchPAT One device	SD362	98.20	125	0

TABLE 19: CY 2024 No PE Refinements

HCPCS	Description
22857	Tot disc arthrp 1ntrspc lmbr
22860	Tot disc arthrp 2ntrspc lmbr
27278	Arthrd si jt prq wo tfxj dev
22836	Ant thrc vrt body tethrg <7
22837	Ant thrc vrt body tethrg 8+
22838	Rev rplc/rmv thrc vrt tethrg
33276	Insj phrnc nrv stim sys
33278	Rmvl phrnc nrv stim sys
33279	Rmvl phrnc nrv stim transvns
33280	Rmvl phrnc nrv stim pg only
33281	Reposg phrnc nrv stim trnsvn
33288	Rmv&rplcmt phrnc nrv stim ld
52284	Cysto rx balo cath urtl strx
61889	Ins sk-mnt crnl nstm pg/rcvr
61891	Rev/rplcmt sk-mnt crnl nstm
61892	Rmv sk-mnt crnl nstm pg/rcvr
63685	Ins/rplcmt spi npgr pocket
63688	Rev/rmv imp spi npgr dtch cn
64595	Rev/rmv prph sac/gstr npgr
64596	Ins/rplcmt prq eltrd ra pn 1
64597	Ins/rplcm prq eltrd ra pn ea
64598	Rev/rmvl nea pn w/intg nstim
65778	Cover eye w/membrane
65779	Cover eye w/membrane suture
65780	Ocular reconst transplant
67516	Sprchoroidal spc njx rx agt
76881	Us xtr non-vasc complete
76883	Us nrv&acc strux 1xtr compre
76937	Us guide vascular access
76987	Dx intraop epicar car us chd
92622	Dx aly aud oi snd prcsr 1st
92623	Dx aly aud oi snd prcsr each
93297	Icm device interrogat remote
93298	Ilr device interrogat remote
99484	Care mgmt svc bhvl hlth cond
99497	Advncd care plan 30 min
99498	Advncd care plan addl 30 min
97550	Caregiver traing 1st 30 min
97551	Caregiver traing ea addl 15
97552	Group caregiver training
99459	Pelvic examination
93150	Therapy activation ipnss
93151	Interrog&prgrmg ipnss
93152	Interrog&prgrmg ipnss polysm
93153	Interrog w/o prgrmg ipnss

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F. Evaluation and Management (E/M) Visits

1. Background

Over the past several years, we have engaged in a multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits, so that they better reflect the current practice of medicine, are less administratively complex, and are paid more accurately under the PFS. This work is critical to improve payment accuracy and help reduce practitioner burnout.

E/M visits comprise approximately 40 percent of all allowed charges under the PFS. The office/outpatient (O/O) E/M visits comprise approximately half of these allowed charges (approximately 20 percent of total PFS allowed charges), and Other E/M visits (such as inpatient/observation visits, nursing facility visits and home/residence visits) comprise the other half (approximately 20 percent of total PFS allowed charges). As we have discussed in prior rules, within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties (84 FR 62844). According to Medicare claims data, E/M visits are furnished by nearly all specialties but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Accordingly, our policies for revaluation of E/M visits have a significant impact on relative resource valuation under the PFS, which could potentially impact patient care more broadly.

In this section of our final rule, we continue our work to address two outstanding issues in E/M visit payment: implementing separate payment for the O/O E/M visit complexity add-on code for separate payment, and our definition of split (or shared) visits, which we delayed last year.

For CY 2018, we solicited public comment regarding how we could comprehensively reform the E/M documentation guidelines to reduce administrative and clinical burden, improve payment accuracy, and better align E/M coding and documentation with the current practice of medicine (82 FR 34078 and 34079, 82 FR 53163). We believed that the documentation requirements for history and physical exam were particularly outdated clinically and that medical decision making (MDM) and time were the more significant factors in distinguishing visit levels (82 FR 53164). Public commenters recommended a transparent, iterative, and perhaps transitional approach, and some commenters suggested that CMS and the AMA should also undertake revision and revaluation of the E/M visit code set itself, in addition to updating the documentation guidelines (82 FR 53165). Having reviewed the public comments, we noted they illustrated how difficult it is to utilize or rely upon such a relatively small set of codes to describe and pay for the work of a wide range of physicians and practitioners in many vastly different clinical contexts; that E/M documentation guidelines were not simply a matter of administrative burden, but were also clinically outdated and intimately related to the definition and description of E/M work as well as valuation; and that there were different opinions on potential redefinition and revaluation of the E/M code set depending on practitioner specialty, and the type of

work dominating the specialty (for example, primary care, so-called ''cognitive'' specialty work, or global procedures that have E/M visits bundled in rather than separately performed and documented) (82 FR 53165). We stated that we would continue working on these issues with interested parties in future years.

Because we agreed with commenters that we should take an incremental approach to these issues, the following year we proposed changes largely limited to the O/O E/M visit code family (83 FR 59628). In our CY 2019 PFS final rule, we finalized documentation changes, some of which took effect in CY 2019 (83 FR 59628 through 59535), while others (notably choice of MDM or time for supporting documentation) would be effective in CY 2021 in conjunction with finalized coding and payment changes for O/O E/M visits (83 FR 59636 through 59645). The coding and payment changes included a single payment rate for levels 2 through 4 O/O E/M visits (retaining separate payment for level 5 visits to account for the most complex patients and visits); two HCPCS add-on codes to provide separate, additional payments for the resource costs involved in furnishing certain types of O/O E/M visit care, specifically visit complexity inherently associated with primary care and non-procedural specialty care; and a third HCPCS code for O/O E/M visits taking extended amounts of time (83 FR 59638).

In January and February 2019, we held listening sessions, and we learned that the AMA was convening an E/M Workgroup to develop an alternative solution to some of these issues (84 FR 40673). The AMA revised and resurveyed the O/O E/M visit code family (see 84 FR 62844 through 62847). Effective January 1, 2021, the CPT Editorial Panel redefined the codes for O/O E/M visits such that the furnishing practitioner may select the level of visit to bill based either on the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM) involved. The CPT Editorial Panel redefined MDM in the CPT E/M Guidelines, which are an accompanying set of CPT interpretive guidelines delineating different levels of MDM and various other reporting parameters. Additionally, history of present illness (History) and a physical exam were no longer used to select the O/O E/M visit level. These service elements were updated to remove reliance on clinically outdated parameters to contribute to the selection of visit level, such as number of body systems reviewed, and to require a medically appropriate history and exam instead. Also, effective January 1, 2021, the CPT Editorial Panel revised the O/O E/M visit descriptor times. Previously, the CPT code descriptors included typical service times, but they were revised to specify new time ranges that must be furnished in order to select a given visit level using time. The AMA RUC resurveyed the O/O E/M visit CPT codes, and provided us with revaluation recommendations that we then addressed in our CY 2020 PFS proposed rule, a year in advance of when the revised codes would take effect in CY 2021 (84 FR 40675 through 40678).

In our CY 2020 PFS final rule, we generally adopted the revised O/O E/M code set and the related changes in the CPT E/M Guidelines, including the revised approach to visit level selection and documentation, for payment purposes under the PFS effective January 1, 2021 (84 FR 62844 through 62859). While we accepted the revised CPT codes and approach for the O/O E/M visits, we finalized Medicare-specific coding for prolonged O/O service codes, because we were concerned that the CPT codes were administratively complex, and their use would have impacted our ability to tell how much total time was spent with the patient and could have resulted in inappropriately inflated payment (84 FR 62849 through 62850, and 85 FR 84572 through 84575).

In our CY 2020 PFS final rule, we generally accepted the RUC recommendations, which reflected increased service times (84 FR 62851 through 62854). This resulted in increased values for the O/O E/M visit codes beginning in CY 2021. However, since we believed these increased valuations still did not account for the resources involved in furnishing certain kinds of care included in the O/O E/M visit code set, in the CY 2021 PFS final rule, we retained our add-on codes for visit complexity inherently associated with primary care and non-procedural specialty care, though we refined and consolidated them into a single code, a HCPCS add-on code G2211 (*O/O E/M visit complexity*) that can be reported in conjunction with O/O E/M visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). (Hereafter in this rule, we refer to this code as the O/O E/M visit complexity add-on).

After we issued the CY 2021 PFS final rule, section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) (CAA, 2021) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for services described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. Accordingly, the O/O E/M visit complexity add-on code can be reported, but it is currently assigned a bundled payment status indicator. See our fact sheet available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet [40] (*cms.gov*).

In the CY 2022 PFS final rule, we established revised payment rules for split (or shared) visits (86 FR 65150 through 65159). The following year the CPT Editorial Panel defined a split (or shared) visit for the first time in the CPT E/M Guidelines for 2023. However, we did not adopt the CPT definition as it did not conform with our established final policy or address which practitioner should report a shared visit.

For CY 2023, the CPT Editorial Panel also revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. We referred to these other E/M visit code families as ''Other E/M'' visits or CPT codes, as relevant. Effective January 1, 2023, the CPT Editorial Panel redefined the Other E/M visits so that they parallel the O/O E/M visits, where visit level is selected based on the amount of practitioner time spent with the patient or the level of MDM as redefined in the CPT E/M Guidelines. As for the O/O E/M visits, a medically appropriate history and/or physical exam is a required element of the services but no longer impacts the Other E/M visit level. The CPT Editorial Panel also revised the service times within the descriptors, the associated CPT prolonged service codes, and the CPT E/M Guidelines for the Other E/M CPT codes. The CPT Editorial Panel also consolidated many of the Other E/M CPT codes, with inpatient and observation visits combined into a single code set and home and domiciliary visits combined into a single code set. The CPT Editorial Panel created one new CPT code for prolonged inpatient services by physicians and other qualified healthcare professionals on the date of

[40] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

the E/M visit. Finally, the RUC resurveyed the Other E/M visits and associated prolonged service codes and provided revaluation recommendations to CMS.

We addressed these changes to the Other E/M visit families in the CY 2023 PFS final rule (87 FR 69586 through 69616). In that final rule, we adopted the revised CPT codes and descriptors for Other E/M visits, except for prolonged services for which we finalized Medicare-specific coding. We also adopted the CPT E/M Guidelines for levels of MDM as revised for 2023. Regarding valuation, we adopted most of the RUC-recommended values for Other E/M visits, increasing their relative valuation in aggregate. However, we believe that certain types of O/O E/M visits remain undervalued, given the moratorium on separate payment for the O/O E/M visit complexity add-on (87 FR 69588). We expressed concern about assumptions made in the RUC recommendations for Other E/M visits that patient needs were inherently more complex, or work was more intense for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) when compared to the office settings (87 FR 69587 through 69588). We stated that this direct comparison between Other E/M visits and the O/O E/M visit codes may not be appropriate or accurate, and laid out reasons why practitioners in office settings may expend more resources than practitioners in institutional and other settings. We noted that the survey times for O/O E/M visits increased significantly when resurveyed (85 FR 50123), while times for Other E/M visits generally decreased significantly or remained the same when resurveyed, despite the level of MDM remaining constant (87 FR 69598, 69605). To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully accounted for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values, since separate payment is not yet made for the O/O E/M visit complexity add-on (87 FR 69588).

During the CAA, 2021 moratorium on separate payment for the O/O E/M visit complexity add-on, interested parties have continued to engage CMS about the appropriate valuation of O/O E/M visits relative to other PFS services, including through public comments on the proposed revaluation of Other E/M visits (87 FR 70218), as well as in meetings and letters submitted to CMS outside of the rulemaking process. Anticipating the end of the CAA, 2021 moratorium, interested parties, including the AMA, several medical associations, and others, recently approached CMS outside of the rulemaking process with recommendations regarding implementation and potential refinements to the service beginning in 2024 to ensure the appropriate relative valuation of O/O E/M visits. Interested parties have also continued to approach CMS and the CPT Editorial Panel with questions and recommendations about payment rules for split (or shared) visits.

2. Office/Outpatient (O/O) E/M Visit Complexity Add-On Implementation

a. Background

As discussed above, in the CY 2021 PFS final rule, CMS refined the O/O E/M visit complexity add-on code, GPC1X (which was replaced by HCPCS code G2211), to describe intensity and complexity inherent to O/O E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition. (85 FR 84569 through 84571). While we adopted the AMA RUC recommendations for the revised O/O E/M CPT visit codes, those values did not fully account for the resource costs associated with primary care and other longitudinal care of complex patients. Under our final policy, which was delayed by the CAA, 2021 before it was implemented, the O/O E/M visit complexity add-on code could be reported with all O/O E/M visit levels. We disagreed with comments suggesting that billing of the O/O E/M visit complexity add-on code should be restricted to higher level office/outpatient E/M visits; and responded that, given the wide variety of visit types billable with the office/outpatient E/M visit code set, we did not believe that the value associated with the typical visit accounts for the additional resources associated with primary care or ongoing care related to a patient's single, serious, or complex chronic condition, regardless of the visit level. The full descriptor for the O/O E/M visit complexity add-on code, as refined in the CY 2021 PFS final rule, is HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established))* (85 FR 84571) We also estimated that the O/O E/M visit complexity add-on service would be reported by specialties that rely on office/outpatient E/M visits to report the majority of their services and would be billed in addition to those E/M visits. While we did not explicitly prohibit billing the O/O E/M visit complexity add-on in conjunction with visits that are reported with various modifiers, and did not exclude those from our utilization estimates, we stated we did not expect the add-on service to be reported for visits billed with a payment modifier, for example, to identify a separately billable E/M visit in conjunction with a minor procedure (85 FR 84571 through 84572). We stated that visits reported with payment modifiers are likely to involve resources distinct from the stand-alone O/O E/M visits for primary care and other longitudinal care of complex patients, and that we may consider this issue in future rulemaking. We further stated that we do not expect the O/O E/M visit complexity add-on code to be reported when the O/O E/M visit is reported with payment modifiers such as modifier -25 which describes separately billed visits on the same day as another visit or procedure (see our fact sheet, identifying additional modifiers, available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet (*cms.gov*)).

Interested parties have continued to express uncertainty about when reporting the O/O E/M visit complexity add-on service would be appropriate. Some interested parties have expressed larger concerns about potential reductions to the PFS CF or redistributive impacts among specialties if we were to implement the O/O E/M visit complexity add-on code. In the CY 2021 PFS final rule, we clarified and refined the service definition to alleviate some of these concerns and revised our utilization estimates (85 FR 84572). Conversely, some interested parties, specifically practitioners who rely on office/outpatient E/M visits to report the majority of their services, who could use the add-on code to better reflect the resources they use to furnish complex longitudinal services, expressed continued support for our policy. We reiterated our belief that the O/O E/M visit complexity add-on reflects the time, intensity, and PE resources involved when practitioners furnish the

kinds of O/O E/M office visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high-risk disease) and to address the majority of a patient's health care needs with consistency and continuity over longer periods of time. In response to comments, we also made further refinements to the HCPCS code descriptor to clarify that the code applies to a serious condition rather than any single condition. We also acknowledged concerns that given the request by some medical societies for additional time to educate their members about the appropriate use of the O/O E/M visit complexity add-on code, ongoing implementation of the revisions to the O/O E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic, practitioners that rely on O/O E/M visits to report the majority of their services are not likely to report the complexity add-on code with every office visit. However, we disagreed with commenters who thought the O/O E/M visit complexity add-on code would be billed with only 10 to 25 percent of O/O E/M services. Because we had not implemented any additional policies that restricted the billing of this code, we estimated that the add-on code would be billed with 90 percent of O/O E/M visits billed by certain physician specialties (roughly 58 percent of all office/outpatient E/M visits).

b. O/O E/M Visit Complexity Add-On HCPCS Code G2211

Interested parties have continued to engage with us and provide recommendations for implementing the O/O E/M visit complexity add-on. Some commenters recommended that CMS delay the implementation of HCPCS add-on code G2211, citing concerns about the expected budget neutrality adjustment necessitated by implementing the O/O E/M visit complexity add-on and redistributive impact on PFS payment (85 FR 84572). Many commenters who rely upon O/O E/M visits to report most of their services continued to support HCPCS add-on code G2211 (85 FR 84570) and have recommended that we speedily implement it. Some commenters also suggested ways to clarify the intended use of the O/O E/M visit complexity add-on code, which could reduce redistributive impacts. Finally, as noted above, the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with a policy that would have provided separate payment for the new add-on code G2211 (87 FR 69588). To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully reflected appropriate relative values, since separate payment is not yet made for HCPCS code G2211.

The CAA, 2021 moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023. We proposed to change the status of HCPCS code G2211 to make it separately payable by assigning it an ''active'' status indicator, effective January 1, 2024. After considering the feedback from interested parties, both through the CY 2021 PFS rulemaking process and during the moratorium, we also proposed several policy refinements (with respect to HCPCS code G2211). We stated in the CY 2021 PFS final rule that we would not expect HCPCS add-on code G2211 to be reported when the O/O E/M service is reported with a payment modifier, such as the modifier-25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service (85 FR 84572). We continue to believe that separately identifiable O/O E/M visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant different payment (85 FR 84572). As such we proposed that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25.

Interested parties have also requested that we reconsider our previous utilization assumptions. In the CY 2021 PFS final rule, we had assumed that specialties that rely on O/O E/M visit codes to report the majority of their services would be most likely to report the O/O E/M visit complexity add-on code and that they would report the add-on code with every O/O E/M visit they report. We acknowledged commenters' concerns that, given the request by some medical societies to educate their members about appropriate use, and ongoing implementation of the revisions to the office/outpatient E/M visit code set and electronic health records integration, practitioners that rely on office/outpatient E/M visits to report the majority of their services would not be likely to report HCPCS code G2211 with every O/O E/M visit they report (85 FR 84572).

Interested parties have presented persuasive reasons that such practitioners would not be likely to report HCPCS code G2211 with every O/O E/M visit they report. They reasoned that many practitioners delivering care in settings specifically designed to address acute healthcare needs, without coordination or follow-up, will regularly have encounters with patients that are not part of continuous care.

Furthermore, in contrast to situations where the patient's overall, ongoing care is being managed, monitored, and/or observed by a specialist for a particular disease condition, we continue to believe that there are many visits with new or established patients where the O/O E/M visit complexity add-on code would not be appropriately reported, such as when the care furnished during the O/O E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, initial onset gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time (85 FR 84570 and 84571).

These considerations taken together with our proposal that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25 have informed our revised utilization assumptions. Considering the comments received by interested parties, and the reasons discussed above, we now estimate that HCPCS code G2211 will be billed with 38 percent of all O/O E/M visits initially. We calculated these revised utilization assumptions by considering the uptake of new codes in prior years and the O/O E/M billing patterns of all specialties. Specifically, we took into account the likelihood that primary care specialties will have a higher utilization of the add-on code than other specialties, surgical specialties will have the lowest utilization since they are less likely to establish longitudinal care relationships with patients, and other specialists are more likely to have

longitudinal care relationships than surgical specialties but less likely than primary care specialists. We also revised our estimates by excluding (1) claims from practitioners participating in CMS capitated models and (2) claims for established patient visits performed by certain specialties that are unlikely to have a longitudinal care relationship with a beneficiary. We also accounted for the number of visits billed that were furnished as consults or to obtain a second clinical opinion and excluded these types of visits from our estimates. We estimated that HCPCS code G2211 could be billed with 54 percent of all O/O E/M visits when fully adopted. This fully adopted estimate was informed by considering the uptake of new codes after several years. We sought comment on these utilization assumptions and the application of this proposed policy for CY 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: MedPAC appreciated our continued focus on ensuring that primary care clinicians and other clinicians who primarily furnish E/M services are accurately and appropriately paid. MedPAC also stated that longstanding misvaluations in the fee schedule that have had a detrimental impact on accurate primary care valuation, focusing on the overvaluation of non-E/M services.

However, MedPAC did not support the agency's proposed approach to establish payment for the add-on code because, in their view (similar to some other commenters), there continues to be too much ambiguity regarding the code's use and the resource costs it is intended to reflect. MedPAC and other commenters expressed concern that without further clarification, the code would likely be misused and could potentially duplicate payments for other services. MedPAC noted that CMS had added several services that describe services related to the provision of longitudinal, comprehensive care, including care management or other non-face-to-face services (for example, chronic care management (CCM), principal care management (PCM), responding to patient portal messages, and remote patient monitoring (RPM)). Similarly, many commenters also questioned how the proposed complexity add-on code would reflect additional work intensity resulting from concurrently addressing multiple health complaints in a single visit, additional clinical staff time or supplies expended during a visit, or additional non-face-to-face activities associated with furnishing comprehensive, longitudinal care. Some commenters went further to assert that the code is duplicative and stated that the selection of visit level by medical decision making (MDM) and/or total time on the date of the encounter is flexible enough to address patient visit complexity requiring unusual resources.

Response: We appreciate the concerns raised by MedPAC and the other commenters. We strongly agree with MedPAC and others who state it is important to clarify what specific additional resources this code would better account for compared to the current available coding and associated valuations, including of care management services, prolonged services, and other non-face-to-face services. As proposed, the inherent complexity code would address what we believe are longstanding issues with coding and valuation of O/O E/M services that do not fully distinguish and account for resource costs for primary care and other longitudinal care for complex patients, but specifically for visits associated with longitudinal, non-procedural care when compared to work RVUs for procedural services and visits furnished in association with procedural-based care. We believe that because E/M visit codes are intended to be used very broadly, the complexity of services required to provide this type of care is not fully incorporated as part of the valuation of the work RVUs when the E/M code itself is used as the primary way to report the work of the professional. In other words, while many medical professionals rely on procedural codes with work RVUs that account—appropriately—for their particular expertise and the intensity associated with their overall costs in furnishing care, the expertise of those who rely predominantly on E/M services to report their services is left relatively underrecognized within the previous and current E/M coding and valuation structure. This is because E/M valuation is broad-based and the same E/M visit codes are routinely reported both alone and with many different procedural codes. We believe that this specific gap in appropriate valuation and coding is in addition to, and not overlapping with, the gaps in coding and valuation that led to the creation of care management coding, remote patient monitoring, etc. As we understand them, these latter codes describe services furnished and resource costs incurred in addition to the intensity and professional work within the visits themselves. Consequently, we do not believe the inherent complexity code would be duplicative of care management services since the inherent complexity better recognizes the professional work within the visit, while the care management codes recognize services that happen outside of the visit. This applies, of course, when the inherent complexity code is appropriately reported as a way to characterize E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.

We recognize that many commenters, especially those concerned with budget neutrality-based payment reductions should the proposal be finalized and implemented, disagree with our assertion that there is historical (and ongoing) underrecognition in coding and valuation of resources involved in primary and nonprocedural care are an inherent part of the coding and valuation system. Instead, we understand that they view the current disparities in overall payment amount as appropriately reflective of different resource costs in professional work between procedural care and primary and non-procedural care.

In contrast, MedPAC acknowledges the disparity as a significant problem but recommends the issue should be addressed outside of the assignment of RVUs and code definitions for primary care. We appreciate the commenters' perspectives and recognize that other payment mechanisms could be utilized (perhaps even less controversially) to address these problems, especially through the kinds of changes MedPAC has recommended to Congress. However, we believe that we have the obligation to value services as accurately as possible within the structure of the resource-based relative value system, and that until changes to coding and valuation are made to specifically address the underrecognition of the complexity inherent to these kinds of visits (either through this rule or another mechanism), the RVUs on the PFS would otherwise perpetuate the systemic undervaluation of primary and longitudinal, non-procedural care.

Comment: Other commenters supported the proposal and agreed that the O/O E/M visit complexity add-on code better accounts for the additional time, intensity, and practice expense inherent to longitudinal care. These commenters offered that the PCM codes account for care management and coordination over time as opposed to the additional complexity and resources

involved in furnishing an office/outpatient E/M visit. They added that primary care physicians may provide care management and coordination services for a condition first addressed in an office/outpatient E/M visit that will not last as long as three months or would not reasonably be expected to result in a risk of hospitalization. These commenters highlighted COVID–19 cases, for instance, as clinical circumstances that generally do not last three months but may require significant acute management, care coordination, and follow-up within a given month, particularly for patients with comorbidities. They further stated that alternatively, physicians, qualified health practitioners, or their staff may provide care coordination and management services for a condition that does meet these conditions, and the time may not reach the required 30-minute interval. Thus, care coordination for a month that includes 20 minutes of consulting with other physicians and modifying medications to address an acute exacerbation of hypertension would not meet the requirements for billing PCM. Despite the inability to bill for these services, ongoing coordination and medication management is a standard part of comprehensive primary care. The commenters stated that the distinctions and limitations of TCM, CCM, and CCCM are similar with specific time thresholds. With respect to prolonged services codes, these commenters noted that primary care physicians often provide complex office visits without requiring additional time given that their training enables them to address a significant number of diagnoses, risk factors, and symptoms in a short time. Commenters added further that when prolonged services codes are billed, they are not valued to include the additional intensity inherent to primary care.

The commenters stated that the complexity inherent in primary care includes evaluating how each condition and resulting treatment, new symptom or challenge, unmet social needs, and recommended preventive services interact and impact a person's overall wellbeing. The visits involve balancing clinical guidelines and recommendations from a multitude of sources including the United States Preventive Services Task Force, the AAFP, the American College of Physicians or the American Academy of Pediatrics (depending on the patient's age), the American Psychiatric Association, the American College of Obstetricians and Gynecologists (when relevant), the Advisory Committee on Immunization Practices, and other evidence such as that published by the CDC. They added that the primary care visit also involves evaluating biochemical processes and drug interactions across several medications, noting the extensive time counseling patients about new and upcoming vaccines, like those for COVID–19 or respiratory syncytial virus. The visit further involves the evaluation of lab and imaging results sent by various care team members, reports from home health aides or nurses, and immunization registries. They added that primary care physicians and practitioners evaluate the persons' understanding of their diseases and treatments and discuss behaviors or habits that could impact their well-being. In the same encounter, primary care practitioners provide several preventive screenings, including for cancer, behavioral health, and substance use disorders. They provide counseling and brief referrals based on the results of those screenings, including help connecting patients to facilities providing mammograms, colonoscopies, or behavioral health diagnoses. The commenters asserted that most Medicare beneficiaries struggle to afford their health care services and medications, so many primary care physicians spend time on pharmacy discount websites alongside their patients to help them get lower prices on their medications. The commenters also stated that most orders for new screening or diagnostic tests will require prior authorization for patients with primary or secondary insurance through a plan administered by a health insurance company. All of these findings and processes require documentation in the medical record and updates to other health team members, such as an endocrinologist, cardiologist, or psychiatrist. Commenters offered clinical examples from primary care physicians.

Response: We appreciate the support from these commenters. After consideration of public comments, we are finalizing changing the status of HCPCS code G2211 to make it separately payable by assigning it an ''active'' status indicator, effective January 1, 2024, as proposed. In addition, in consideration of the many comments we received, we recognize that we should clarify when this code can be used. Specifically, this add-on code is intended to characterize the base service (that is, O/O E/M visits) based on the kind of care being furnished (medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition) to better account for the inherent complexity of these visits that would otherwise be unaccounted for. We note that the application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs) but rather the relationship between the patient and the practitioner. We agree with commenters who have pointed out that O/O E/M visit levels, care management codes, and prolonged service codes are intended to account for additional minutes of time or complexities for individual patients. This code should be used when furnishing O/O E/M visit associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.

We clarify that it is the *relationship* between the patient and the practitioner that is the determining factor of when the add-on code should be billed. First, the ''continuing focal point for all needed health care services'' describes a relationship between the patient and the practitioner, when the practitioner is the continuing focal point for all health care services that the patient needs. For example, a patient has a primary care practitioner that is the continuing focal point for all health care services, and the patient sees this practitioner to be evaluated for sinus congestion. The inherent complexity that this code (G2211) captures is not in the clinical condition itself—sinus congestion—but rather the cognitive load of the continued responsibility of being the focal point for all needed services for this patient. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship itself in the diagnosis and treatment plan and weighing the factors that affect a longitudinal doctor patient relationship. In this example, the primary care practitioner could recommend conservative treatment or prescription of antibiotics. If the practitioner recommends conservative treatment and no new prescriptions, some patients may think that the doctor is not taking the patient's concerns seriously and it could erode the trust placed in that practitioner. In turn, an eroded primary care practitioner/patient relationship may make it less likely that the patient would follow that

practitioner's advice on a needed vaccination at the next visit. The primary care practitioner must decide—what course of action and choice of words in the visit itself, would lead to the best health outcome in this single visit, while simultaneously building up an effective, trusting longitudinal relationship with this patient for all of their primary health care needs. Weighing these various factors, even for a seemingly simple condition like sinus congestion, makes the entire interaction inherently complex, and it is this complexity in the relationship between the doctor and patient that this code captures.

The second part of the add-on code also describes a *relationship* between the practitioner and patient, but for specific types of conditions. The add-on code describes ''medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.'' Again, the ''ongoing care'' describes a longitudinal relationship between the practitioner and the patient. In comparison to the previous example, though, this is specifically in reference to a single, serious condition or a complex condition. For example, a patient with HIV has an office visit with their infectious disease physician, who is part of ongoing care. The patient with HIV admits to the infectious disease physician that there have been several missed doses of HIV medication in the last month. The infectious disease physician has to weigh their response during the visit—the intonation in their voice, the choice of words—to not only communicate clearly that it is important to not miss doses of HIV medication, but also to create a sense of safety for the patient in sharing information like this in the future. If the interaction goes poorly, it could erode the sense of trust built up over time, and the patient may be less likely to share their medication adherence shortcomings in the future. If the patient isn't forthright about their medication adherence, it may lead to the infectious disease physician switching HIV medicines to another with greater side effects, even when there was no issue with the original medication. It is because the infectious disease physician is part of ongoing care, and has to weigh these types of factors, that the E/M visit becomes inherently more complex and the practitioner bills this code (G2211). Even though the infectious disease doctor may not be the focal point for all services, such as in the previous example, HIV is a single, serious condition, and/or a complex condition, and so as long as the relationship between the infectious disease physician and patient is ongoing, this E/M visit could be billed with the add-on.

We appreciate the clarifying questions raised by commenters on the appropriate usage of this add-on code. We will continue to engage with interested parties on the use of this code and will consider developing additional educational materials as needed.

Comment: Another commenter who supported our proposal offered clinical scenarios they thought were excellent examples of the complexity of care this code was intended to address:

Example A: A patient with sickle cell disease (SCD) visits the clinic to see her hematologist and has clearly deteriorated cognitively. The physician needs to understand if this is dementia or SCD-related. Most of the time during the patient's visit is spent ordering neurocognitive testing fand consulting with psychiatry.

Example B: A patient with SCD needs to be prescribed oxycontin for their chronic pain. The provider also spends time during the patient's visit managing other medications and then seeking the appropriate pre-approval and prior authorization for oxycontin.

Response: We thank the commenter for providing these clinical scenarios. However, the most important information used to determine whether or not the add-on code could be billed is missing: the relationship between the practitioner and the patient. If the practitioner is the focal point for all needed services, such as a primary care practitioner, this add-on code could be billed in these examples. Or, if the practitioner is part of ongoing care for sickle cell disease (a single, serious and complex condition) then the add-on code could be billed. Otherwise, this add-on code could not be billed. Again, this add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship.

We also note unequivocally that this code is not restricted to medical professionals based on particular specialties. Instead, it should be used by medical professionals, regardless of specialty, with O/O E/M visits (other than those reported with the –25 modifier) for care that serves as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. We reiterate that when physicians and other practitioners provide care that serves as the continuing focal point for all needed healthcare services, they should report the inherent complexity add-on code along with all reasonable and necessary O/O E/M visits (not reported with the –25 modifier).

Comment: We received many comments on our proposal to not make payment for HCPCS G2211 when the underlying O/O E/M visit had been reported with modifier –25. Many commenters were supportive. Some commenters opposed our proposal excluding payment when there were underlying visits with modifier –25 because they believed some preventive services would be rescheduled to a later date. One of these commenters suggested that a more appropriate mechanism for addressing any distinction between a stand-alone O/O E/M service and one at which a physician elects to also perform a minor procedure is the National Correct Coding Initiative (NCCI) edits that could be revised to bundle code G2211 to codes for minor surgical procedures that are commonly performed in the primary care or other non-procedural specialty care setting. She further suggested a better option could be the creation of HCPCS codes that are not add-on codes but rather adequately valued codes representing visits for longitudinal care for all of a patient's health care needs and/or ongoing care related to a patient's single, serious, or complex condition which she believed might represent a significant reduction in the burden of the add-on code assignment, audit/overpayment risk, and stress until in her view a better health care system design can be established for delivering and funding these services.

Several commenters echoing the concern for preventive services requested that the annual wellness visit be excepted from the policy. Another commenter stated that modifier –25 is often used in cases where clinicians are treating complex patients since these patients are likely to receive multiple services on the same day. They stated that excluding these cases therefore may be counter to the ultimate goal of appropriately valuing complex O/O E/M services.

Another commenter wrote that patients often travel long distances to receive care at their facilities requiring multiple visits with different specialists for a variety of medical management and interventions on the same day to treat a variety of disease co-morbidities related to their cancer care. They stated it would be appropriate for their primary treating physician to bill the G2211 add-on code for the on-going coordination effort related to these complex treatment plans regardless of the multiple visits occurring on the

same day. Another commenter stated that urologists frequently manage multiple chronic conditions simultaneously and that certain diagnostic procedures are commonly performed as part of the ongoing management of a patient with chronic genitourinary disease. They recommended that CMS consider permitting the use of modifier –25 in those situations where the surgical code is associated with a 0-day global period and where the sites of service are any of the O/O settings. They also suggested that specific CPT codes 52000 and 51741 be exempt from our policy to not pay the inherent complexity add-on when modifier –25 is reported on the base O/O E/M code so that urologists could continue to perform these tests and be appropriately paid for providing longitudinal care for the multiple chronic conditions the manage simultaneously.

Response: We thank commenters for raising these concerns and offering suggestions on how we might refine the policy. First, we are clarifying that modifier –25 is reported in instances where the physician or practitioner billing the O/O E/M is the same one who is billing the significant separately identifiable procedure or other service on the same day. Commenters seemed to incorrectly suggest modifier –25 was reported with an O/O E/M visit if the patient had a visit or procedure with another physician or another practitioner on the same day as the physician or practitioner billing the O/O E/M visit. With respect to the concern that a physician or practitioner would not perform a preventive service on the same day as an O/O E/M visit merely to avoid our policy to not pay G2211 when the O/O E/M visit is reported with modifier –25, we intend to monitor the utilization of this code and continue engagement with interested parties as this policy is implemented. With respect to the suggestion for a new set of parallel codes for the kind of care captured by inherent complexity add-on code we believe such a set of codes could increase administrative burden with minimal benefit gained and unnecessarily delay reactivation of the complexity add-on code and payment. Similarly, we believe relying on NCCI edits to single out unbundled procedures or services with which G2211 should not be billed would also increase administrative burden and delay reactivation. Finally, for future rulemaking and as discussed in the next section, we remain open to considering additional iterations in coding and valuation within the PFS that would meet the same goals regarding the appropriate valuation of these services.

Comment: Many commenters expressed concerns or disagreed with our utilization estimates for G2211. Many commenters were appreciative that we have revised our utilization estimates resulting in a smaller negative impact on the budget neutrality conversion factor. However, most commenters urged to further refine these assumptions to prevent reductions in the conversion factor that they noted might, in fact, not be warranted by actual usage. They suggested that there continues to be a lack of clarity surrounding the appropriate circumstances for reporting the inherent complexity add-on code and that combined with potential implications for patient cost-sharing, health care practitioners would experience ambiguity toward billing the code, which could result in our having overestimated utilization. Many other commenters asked that we align utilization estimates with the actual first year utilization of care management codes for transitional care management (TCM) and chronic care management (CCM). Some commenters asked us to make mid-year adjustments to the conversion factor if in our monitoring we find that we overestimated utilization of the code.

Response: We have considered the suggested factors but do not believe those care management codes are an apt comparison for G2211 utilization, given several limitations in their code descriptors and other requirements which are not applicable to the inherent complexity add-on code. We also believe that the documentation requirements specific to the care management codes may have contributed to the slower uptake in utilization than was estimated for the first year. Additionally, we believe the additional clarifications we are making in this final rule about when it is appropriate to bill the inherent complexity add on code will give practitioners increased confidence to bill the inherent complexity add-on code appropriately. Finally, we note that we make budget neutrality calculations on a prospective annual basis and would not be able to make mid-year retrospective adjustments to the conversion factor as was suggested by some commenters. CMS uses claims data for the services as they become available in subsequent years, to inform budget neutrality adjustments that would apply for a given year.

c. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

Over the last several years, we have received suggestions/recommendations outside of the rulemaking process that CMS consider using a different approach for valuing services that rely on research and data other than the AMA RUC's specialty-specific valuation recommendations. These commenters have highlighted that the evolving practice of medicine looks significantly different than it did when the resource-based relative value scale (RBRVS) was established three decades ago. Disease prevention and health promotion have grown in practice, and patient expectations are higher for managing hypertension, diabetes, and hypercholesterolemia. Additionally, more pharmaceuticals and new biologics have expanded therapeutic options for non-procedural care. Commenters have suggested convening expert panels that might review pertinent research and recommend resource recalibrations to update relative values under the PFS. The commenters suggested that such independent assessments could support CMS and the broader health delivery and health finance community in addressing growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management visits and other non-procedural/non-surgical services.

For many years, CMS has worked to address coding and payment deficiencies, explicitly focusing on instances where resources are not well accounted for in the inputs for certain services, including where significant differences in relative resources involved in furnishing care are not reflected in the coding distinctions, or where too-specific coding makes valuation at appropriate intervals impractical. As we continue ongoing work to establish resource-based relative units for PFS services, we have sought and still seek public comment about the potential range of approaches CMS could take to improve the accuracy of valuing services. We continue to be interested in how we might improve the accuracy of valuation for services, and sought information about how we might evaluate E/M services with greater specificity, more regularly and comprehensively in the proposed rule.

As we consider how CMS can potentially move forward with reforms to the way we establish values for E/M and other services, we specifically sought comment in the proposed rule

from the public on the following questions:

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

c. Are the current Non-E/M HCPCS codes accurately defined?

d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?

e. What are the consequences if services described by HCPCS codes are not accurately defined?

f. What are the consequences if services described by HCPCS codes are not accurately valued?

g. Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?

In the proposed rule, we stated that we are particularly interested in ways CMS could improve processes and methodologies. We requested that commenters provide specific recommendations on improving data collection and making better evidence-based and more accurate payments for E/M and other services. We expressed particular interest in ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines, and new technologies that represent standards of care. We also asked for recommendations to ensure that data collection from and documentation requirements for physician practices are as least burdensome as possible while maintaining strong program integrity requirements. Finally, we also expressed interest in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

We received public comments on some or all of these questions from more than 50 commenters. The following is a summary of the comments we received and our responses.

Comment: In response to a., ''Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?'' some commenters responded that recent revisions of the E/M services were extensive and specifically addressed the granularity of services by allowing for gradation in reporting through allowing use of medical decision making or time on the date of the encounter (straightforward, low, moderate, and high), further enhanced by the development of coding for prolonged services. They believe the prolonged services codes, non-face-to-face services codes, clinical staff services codes, screening codes, care management codes, and HCPCS Category II codes reported for the evaluation and management of a patient allow for reporting of many nuanced interactions with a patient both on the day of encounter and between encounters. They expressed concern that HCPCS codes that CMS has added have created an unbundled component coding system with significant overlap of codes billable for the evaluation and management of Medicare beneficiaries and believe that while E/M and care management services have a sufficient gradation of intensity of work, they do not comprehensively define typical work, resulting in duplicative payment that CMS has not audited.

Other commenters believed that the acuity between higher-level E/M codes is often quite steep and inconsistent with the differential between lower-level codes. They believed that rapid implementation of G2211 is necessary in accounting for this higher acuity and complexity. Similarly, another commenter stated that O/O E/M encounters represent a broad and diverse range of diagnoses and that the full set of E/M codes is relatively small, given the wide variety of encounters they are meant to describe. They added that CPT is better at describing discrete procedures than E/M services, especially E/M services that represent continuous, comprehensive primary care. Another commenter stated that the RUC tends to value codes primarily based on the physical skill involved and that cognitive services (that is, critical thinking involved in data gathering and analysis, planning, management, decision making, and exercising judgment in ambiguous or uncertain situations) are routinely undervalued. Another commenter suggested that many primary care activities are not accounted for under fee-for-service (FFS) payment. They stated that over the past decade, CMS has expanded the range of E/M services separately billable under the PFS but are concerned this piecemeal, code-by-code approach within the PFS may never fully account for the resources used to furnish primary care. They do not see the PFS as it is currently configured to be a platform allowing Medicare to pay for a broad range of elements defining primary care. Another commenter stated that the current high-level O/O E/M service codes do not distinguish between managing a few concurrent conditions, many concurrent conditions, and a single highly intense condition effectively. They further asserted that the original gradations within the outpatient and inpatient E/M service code families were not based on clinical evidence but rather Medicare payment data, which was likely distorted, and there has been no attempt to address these gradations. Another commenter stated they did not believe that the current outpatient and other E/M service codes reflect the work and resources required to deliver non-procedural and cognitively intense care to Medicare beneficiaries. They stated that the most recent revisions of E/M service code definitions and valuations have not remedied the original problems and failed to capture the intensity of E/M care, particularly the care provided to Medicare beneficiaries with one or more complex comorbid conditions.

Response: We appreciate commenters' assertion that the current E/M coding structure does not adequately capture certain types of primary care. Our established policy for the complexity add-on code, as finalized in the CY 2019 PFS final rule and proposed with modifications for CY 2024, is rooted in our long-standing assessment that there are certain complexities inherent in furnishing some kinds of E/M visits that the current E/M coding and visit levels do not fully recognize, similar to what the commenters have highlighted. We continue to believe about how best to address this issue within the framework of the PFS and welcome ongoing dialogue with all interested parties.

Comment: In response to b. ''Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?'' many commenters responded that they believed the methods used by the RUC and CMS are appropriate to value E/M and other HCPCS codes. They stated that standard packages for pre-service time, post-service time, practice expense direct input benchmarks, and pre-service clinical staff time packages were implemented, allowing for enhanced relativity and comparison among all services. They relayed that the median number of RUC survey respondents in recent years is 70, with surveys for high-volume services having more than 100 physician respondents. They added that the recent office visit RUC survey yielded the highest number of responses in the history of the RUC process, with 1,700 physicians completing the survey.

They stated that the survey was the concerted effort of 51 specialty societies and other healthcare professional organizations that represented 95 percent of Medicare claims for E/M office visits. They further added that the RUC incorporates extant data when possible, such as data from the Society of Thoracic Surgeons, American College of Cardiology, and National Surgical Quality Improvement Program (NSQIP). These commenters requested that CMS make one methodological improvement to restore the Refinement Panel process, serving as an appeal process for those commenting on CMS's proposed relative values. Another commenter expressed concern that unlike the RUC's process, which they stated is based on statistics, CMS's methods to assign values to E/M and other HCPCS codes, especially G-codes, are opaque and not scientifically sound. They stated in doing so, CMS undermines the relative nature of the PFS. Another commenter explained that to identify potentially misvalued services, the RUC identifies, maintains, and reviews a list of new services and services that use new technology, develops objective screens based on defined criteria, and examines all services in which utilization estimates are more than expected.

In their comment letter to the proposed rule, MedPAC highlighted their long-standing problems with the data and processes used to set different services' RVUs, which they concluded have led to certain services (for example, procedures, imaging, and tests) becoming overvalued relative to other services (for example, E/M services). They believe CMS relies heavily on RUC recommendations when setting RVUs, even though most of the RUC's members have a financial stake in setting payment rates, about which researchers have expressed RUC transparency and objectivity concerns. MedPAC further stated that as far back as 2006, they recommended that CMS augment the RUC with a standing panel of experts that could help the agency identify overvalued services and review recommendations from the RUC. They also recited some of their other past recommendations. They added that, in their view, a wide range of codes should be reviewed using new data and analyses, beginning with the 10- and 90-day global surgical codes. They noted that because of the evidence of the substantial overvaluation of 10- and 90-day surgical global codes, they have continued to support CMS's prior proposal to convert all 10- and 90-day global surgical codes to lower-priced 0-day global codes and allow practitioners to separately bill for postoperative visits on a FFS basis (that is, outside of the global package). Some commenters shared this view about global surgical codes, whereas others took an opposite view in response to the questions below.

Other commenters stated that the methods used by the RUC and CMS do not lead to accurate valuation and that the problems lie with the nature of E/M services and the PFS's budget neutrality adjustment. They stated that the resources used in furnishing the work portion of E/M services are primarily a function of the time the clinician spends with the patient and, therefore, are not amenable to efficiency gains and that the valuation process is not responsive to efficiency gains, leading to passive devaluation of E/M services under the constraints of budget neutrality. They recommend a robust process, supported by an expert advisory panel, to review misvalued services, which would focus on replacing magnitude estimation with a building block approach to valuation. Other commenters stated that they believed there were several methodologic issues in the RBRVS initial work done by Bill Hsiao and Peter Braun, some of which were identified by the original investigators, undermining its ongoing value. They stated that clinically significant factors, such as the expertise needed to manage specific complex clinical conditions or multiple simultaneous clinical conditions, are not currently recognized. They stated low response rates and small sample sizes for the RUC surveys distinguished this feature from the original methodology employed by Hsiao et al., whose validity depended critically on robust sample sizes. These commenters suggested additional data sources could result in more robust recommendations and recommend that CMS invest resources in other supplemental sources of information, especially physician time, rather than relying almost exclusively on the RUC. Another commenter stated that the current survey methodology has several limitations that impact both E/M and non-E/M services, including low response rates, an inability to determine if the responses received are accurate reflections of real-world clinical practice and substantial variations in modern-day clinical practice for the same HCPCS code across different specialties. They added that more direct methodologies might be more costly and burdensome. Still, they would reflect the actual time and effort inherent to a particular HCPCS code more accurately. They believe that time and motion studies could be used to determine the required resources for RBRVS. Another commenter stated that it is more difficult to quantify the physician work involved in E/M services than for more specific procedural service vignettes in the RUC survey process, given that the survey focuses on the ''typical'' patient and distributes surveys based on vignettes for E/M services that are much less specific. They added that the input of the primary care specialties that provide the most complex E/M services and do so most commonly is undervalued when these broad E/M vignettes are surveyed across more than 50 specialty societies, many of which do relatively few and much more straightforward E/M visits than primary care.

Another commenter stated that fundamental problems with the outpatient and other E/M codes would not be solved by the existing processes employed by the Current Procedural Terminology (CPT)® Editorial Panel and the American Medical Association (AMA) RUC. They stated there is an expertise bias on the RUC toward procedural care based on the panel's composition influencing how services are valued. They posited that a significant portion of the value of E/M and other non-procedural services lies in the physicians' skills and expertise in diagnosing and managing complex conditions, coordinating care, considering the patient's overall health and well-being, and making treatment decisions that consider various factors beyond just the face-to-face interaction between the physician and patient, which is harder to quantify in a survey.

Response: We appreciate the perspectives shared by commenters and recognize that there are opportunities to improve how all services are valued and better account for resource variation for different types of care under the PFS. Our policy for the complexity add-on code reflects several years of consideration and engagement with interested parties to address these long-standing issues. However, we view our implementation of the inherent complexity add-on code as an improvement in valuation and coding compared to the status quo, not necessarily an end in itself. We welcome engagement on this broader issue of recognizing costs for specific services as we have described, including through our usual review of coding and recommendations for PFS services from the AMA editorial panel, RUC, and other interested parties.

Comment: In response to c., ''Are the current Non-E/M HCPCS codes accurately defined?'' some commenters responded, yes, the current non-E/M

HCPCS codes are accurately defined through the CPT Editorial Process and called the process a respected method that is best suited to preserve accurately defined medical codes. They added that not only are HCPCS level I CPT codes generated and accurately defined, but the reporting guidelines and instructional parentheticals are also established to ensure proper usage and reporting of such codes. These commenters stated that, in contrast, descriptors for HCPCS level II codes developed by CMS through an application process twice per year or as C-codes and G-codes are often ill-defined because CMS does not differentiate them from existing HCPCS level I CPT codes, resulting in reporting confusion. Other commenters stated that the PFS has experienced a proliferation of non-E/M codes whose fine-tuning of time and intensity to distinguish minor variations in resource costs creates a false sense of accuracy because empirical times are subject to unavoidable measurement error and intensity estimations should be limited to a few clearly-defined intervals.

Response: We thank the commenters for their feedback. We recognize the role that certain interested parties play in establishing the HCPCS level I coding that healthcare practitioners use to bill for the services they furnish and note that we routinely rely on the CPT coding process as a critical part of our process for recognizing and paying for such services under the PFS. We also acknowledge that in some circumstances, when we must act to address beneficiary access or practitioner payment issues, we can establish HCPCS level II coding, and we do so in the public interest, reflecting our consideration of appropriate coding and provider administrative burden. We also recognize that there are intrinsic limitations in the level of specificity in time and intensity as reflected in the RBRVS, regardless of the origin of the service definition in coding or how many survey responses are considered in the valuation process.

Comment: In response to d., ''Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?'' commenters stated that it is important that all services be examined via the same resource-based relative value scale methodology to ensure fairness, consistency, and relativity. Another commenter stated that CMS has often discounted intensity and over-relied on time as a measure of value. They characterized intensity as based on requisite education and training, dealing with complex patient cases that are physically challenging during treatment with a risk of unexpected intraoperative complications. They stated that managing these patients requires considerable mental effort and judgment, with the procedure's outcome more dependent on the surgeon's skill than the time necessary to accomplish it. Other commenters believed that the process used by CMS is typically a calculation made by a nonphysician practitioner (NPP) using math without physician validation. They stated that a glaring example of CMS inaccurately valuing non-E/M codes is the failure to incorporate the RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes into global codes. They noted that CMS did finalize adjustments for other bundled services, such as maternity codes, in the CY 2021 PFS. They implored CMS to follow precedent and correct this issue. They also believed that recent decisions had been incorrectly made solely on time, without adequate consideration of the intensity involved, and that time should not be the deciding factor in code valuation. Some commenters stated that the methods used by the RUC are appropriate to value E/M and non-E/M codes. They believed the underlying RBRVS methodology remains relevant today and that the RUC valuation process continues to improve with the development of numerous standards/policies/conventions to improve relativity and ensure consistency. They remarked that standard packages for pre-service time, post-service time, practice expense direct input benchmarks, and pre-service clinical staff time packages have been implemented, allowing for enhanced relativity and comparison among all services. Another commenter voiced frustration at what they characterize as a lack of rationale provided for CMS' decisions when they differ from RUC recommendations. They stated that it is difficult to respond when CMS' rationale is only a ''belief'' that a crosswalk to another code is better than the RUC recommendation or the data from the survey. They added that, without additional substantive rationale, just because a CPT code has the same intra-service or total time, does not mean another code should share its exact physician work RVU. They and other commenters urged CMS to consider restoring the Refinement Panel process that served as an appeals process for those commenting on CMS proposed relative values.

Other commenters stated that there is ample evidence that many non-E/M services are overvalued due to time over-estimations and payment for bundled post-operative visits that rarely occur. Additionally, they stated that unlike under the original Harvard study methodology, on which the RUC magnitude estimation process relies, RUC survey respondents are likely aware that a higher rating of time and work directly leads to a higher work RVU for the rated procedure. They added that this problem is illustrated in the CMS proposed rule section on the valuation of specific codes where estimates and work RVUs, originating with whom they termed self-interested participants in the process, are evaluated at the statistical median, whereas others, out of a concern about inadequate data, are evaluated at the 25th percentile. They stated that choosing statistics this way does not overcome the problem of inadequate data and invites conflicts of interest. Furthermore, they stated that many survey respondents have not performed the service in question, as there is no requirement for it, calling into question the validity of their assessments. They recommended: (1) Moving the estimation of work from subjective magnitude estimation to analysis relying primarily on a measured-time-data-informed building block approach; (2) Routinely and periodically observing and collecting measured, actual-time data for work (and direct PE) from a rotating panel of practices and other healthcare providers; and (3) Adoption of a criterion for the misvalued codes initiative to identify codes within BETOS families that have aberrant intensity values, what the RUC has termed ''rank order anomalies.'' They recommended that accurate data collection, particularly for code-specific time data from practices, should be central to this review. Another commenter, taking a similar approach, suggested that CMS develop an agency-based independent process parallel to the RUC for service valuation. They envisioned this parallel process would take a fundamentally different approach to valuation that would use empirical data and the building block approach to value services. CMS might use the RUC estimates to determine valuation in selected situations. They posited that a CMS process would not be bound by the inherent distortions in representation between cognitively intense and procedural specialties currently found in the RUC.

Response: We thank the commenters for their feedback on this specific question. We share the same concerns about effectively valuing and accounting

for resources involved in furnishing in the services paid under the PFS, especially when considering codes of dissimilar structures. We recognize that there are varying perspectives on how to best reflect the inputs for services paid under the PFS, which is why we are engaging in this dialogue and asking these questions. As part of our obligation to maintain the PFS and ensure access to services for Medicare beneficiaries, we thoroughly review and consider available information, including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. In response to the comments expressing concern about our valuation review process, we note that our approach does consider the expertise supporting the RUC process. We primarily use the RUC-recommended values as a starting reference for services under review and then apply one of these several methodologies, which we have discussed in detail in past rules to account for adjustments to specific inputs that we believe were not otherwise reflected in the RUC-recommended value. We note our current process of proposing the majority of code values in a proposed rule, allowing the public to comment on those proposed values, and then finalizing those values in a final rule offers greater transparency and accountability than the refinement panels which we established to assist us in reviewing the public comments on CPT codes with interim final work RVUs. Our process also offers greater transparency and accountability than the refinement panels in balancing the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. Further, we have established an annual process for the public nomination of potentially misvalued codes, which allows those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking, including possibly through the RUC process, to bring those codes to our attention. We disagree with the comments asserting that we discount intensity entirely and rely on time alone as a measure of value for certain services, though we acknowledge commenters for particular codes have sometimes urged us to give more weight to assertions regarding greater relative intensity, much like some interested parties have urged us to consider intensity as reflected in survey data overall. Following our statutory authority, we have consistently considered revisions to valuations based on the relative resources involved in furnishing the service, which include time and intensity. We have always stated in past discussions on this issue that we believe that changes in time and intensity must be accounted for when developing work RVUs. Thus, when our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values, and that is not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2024 PFS final rule, CPT codes 76987, 97550, and 99497 all share the same total work time of 40 minutes. However, these codes had very different proposed work RVUs of 1.62, 1.00 and 1.50, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple factors in our review process, and we anticipate continuing to engage in constructive dialogue with the community regarding the appropriate weighing of time and intensity in establishing work RVUs.

Comment: In response to e., ''What are the consequences if services described by HCPCS codes are not accurately defined?'' some commenters stated that the RUC's Relativity Assessment Workgroup (RAW) process helps to identify a lack of clarity or the need for change in descriptions due to changing technology. They believed that CMS's differing coding methodologies for reporting prolonged services deepen the administrative burden for healthcare professionals and increase the potential for improper coding. Many commenters expressed that it is imperative that physicians have one set of clear codes and guidelines to report medical procedures and services and that if other HCPCS level II codes are created that are not accurately defined, it could lead to improper reporting of medical services to Medicare and other insurers. Another commenter stated that inappropriate utilization, particularly if no health benefit is obtained for the patient or population, can lead to high healthcare costs. Another commenter stated that when HCPCS codes are poorly defined, clinicians and other healthcare professionals may be challenged with when and how to confidently adopt HCPCS codes in their clinical practice, which can lead clinicians, other healthcare professionals, and their administrative staff to inadvertently misuse or misapply a HCPCS code, leaving them vulnerable to program integrity audits.

Response: We recognize the role that certain interested parties play in establishing HCPCS level I coding that healthcare practitioners use to bill for the services they furnish and note that we routinely rely on the CPT coding process as a critical part of our process for recognizing and paying for services under the PFS. We also acknowledge that in some circumstances, when we must act to address beneficiary access or practitioner payment issues, we establish HCPCS level II coding, and we do so in the public interest, reflecting our consideration of Medicare policy goals, appropriate coding, and healthcare provider administrative burden.

Comment: In response to f., ''What are the consequences if services described by HCPCS codes are not accurately valued?'' some commenters stated that the intent of the RBRVS is to ensure that the payment of one service is relative to the payment of another when accounting for the resources consumed in the provision of the service. They furthermore stated that if the relativity of one service is undervalued, physicians may not be able to sustain the practice of providing that service in an office setting. Likewise, a significant overvaluation of a service may provide a financial incentive to perform the service. They added that the RUC created the RAW to develop objective and fair screens to identify potentially misvalued services and address these issues. Another commenter stated that there may be services described by multiple overlapping codes, likely resulting in duplicative billing and overpayments for a single service. They urged CMS to research and audit utilization of the over 150 CPT codes and HCPCS G-codes for reporting unbundled, finite pieces of E/M services for which they stated a potential for overpayment may result in fraud, waste, and abuse under the Medicare program.

MedPAC commented that when subsets of services are overvalued, it

causes the gap between the compensation of different clinical specialties to be more significant than it otherwise would be. They reported that in 2021, the median compensation for surgical specialties was $441,000, well above the $264,000 that primary care physicians earned. They added that this large compensation gap makes careers as primary care providers less financially attractive than careers as specialists and may be a factor in why the supply of primary care physicians in the U.S. has been declining in recent years. Other commenters expressed similar views, citing MedPAC and a National Academies of Science, Engineering, and Medicine (NASEM) 2021 consensus report that concluded that the current approach to FFS valuation has ''resulted in systematically devaluing primary care services relative to other services and its population health benefit . . .''

Response: We agree that there may be distortions in the PFS that result from disparities in coding and valuation, which is at the core of the issue we have highlighted and are working to address by implementing the inherent complexity add-on code as discussed above.

Comment: In response to g., ''Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?'' some commenters stated that CMS should not consider valuation changes like the approach in section II.J.5. of the CY 2024 PFS proposed rule. They remarked that the calculation proposed for the increase in behavioral health services is not resource-based and could potentially distort the RBRVS. They added that section 6102 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) that created the RBRVS requires that the relative values are based on resource costs. They stated that CMS should not use arbitrary calculations to adjust specific services performed by one specialty to tackle issues outside of the scope of the RBRVS payment system and that access and shortage issues should be addressed through legislative solutions and funded by Congress.

Response: We do not agree that recognizing distortions in valuation and accounting for them within the RBRVS departs from basing valuation on resources. Instead, we believe that deliberate failure to account for systemic distortions in the methodologies, once recognized, would violate resource-based valuation. We look forward to continued engagement with interested parties so that more comprehensive and consensus-based solutions to address these distortions within the ratesetting methodologies can be implemented. We received public comments in response to our requests, following the items a. through g., for recommendations on a series of specific topics: improving data collection and making better evidence-based and more accurate payments for E/M and other services; making more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines, and new technologies that represent standards of care; ensuring that data collection from and documentation requirements for physician practices are as least burdensome as possible while maintaining strong program integrity requirements; and finally whether commenters believe that the current AMA RUC is the entity that is best positioned to provide—recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services, or if another independent entity would better serve CMS and interested parties in providing these recommendations.

Comment: In response to the interest we expressed in hearing potential ways that we could improve processes and methodologies, and our request that commenters provide specific recommendations on ways that we can improve data collection and make better evidence-based and more accurate payments for E/M and other services, some commenters stated that the RUC is continuously improving its processes to ensure it best utilizes reliable, extant data., as noted above, in response to ''b.'' Another commenter stated that while the RUC can recommend relative work RVUs and direct PE details, because adjustments for inflation have not been applied to such services via statute, CMS cannot pay providers at the appropriate rate for the work and PE measured. They stated that to make more accurate, evidence-based payment for E/M and other services, Congress must adjust the factors that impact reimbursement rates under the PFS, and they urged CMS to support such Congressional efforts. They also encouraged CMS to consider examining electronic health record (EHR) data as a credible source for provider work, not only for global codes but also for services provided by PCPs over a 30-to-90-day period to ensure there is no overlap in work. They added that services reported over the 10-day global period for E/M office visits should also be reviewed for duplicative work and that because many services can be reported using time, a time modifier could enhance the ability for EHR and other program integrity audits to identify overlapping services provided in person or via telehealth.

Another commenter recommended that CMS consider using a supplemental independent panel of experts to provide recommendations on evidence-based and accurate valuation of services under the PFS. They stated that a more formalized process for submitting data to CMS (including publicizing how, where, and by when to submit available data) could also be helpful to stakeholders who are not as regularly engaged with the staff who draft the PFS proposed and final rules to share any data they do have access to.

We also received public comments in response to our particular interest in recommendations on making more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines, and new technologies that represent standards of care.

Response: We appreciate the commenters' concerns and acknowledge that there are changes in treatment standards and new technologies that should be recognized better in the PFS. Moreover, we realize that aspects of the PFS methodology need to be revised to better account for these changes. Over the last several years, we have engaged in research to identify viable approaches to updating the data inputs we use to better set payment rates to reflect these changes. We thank the commenters for their thoughts, as your engagement is crucial to our ongoing efforts to understand critical variables in any attempt to reform the PFS, including identifying alternate data sources (like EHRs) to support the refinement of data inputs or, more broadly, identifying how to proceed within our existing statutory authority or when congressional may be required to facilitate necessary fundamental changes to calculating physician payment rates.

Comment: Many commenters suggested that CMS may improve methodologies by improving access to Medicare and Medicaid data. They added that disseminating Medicare utilization data earlier would be particularly helpful to immediately understand if the utilization of a service is as anticipated. They suggested that the first quarter of Medicare claims data should be available by July 1st of each year, and a full year of claims data should be available by April each year (for example, 2023 data should be publicly available by April 2024). They

requested that CMS share recent Medicaid data and investigate mechanisms to collect and share Medicare Advantage encounter information.

One commenter stated that the RUC identifies, maintains, and reviews a list of new services and services that use new technology, develops objective screens to identify potentially misvalued services, and examines all services in which utilization estimates are more than expected. They stated that since its inception in 2006, the RAW and CMS have identified over 2,700 services through over 20 screening criteria for further review by the RUC. Another commenter stated that due to a lack of transparency, they do not know what methodologies CMS employs to be able to provide recommendations on more timely improvements for HCPCS G-codes. They stated that from their perspective, CMS often reacted to stakeholder requests by creating G-codes—sometimes for services that do not need to be urgently reportable—and often based them on new technology that has not reached sufficient evidence for support.

Response: We appreciate the commenters' concerns and acknowledge that there are changes in treatment standards and new technologies that could be recognized better within the PFS. We thank the commenters for their thoughts, as their engagement is crucial to our ongoing efforts to understand critical variables in any attempt to reform the PFS, including identifying alternate data sources (like EHRs) to support the refinement of data inputs or, more broadly, identifying how to proceed within our existing statutory authority or when congressional action may be required to facilitate necessary fundamental changes to calculating physician payment rates.

We also received public comments in response to our interest in recommending that data collection and documentation requirements for physician practices are as least burdensome as possible while maintaining strong program integrity requirements.

Comment: Some commenters supported addressing the significant administrative burden plaguing physicians and other healthcare professionals. They added that physicians and other healthcare professionals have limited time and other resources to participate in data collection efforts. Another commenter stated documentation should be utilized for clinical purposes and should not burden physicians to satisfy administrative or billing requirements. They noted that supporting the national medical specialties and other health care professional organizations is imperative in obtaining adequate data on the resources required to provide services. Another commenter believed that modifiers (for example, a modifier when an E/M service is reported using time) would be very useful to assist with program integrity audits. They thought CMS should collect data (for example, service times, the number and types of services reported on any day by a given provider) from EHR vendors to evaluate billing patterns better. They believed that without this information from EHRs regarding times and visits, in some scenarios, patients may not receive the care they expect and deserve.

Response: We appreciate commenters' interests and will consider them both for future rulemaking and as part of ongoing efforts to improve transparency.

Finally, we also received public comments in response to our interest in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide—recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

Comment: Many commenters objected to the question and noted that any individual or entity, including the RUC, has a constitutional right to provide recommendations to CMS on resource inputs for work and practice expense valuation. One commenter stated that it is when CMS deviates from the RUC process, such as with creating the add-on code and providing no evidence of its time or relative intensity, that the entire RUC process' legitimacy becomes threatened, positing that if medical societies perceived that CMS would ignore their good-faith participation in a consensus-based process, there would be even more efforts to seek legislative action, thereby resulting in an even more inconsistent system. Several commenters stated that the RUC recommendations to CMS are based on extensive granular data to describe physician time, work relativity, and PE resources associated with providing procedures and other services. They stated that CMS is not required to accept RUC recommendations and that they will continue to support and advocate for the RUC process in maintaining Medicare relative values. Other commenters stated they played a significant role in valuing new or revised services within their specialty, supported the work of the AMA CPT® Editorial Panel to revise the entire E/M code set, with those revised services then valued by the AMA RUC, and believed that the processes used by the RUC provided an avenue for physician input that helped to maintain an appropriate resource-based payment system. They and other commenters noted that the RUC is best suited for valuing physician services. Another commenter expanded upon this view and noted that the AMA CPT Editorial Panel and the RUC are the best-situated entities to provide input to CMS on values, documentation, and coding as a part of the annual PFS rulemaking cycle, including for E/M services. They stated the physician experts who provided input at all stages of defining codes and valuing services as part of the CPT and RUC continuum provided the essential clinical knowledge needed to conduct these functions. They stated it also involved members from across the medical community, not just the specialty that delivers the service under review, to serve as a sounding board and safety net in defining and valuing codes. This commenter expressed concern that CMS attempted to marginalize the input of CPT and RUC and another entity may serve as a mechanism to reverse-engineer some other policy goal beyond providing medical expertise about the resources and work that are provided when furnishing a well-defined set of services. They and other commenters noted that CMS is not bound by the recommendations of the RUC and posited that any stakeholder is free to establish the infrastructure to generate detailed, data-driven recommendations for the valuation of services. They also noted that CMS continues to consider RUC recommendations precisely because the RUC provides the best available information and offers an unmatched coherent, data-driven rationale to its recommendations. Another commenter stated that there is no need for another independent entity to provide recommendations regarding the valuation for services that are reported on the PFS. They noted the RUC process for valuing services is fair and balanced, as experts across all specialties engage in deeply informed discussions and must come to a consensus (a two-thirds vote) to approve any recommendations. They stated that having all major specialties at the table, within the budget neutrality confines of the PFS, ensured that any changes are evidence-based and justifiable. Another commenter believed CMS should defer to the RUC process, especially when CMS does not have the appropriate specialty representation to make

informed decisions about the RUC recommendations. They further opined that CMS should communicate with the RUC and work to alter the process requirements so all interested parties can work together on a desired outcome.

In contrast, several commenters offered strong support and thoughts in response to CMS's request for information. These commenters opined that CMS should not view the RUC as the sole source of knowledge and expertise to ensure that physician services are valued appropriately. They encouraged CMS to invest in additional adjunctive sources to ensure its recommendations are well-informed, balanced, and reflective of the evolving healthcare environment. One commenter supported CMS in considering another independent entity, including pharmacists and other clinical staff, that would serve CMS in providing recommendations on resource inputs for work and practice expense (PE) valuations and to more accurately establish values for E/M and other physician services that better reflect modern-day team-based health care delivery and the actual services provided by pharmacists and other clinical staff to provide E/M services. Other commenters greatly appreciated CMS posing this question, as they did not believe that the AMA RUC is the entity best positioned to provide recommendations to CMS on resource inputs for work and PE valuations and how to establish values for E/M and other physicians' services. They stated that the valuations established during this process no longer represent the valuation of services for 'physicians' but all healthcare providers who bill Medicare, advanced practice nurses, physician assistants, limited license practitioners, and allied health professionals. They noted the valuation process relegated them to be represented by the Health Care Professionals Advisory Committee (HCPAC), which only has one seat on the RUC. These commenters asserted that there are inherent conflicts in the valuation process, which led to a historical undervaluation of E/M services, a foundational aspect of the primary care system. They also raised concerns about the data from surveys conducted by specialty societies having low response rates and total number of responses, which they claim raises questions about the representativeness of the results. They added that the lack of public accessibility of this information is not addressed by CMS's fee schedule notice and comment process, as the fee schedule itself is often used the valuations determined by the RUC as the basis for CMS's rationale. They requested CMS develop an equitable, accessible, and accurate valuation process reflective of the modern healthcare system, ensuring that nurse practitioners and other providers directly billing Medicare can participate in the entirety of the valuation process, which must be transparent and accessible for all. Another commenter echoed concerns that there are structural flaws with the RUC that undermine the accuracy of its recommendations, including inherent conflicts of interest among RUC members and a reliance on surveys from medical societies that lead to overvaluation of certain specialty services. They also stated that current CMS processes for valuing services lack external validation and do not leverage a diverse, evolving data set, which would be more accurate and comprehensive. They suggested that CMS supplement the RUC's recommendations with additional research and external data, positioning CMS to more actively lead the determination of relative values, with consultation from the RUC, consistent with expert recommendations. They recommended implementing accurate and ongoing data collection to independently validate RVUs, establish an empirical source of information on time and costs associated with services, and establish an expert advisory panel within CMS to provide crucial advice on improving valuation processes and ensure independence and transparency. Another commenter asserted that from the very first implementation of the PFS based on the RBRVS, there has been no CMS agency-level commitment to ensure that both the definition and valuation of physicians' services are based on the best evidence possible, that the determination of relativity has internal checks and balances, and that the entire process is publicly accountable. They and other commenters suggested that an expert panel will be best equipped to ensure these services are evaluated regularly, limiting the significant redistributive effects associated with major valuation and policy changes, as we recently saw when the outpatient E/M codes were revalued. They stated that a regular, independent assessment of available data and the resulting data-driven policy recommendations would stabilize an irregular process, significantly contributing to the declining primary care workforce.

Another commenter urged CMS to initiate the expert panel as part of the CY 2024 PFS final rule. They stated that the transition to more accurate, evidence-based, and accountable processes for defining services within the PFS and their relative pricing is long overdue and that the work to address the many distortions within the PFS should begin as quickly as possible.

Response: We recognize that there are varying perspectives on how to best reflect the inputs for services paid under the PFS. We appreciate the depth of consideration different interested parties have offered in their comments, and we will consider all the public comments regarding the potential range of approaches CMS could take to improve the accuracy of valuing services and how we might evaluate E/M services with greater specificity, more regularly, and comprehensively for future rulemaking.

3. Split (or Shared) Visits

The split (or shared) ''substantive portion'' policy for services furnished in facility settings was reflected in subregulatory guidance until it was withdrawn in May 2021 in response to a petition under the, since rescinded, Good Guidance regulation (see 87 FR 44002 (February 25, 2022). In the CY 2022 PFS final rule (86 FR 65150 through 65159), we finalized a policy for evaluation and management (E/M) visits furnished in a facility setting to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP in the same group practice provide the service together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. Commenters generally supported our CY 2022 proposals; however, there were divided comments regarding our proposed definition of ''substantive portion.'' Some commenters preferred the use of medical decision making (MDM) or one of the three key visit components as opposed to time for purposes of defining the ''substantive portion'' of the service.

a. Background

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. In the non-facility (for example, office) setting, the rules for ''incident to'' billing apply under this circumstance. However, ''incident to'' services are not available for services furnished in a facility setting. Longstanding CMS policy has been that, for split (or shared) visits in the facility (for example, hospital) setting, the physician can bill for the services if they perform a substantive portion of the encounter.

Otherwise, the NPP would bill for the service. Section 1833(a)(1)(N) of the Act specifies that payment is made for services furnished and billed by a physician at 100 percent of the PFS rate, while under section 1833(a)(1)(O)(i) of the Act, certain NPPs are paid for the services they furnish and bill for at a reduced PFS rate (for example, 85 percent of the PFS rate).

We defined ''substantive portion'' in the CY 2022 PFS final rule (86 FR 65152 through 65156) and provided for billing of split (or shared) visits in certain settings (86 FR 65156 through 65157) and for certain patient types (new and established) (86 FR 65156). After consideration of the public comments on the CY 2022 PFS proposed rule, we finalized a phased-in approach to this policy (86 FR 65153). For CY 2022, we finalized the definition of ''substantive portion'' as one of the following: either one of the three key E/M elements (that is, history, exam, or MDM) or more than half of total time. We also stated that we would delay the full implementation of the definition of ''substantive portion'' as more than half of total time until CY 2023 (86 FR 65152 and 65153).

Additionally, in the CY 2022 PFS final rule (86 FR 65158 through 65159), we finalized our proposal to create a payment modifier (modifier FS), to describe split (or shared) visits (see 86 FR 65158 through 65159 for this discussion). Over time, implementing and using this modifier will better enable us to quantify split (or shared) visits and better understand the billing patterns of practitioners that typically furnish them. Such information is helpful to CMS for program integrity purposes and may also inform us on whether we need to clarify or further revise the policy for these services in future rulemaking. We have roughly one year's worth of claims data from the time we implemented the modifier as part of our ongoing engagement with interested parties. We have continued to hear concerns about our intent to implement our policy to use more than half of the total time to define the ''substantive portion'' of a split or shared visit, and have received requests to continue to recognize MDM as the ''substantive portion.'' Many of these concerns specifically reference disruptions to current team-based practice patterns, and the potential for significant adjustments to the practice's internal processes or information systems to allow for tracking visits based on time, rather than MDM. With these concerns in mind, in the CY 2023 PFS final rule (87 FR 69614 through 69616), we finalized a policy to delay implementation of our definition of substantive portion as more than half of the total practitioner time until January 1, 2024.

After much consideration, we proposed to delay the implementation of our definition of the ''substantive portion'' as more than half of the total time through at least December 31, 2024, for the same reasons outlined in the CY 2023 PFS final rule (87 FR 69614 through 69616). We proposed maintaining the current definition of 'substantive portion' for CY 2024, which allows using any of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit. We stated that the additional delay would allow interested parties to have another opportunity to comment on this policy and would give CMS time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy. We expressed interest in how facilities currently implement our split (or shared) services policy in their workflows and how facilities now account for billing practitioners' services that are performed split (or shared). We expressed interest in better accounting for the billing practitioner's services in team-based care clinical scenarios. We recognized that the AMA CPT Editorial Panel was considering revisions to aspects of split or shared visits for CY 2024 that may impact our policies, but those changes had not been finalized before our proposed rule was published. We stated we would review the AMA CPT Editorial Panel's changes to split or shared visits when and if available before the final rule and in the context of our policy proposal. We indicated that we would consider any changes that are made by CPT and their relationship to our previously finalized policies and whether a further implementation delay beyond CY 2024 or revision of the definition of ''substantive portion'' is warranted.

We proposed to amend § 415.140 to delay implementation of the definition of ''substantive portion'' as more than half of the total time through CY 2024 in the interim while we continued to analyze and collect information from interested parties and commenters as to whether we should permanently modify our current definition. We proposed that the current definition of ''substantive portion'' would apply for visits other than critical care visits furnished such that *substantive portion* means either one of the three key components (history, exam, or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit for services furnished through the end of CY 2024.

We received public comments related to our proposal to delay the implementation of the definition of substantive portion, as more than half of the time spent by the physician and NPP through at least December 31, 2024.

Below is a summary of the comments we received and our responses.

Comment: Most commenters supported at least our proposed additional year delay in the implementation of time being used as the substantive portion. Additionally, one commenter expressed support for the overall goal of this policy, which is to require transparency.

Response: We thank commenters for their feedback.

Comment: While many commenters supported the delay, several asked that our permanent policy add the option to use time or MDM to determine who has furnished the substantive portion of the service, which is broadly consistent with the new set of E/M codes. Many commenters who supported using MDM stated that basing the policy solely on time could result in administrative burden and a possible disruption to team-based care. One commenter also noted that MDM would allow for the physician and NPP to decide which of them will bill for the services based on who furnished the substantive portion of the visit and assignment of the billing provider.

Other commenters stated that the physician should always bill for the shared visits because their level of expertise and efficiency was medically necessary, regardless of who spent more time with the patient. One commenter noted that if CMS is concerned that facility-based practices will take advantage of the E/M code changes that no longer utilize the examination elements in code selection, CMS could still require face-to-face care by the physician to bill for the shared visit as a simplified way to determine and audit when the physician level of expertise was necessary and when an independent visit without the physician was more appropriate.

Response: These comments were consistent with the public comments that we received and addressed in our CY 2023 PFS final rule (87 FR 69614 through 87 FR 69616). We define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group practice, in accordance with applicable laws and regulations. We note that the policy is not about whether the physician's expertise is ''necessary'' for the visit but

rather whether the physician or the NPP should bill for the service when each of them are performing part of an E/M visit.

Comment: Several commenters expressed that the policy to define ''substantive portion'' as more than half of the total time should never be fully implemented, other commenters asked CMS to permanently delay the implementation of this policy, while others urged CMS to withdraw the ''substantive portion'' policy altogether or continue the current policy to allow use of the three key components or time to determine who bills for the visit.

Response: We continue to believe that application of a substantive portion policy is appropriate for purposes of determining which clinician should bill for split (or shared) services as the higher PFS payment rate should apply only when a physician performs the substantive portion of the visit. Otherwise, the visit should be billed by the NPP who performs the substantive portion of the visit.

Comment: A couple of commenters expressed that this policy is troublesome for rural healthcare providers where the NPPs provide most of the care, and the practitioners receive less payment for split (or shared) visits as compared to physicians. The commenter stated this 'substantive portion' policy of more than half of total time by the physician and NPP performing the split (or shared) visit) would disenfranchise rural beneficiaries and providers. A few commenters urged CMS to withdraw the ''substantive portion'' policy and continue using its current history, exam, or medical decision-making policy and do not believe that ''over half'' is an appropriate definition of ''substantive portion'' for the purpose of paying for split/shared services.

Response: We appreciate the commenters' concerns and will continue to consider the potential impact of our policy on rural or health professional shortage areas for future rulemaking.

Comment: A few commenters expressed general concerns with the proposed delay in implementing our revised definition of ''substantive portion'' for split (or shared) services. Specifically, commenters stated that each year CMS proposes a delay, the facilities and practices spend time and resources preparing for potential changes that never come to fruition. To mitigate this burden, commenters urged CMS to finalize the current rules for split (or shared) visits.

Response: We note that we previously delayed finalizing the split (or shared) policy to consider additional feedback from interested parties, especially regarding administrative burden on professionals and concerns about the policy potentially deterring appropriate team-based care. Commenters continue to echo those same concerns with requests that we continue to recognize MDM as the ''substantive portion.'' We also acknowledge the commenters concerns surrounding the time and resources spent to prepare for changes in their practice patterns.

Comment: Several commenters noted that the AMA CPT Editorial Panel was in the process of strengthening their guidance for reporting split (or shared) visits using MDM, and this information would be included in the 2024 CPT publication. Other commenters asked CMS to adopt the new CPT guidance for split/shared visits and to delay its application until January 1, 2025. One commenter expressed that having two definitions of 'substantive portion' will create confusion, and stated that it is important for physicians to stick with one set of guidelines in reporting services.

Response: Over the past 2 years, CPT has reviewed and revised its guidelines involving E/M visits, including split (or shared) services. CMS has been concurrently reviewing those additions, revisions, and changes made by CPT, and addressing and incorporating them as appropriate for Medicare billing through our rulemaking process to provide greater alignment between the CPT E/M Guidelines and PFS billing rules for E/M services, including the split (or shared) visits.

We note that the CPT Editorial Panel recently issued its revised guidelines for ''split or shared visits'' for CY 2024. Specifically, the Editorial Panel changed the definition of a '' split or shared visit'' to refer to the substantive portion of a service as either more than half of the total time spent by the physician and NPP performing the split (or shared) visit or a substantive part of the medical decision making, and to indicate that these guidelines should be applied to determine whether the physician or NPP may bill for the service. For CY 2024, the CPT E/M Guidelines for billing split or shared services now state that ''*physician(s) and other QHP(s) may act as a team in providing care for the patient, working together during a single E/M service. The split or shared visits guidelines are applied to determine which professional may report the service. If the physician or other QHP performs a substantive portion of the encounter, the physician or other QHP may report the service. If code selection is based on total time on the date of the encounter, the service is reported by the professional who spent the majority of the face-to-face or non-face-to-face time performing the service. For the purpose of reporting E/M services within the context of team-based care, performance of a substantive part of the MDM requires that the physician(s) or other QHP(s) made or approved the management plan for the number and complexity of problems addressed at the encounter and takes responsibility for that plan with its inherent risk of complications and/or morbidity or mortality of patient management. By doing so, a physician or other QHP has performed two of the three elements used in the selection of the code level based on MDM. If the amount and/or complexity of data to be reviewed and analyzed is used by the physician or other QHP to determine the reported code level, assessing an independent historian's narrative and the ordering or review of tests or documents do not have to be personally performed by the physician or other QHP, because the relevant items would be considered in formulating the management plan. Independent interpretation of tests and discussion of management plan or test interpretation must be personally performed by the physician or other QHP if these are used to determine the reported code level by the physician or other QHP*'' (2024 CPT Codebook, pg. 6). We remind our readers that for CY 2023, the CPT E/M Guidelines define a shared or split visit as a visit in which a physician and other qualified health care professional(s) (QHP) both provide the face-to-face and non-face-to-face work related to the visit. In past discussions in rulemaking on this issue, we stated that MDM was not easily attributed to a single physician or NPP when the work is shared because MDM is not necessarily quantifiable and could vary depending on patient characteristics (for example, risk), in contrast to time, which we believe is a more precise factor than MDM to use as a basis for deciding which practitioner performs the ''substantive portion of the visit.'' However, given these recent changes in the CPT Guidelines for split (or shared) visits and our interest in reducing coding and billing administrative burden on health professionals through continued alignment with revised overarching guidelines for E/M visits, we are reconsidering our policy for defining 'substantive portion' as it applies to split or shared visits.

After reviewing the revisions made by the AMA CPT Editorial Panel that were included in the 2024 CPT codebook

publication, specifically the Evaluation and Management (E/M) Services Guidelines language surrounding ''substantive portion'' for split (or shared) services, and in light of public comments on our policies, we agree that we should align our definition of substantive portion with the CPT E/M guidelines for this service. Although we continue to believe there can be instances where MDM is not easily attributed to a single physician or NPP when the work is shared, we expect that whoever performs the MDM and subsequently bills the visit would appropriately document the MDM in the medical record to support billing of the visit. Generally, commenters were in support of CMS delaying for an additional year the requirement to use total time to determine which practitioner performs the substantive portion of the service. However, we also heard concerns about CMS implementing this definition of substantive portion at all, with many requests that we also recognize MDM as the substantive portion of the visit. In consideration of the changes made by the CPT Editorial Panel, we are revising our definition of ''substantive portion'' of a split (or shared) visit to reflect the revisions to the CPT E/M guidelines. Specifically, for CY 2024, for purposes of Medicare billing for split (or shared) services, the definition of ''substantive portion'' means more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the medical decision making as defined by CPT. We continue to note that for critical care visits which do not use MDM, ''substantive portion'' continues to mean more than half of the total time spent by the physician and NPP performing the split (or shared) visit (42 CFR 415.140). In summary, we are finalizing a policy that reflects a revised definition of ''substantive portion'' of a split (or shared) visit to reflect the revisions to the CPT E/M guidelines, such that for Medicare billing purposes, the ''substantive portion'' means more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the medical decision making except concerning critical care visits which do not use MDM and only use time, ''substantive portion'' continues to mean more than half of the total time spent by the physician and NPP performing the split (or shared) visit. We will revise our regulations at 42 CFR 415.140 to reflect this change for split (or shared) visits. We note that we are finalizing this policy for CY 2024, in part, to avoid the administrative burden, as described by commenters, that would otherwise be present for facilities and practices that spend time and resources preparing for potential policy changes that are delayed year after year. If warranted, we would address any subsequent change in policy through notice and comment rulemaking.

G. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires CMS to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs for the purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2024. Congress recently extended the 1.0 work GPCI floor only through December 31, 2023, in division CC, section 101 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020). Therefore, the CY 2024 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. See Addenda D and E to this final rule for the CY 2024 GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2024 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. Review of the California Fee Schedule Areas Used for Payment for CY 2024

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, April 1, 2014) added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-State fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the previous locality structure to 27 under the MSA-based locality structure; although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-State locality, and locality 3, which was comprised of Marin, Napa, and Solano counties. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-State locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would

have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We noted that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, in the CY 2017 PFS final rule (81 FR 80266), we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

a. Refinement to Number of Unique Fee Schedule Areas in California for CY 2024

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. This refinement would ultimately change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. In the CY 2023 PFS proposed rule (87 FR 46008), we proposed to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to three, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. Based on support from commenters in the CY 2023 PFS final rule (87 FR 69621), we finalized to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. We noted that, while we believed these changes were appropriate to consolidate fee schedules areas that are no longer operationally necessary, we were unable to operationalize these changes for CY 2023 due to timing constraints relating to the actions and coordination with the various systems maintainers required to effectuate changes to claims processing (87 FR 69621). Therefore, for CY 2023, there were no changes to the existing locality numbers 05, 06, 08, 18, or 26. We noted in the CY 2023 PFS final rule that we would operationalize these finalized changes for CY 2024. We reiterate here that we are operationalizing these locality number changes for CY 2024 via instruction to the MACs, and therefore, locality numbers 06, 07, and 26 will no longer be used for the PFS starting January 1, 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS because these counties are not transition areas and will receive the same GPCI values, for PFS payment purposes, going forward.

The following is a summary of the public comments received on the CY 2024 GPCIs and our responses:

Comment: We received several comments that were outside the scope of the proposed rule, and some are reiterations from last year's GPCI update.

Response: We appreciate the feedback from commenters. We note that we responded to these comments in the CY 2023 PFS final rule (87 FR 69630 through 69634) and will not be summarizing or responding to them in this final rule. Also, it is important to note that although the comments did not relate to any proposals for CY 2024, we will take them into consideration for potential future rulemaking.

Comment: One commenter encouraged CMS to consider the potential effects of the COVID–19 pandemic on the malpractice GPCIs. The commenter asked that CMS withdraw the MP component update from the CY 2023 PFS final rule and reinstate the prior MP component in the CY 2024 PFS final rule.

Response: We appreciate the feedback from the commenter. We did not make any proposals associated with the MP

GPCI or MP RVUs, but will take these comments into consideration for potential future rulemaking. We encourage commenters to submit comments on the next proposed MP GPCI and MP RVU update which is anticipated for CY 2026.

Comment: Some commenters highlighted the expiration of the work GPCI floor of 1.0 on December 31, 2023, and expressed concern with the CY 2024 work GPCIs that are calculated without the work GPCI floor in place. Commenters asked that CMS consider a two- or three-year phase in of the work GPCI floor expiration and recalculate the CY 2024 work GPCIs based on a transition period if the statutory floor is allowed to expire. Some commenters asked that CMS implement a permanent policy to set a work GPCI floor so statutory extensions would no longer be necessary. Some of the commenters stated an objection to any changes that could have a negative impact on rural areas, such as the expiration of the work GPCI floor.

Response: We appreciate the commenters' feedback. The 1.0 work GPCI floor is required by statute and set to expire on December 31, 2023. We do not have the authority to extend the 1.0 work GPCI floor beyond December 31, 2023, or to establish a permanent policy to establish the 1.0 work GPCI floor. We note that 34 States have statewide payment localities, which means that the same geographic adjustment applies to PFS payments throughout the State without any differential between rural and urban areas.

Comment: One commenter stated that there is a lack of transparency into the GPCI data and methodology used to derive the GPCIs. The commenter stated that they cannot accurately validate CMS' GPCI calculations because there is little transparency and access to the data and methods used. The commenter stated that CMS provided these data prior to 2020 and that they used it to reproduce and validate the CMS methodology for calculating the GPCIs each year.

Response: We direct the commenter to the step-by-step instructions provided in the final report entitled, ''Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS,'' which is available on our website located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* We also refer readers to Table 4.A.1: Summary of Elements Required for GPCI Calculation in the final report, and the discussion in the CY 2023 PFS final rule (87 FR 69621) for the data sources used for the work GPCI and each component of the practice expense GPCIs noted in the CY 2023 PFS final rule, we discussed the years and timeframes of data used from each source and provided web links to the publicly-available data sources used in the CY 2023 GPCI update. Consistent with the information provided for previous GPCI updates, we also provided the methodological parameters, as well as an overview of how we develop each GPCI component in the final report. We also note that there is detailed information about the budget neutrality adjustment and statutory floors that are applied after the budget neutrality adjustment in the note, ''CY 2023 GPCI Update Note_County_Data,'' on our website, also located under the supporting documents section for the CY 2023 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

We remind the commenter that, in response to commenters' concerns expressed in rulemaking for the CY 2020 GPCI update, we added more detailed descriptions of the steps in the final report entitled, ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Phys Fee Sched_v19Feb2020,'' which is available on the CMS website under the downloads section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-forService-Payment/PhysicianFeeSched/index.html*, to assist interested parties in navigating these data. Additionally, as part of our ongoing commitment to transparency, we post the county-level data that we use to develop the proposed GPCIs, which allows interested parties to further examine and replicate our GPCI methodology. This file is available on the CMS website on our website under the Downloads section, titled ''CY 2023 Proposed Rule GPCI County-Level Data File.''

We did not receive any comments about the announcement in the CY 2024 PFS proposed rule of our planned operationalization of the changes to the California localities that we finalized in the CY 2023 PFS final rule beginning for CY 2024. Therefore, we are proceeding with implementation as planned for CY 2024. We note that these changes to California localities, when operationalized, do not have any payment implications under the PFS. The final CY 2024 GPCIs and summarized GAFs in Addenda D and E to this final rule reflect the California locality changes, and locality numbers 06, 07, and 26 are not present in these Addenda for CY 2024.

H. Payment for Skin Substitutes

1. Background

In the CY 2023 PFS proposed rule, CMS outlined several objectives related to refining skin substitute policies under Medicare, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, to incorporate more consistent payment methodologies; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology. Generally, we determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. For a detailed explanation of the direct PE methodology, including examples, we referred readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

Similar to the way we assess costs for other incident to supplies, our approach to identifying appropriate PE direct costs for skin substitute products may include: reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or reviewing cost information on Medicare claims. Further, we would assess how the incident to supplies are billed or represented while also considering the service with which it is typically furnished. For example, if the supply is billed separately, with the base service, or usually bundled and incident to the base service. Also, we would consider whether there are different supply costs or other meaningful stratifications (for example, a unit of measure or product type) that should be accounted for as we develop direct PE costs, considering how the base service is furnished.

We solicited comments on these approaches under our PFS ratesetting

methodology as potential methods to establish appropriate payment for skin substitute products under the PFS.

We received public comments on these potential approaches. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters were in support of our efforts to achieve a consistent payment approach for skin substitute products across different settings of care. Additionally, many commenters stated that they appreciated the opportunity to further engage with CMS on skin substitute policies through the CMS Skin Substitutes Town Hall in January of 2023.

Response: We thank commenters for their support and for their participation in the CMS Skin Substitutes Town Hall, which was held virtually on January 18, 2023. More information regarding the CMS Skin Substitutes Town Hall such as links to recording and transcripts is available at *https://www.cms.gov/medicare/payment/fee-schedules/physician/skin-substitutes#:~:text=The%20CMS%20Skin%20Substitutes%20Town,Physician%20Fee%20Schedule%20(PFS).*

Comment: Many commenters opposed the idea of packaging and paying for skin substitutes as supplies and recommended that CMS retain separate coding and payment for these products. The commenters did not view skin substitutes as supplies because the products are affixed to a wound, and their function is similar to a drug or biologic.

Response: CMS recognizes there are numerous factors to consider when establishing a consistent payment approach for all skin substitute products. Additionally, CMS will take into consideration concerns raised by interested parties to help inform how we might best achieve an appropriate payment approach for future rulemaking.

Comment: Many commenters opposed to treating skin substitute products as supplies recommended that CMS instead assign HCPCS Q codes to all skin substitute products and pay for all skin substitute products using the ASP+6% payment methodology. Some commenters expressed their support for separate payment under the ASP +6% payment methodology by citing an OIG report (OEI–BL–23–00010) that highlighted significant cost savings for Part B payment amounts if ASP data were to be reported by all skin substitute manufacturers. More information regarding this OIG report is available at *https://oig.hhs.gov/oei/reports/OEI-BL-23-00010.asp.*

Response: We appreciate the feedback from commenters. We maintain our commitment to establishing a consistent payment approach for all skin substitute products.

Comment: A few commenters noted that most skin substitute products in the physician office setting meet the statutory definition of a biological product and question whether this move is legal under the mandatory payment laws for drugs and biologicals. Another commenter noted that CMS must support the reversal of prior policy under the Administrative Procedure Act.

Response: The CY 2024 PFS proposed rule includes no proposals for skin substitute polices. Instead, CMS solicited comments from interested parties to help us consider an approach to pricing these products as supplies.

Comment: Some commenters noted that CMS did not provide enough information on these different pricing approaches in order to meaningfully comment.

Response: We remind commenters that, in response to concerns expressed by commenters in CY 2023 PFS rulemaking, we included more information in the CY 2024 PFS proposed rule on how CMS could incorporate skin substitutes as a supply under the PFS and solicited comments on the different approaches we could consider. Additionally, we refrained from making any proposal for CY 2024 to allow more opportunities for us to receive and consider feedback from interested parties, including through the Skin Substitutes Town Hall and the CY 2024 PFS proposed rule.

Comment: A few commenters noted that as CMS reviews skin substitute policies, the terminology should not be changed to ''wound care management products'' and that skin substitutes is the appropriate term. Additionally, one commenter suggested creating a new taxonomy code for wound care specialists to acknowledge the providers delivering this specific type of enhanced care. Lastly, one commenter recommended that CMS require the physician applying the product to the wound cover the entire wound surface area in order to receive payment for the application procedure.

Response: We appreciate the commenters' feedback.

2. Sources of Price Information

We have refined specific PE data inputs in recent years, using market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Historically, the PFS uses a variety of sources to help inform payment for specific services that are then used to establish direct PE inputs. Direct PE inputs may derive from assessing the current value of products on the market, which may be achieved by utilizing Average Sales Price (ASP) data or Wholesale Acquisition Cost data (WAC). Since some manufacturers self-report ASP/WAC data at the end of every quarter, this may help to inform CMS of the current market value of these products.

We also review submitted invoices, which reflect the specific cost of products that practitioners are paying manufacturers for these products. We noted in the CY 2011 PFS final rule (75 FR 73205) that we update supply and equipment prices through an invoice submission process. In this process, we consider the invoice information and incorporate it into our direct costs database if the submitted pricing data indicates the typical market price of the supply or equipment item.

While performing market research and the invoice submission process are different methods to derive pricing for specific products, reviewing cost information on Medicare claims may also help us identify the variability in product costs. For example, assessing detailed cost information on claims with skin substitute products could inform how these products are priced and allow us to consider how the skin substitutes are typically furnished and where these services are performed. This information would enable us to refine our payment policies for these products across different care settings.

We solicited comment on the cost-gathering approaches we described in order to inform how we would establish direct PE inputs for skin substitute products and appropriately develop payment rates for physicians' services that involve furnishing skin substitute products. The following is a summary of the comments we received and our responses.

Comment: A few commenters noted that if CMS were to consider skin substitute products as direct PE inputs, then ASP data would be the best estimate of cost.

Response: We appreciate this feedback from commenters.

Comment: Some commenters mentioned that to capture supplies in the PE RVU methodology, CMS must consider the following: the single use supply item, unit of measurement, per unit price, and the quantity of the

specified item. These commenters also believe the PE methodology relies on evaluation of a 'typical service' for a single-use supply item, but because skin substitute products may change based on patient-specific factors and can vary by application code, commenters state that no single skin substitute product stands out as ''typical.'' Additionally, one commenter noted that claims data show variations in the number of product units reported per claim and the per unit payments for products.

Response: We thank these commenters for their feedback and will take this information into consideration.

3. Approaches to Billing

We acknowledged that there are various approaches that we could use to identify and establish direct cost inputs for the skin substitute products. We are also considering how to account for these products' variability and resource costs, especially as new products increasingly become available.

Similar to the way different sources of information can influence cost information for supplies, specifically considering variables such as different units of measurement, product type, product composition, or in what clinical circumstances the product is used, for example, would help us appropriately reflect costs in payment for the services that include the specific supply. We believe this to be pertinent to any proposal to pay for skin substitute products. For instance, grouping the direct costs for particular skin substitute products based on the typically associated application procedure could help us systematically incorporate the resource costs involved for different product billing scenarios. This approach can be seen in the Outpatient Prospective Payment System (OPPS), where a high-cost/low-cost system is used for skin substitute products billed with a specific procedure code based on their cost grouping.

Alternatively, when services and products are not performed frequently enough to be grouped, retaining separate procedure coding can help inform specificity and granularity for coding and payment of these services. Specifically, we could create separate procedure coding for specific product types, which could be billed with the appropriate skin substitute application services. We would account for cost variability for the different products (that is, establishing individual or group direct cost profiles and allocating direct cost inputs based on these groupings) under any combination of approaches discussed above. We could also review the unit of measurement for billed products, as available in our internal data or received in submissions, and create direct cost groupings for the products based on the reviewed/billed units of measurement. We could also establish direct cost inputs by employing our standard 'crosswalk' method using information from interested parties. Specifically, we would derive PE inputs by reviewing similarly resourced services to establish RVUs for a service that includes the cost of the skin substitute products and other information to account for the physician's work in furnishing the skin substitute product. We would employ this method to establish payment for individual services that include specific skin substitute products or services that describe cost groupings of similarly priced skin substitute products. As we have discussed in prior rulemaking, we believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. There is a long history of using crosswalk codes for this kind of valuation under the PFS, which is generally established through notice and comment rulemaking.

We solicited comment on how these methods may help reflect the resource costs involved with skin substitute products as furnished with different skin application procedures. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters were concerned with the idea of incorporating skin substitute products into the PE as they believe this would exert pressure on all other PE RVUs, resulting in cuts to other areas of physician reimbursement due to budget neutrality. Commenters raised this concern to highlight that packaging skin substitute products in an office setting could lead to decreased patient access. One commenter suggested that if CMS were to incorporate skin substitute products in direct PE, we should ensure that it does not result in budget neutrality reductions.

Response: As stated in the CY 2024 PFS proposed rule, our goal is to achieve a consistent payment approach for skin substitute products that does not negatively impact beneficiary access. We recognize the budget neutrality concerns from interested parties and note that commenters raised similar concerns in the CY 2022 PFS final rule when we finalized the implementation of the clinical labor pricing update. In response, we noted that the PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs. We also noted that for many services that involve proportionally more clinical labor, payment rates were reduced as a result of the prior market-based supply and equipment pricing update, and payment rates will increase with the clinical labor pricing update, due to the same PFS budget neutrality requirements (86 FR 65025 through 65027). Therefore, any changes to the RVU does not necessarily result in negative consequences for other areas of physician reimbursement.

Comment: A few comments suggested that CMS should include additional Part B funding to account for the change in methodology, as well as work with the AMA CPT Editorial Panel/RVS Update Committee to address potential changes. A few commenters also recommended that CMS mirror the existing OPPS reimbursement methodology for skin substitutes, where payment is based on a high cost/lost cost model.

Response: We thank these commenters for their suggestions.

Comment: Some commenters offered alternative suggestions such as to pay for high-cost disposable supplies priced at more than $500 using appropriate HCPCS codes, where pricing of these supplies is based on a transparent process that is annually reviewed and updated. Additionally, one commenter recommended that CMS replace application HCPCS codes 15271–15278 with newer, temporary codes to describe the more complex wound procedures and offer revisions to the sizing increments, for example: G5271–G5XXX Application of cellular and/or tissue-based product graft to trunk, arms, legs; G5275–G 5XXX Application of cellular and/or tissue-based product graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits.

Response: We thank these commenters for these suggestions.

Comment: Some commenters also stated that in order for interested parties to meaningfully comment on the different pricing methodologies for skin substitute products, CMS should: (1) explain specific direct inputs CMS proposes to incorporate into each HCPCS code that may include a skin substitute as a supply (HCPCS 15271–15278 or replacement codes if established); (2) provide information on estimates of proposed rates; (3) describe the valuation of the application procedure code and any redistribution effects on other PFS services with PE RVUs; and (4) provide the impact that the proposal will have on vulnerable populations.

Response: We did not propose any policies for skin substitutes in the CY

2024 PFS proposed rule, so did not include specific proposed direct resource inputs or pricing information, or any impact analysis.

We will consider the suggestions and concerns raised by commenters to help inform future rulemaking. We will also continue our dialogue with interested parties,with our continued goal to achieve a consistent payment approach for skin substitute products across different sites of service.

I. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services

1. Supervision of Outpatient Therapy Services in Private Practices

(a) Remote Therapeutic Monitoring for Physical Therapists and Occupational Therapists in Private Practice

In the CY 2023 PFS final rule, we finalized new policies allowing Medicare payment for remote therapeutic monitoring (RTM) services, including allowing RTM services to be furnished under general supervision (87 FR 69649). RTM refers to the use of a device to monitor a patient's health or response to treatment using non-physiological data (please see a more detailed list of RTM services at section II.D. of this proposed rule). The current regulations, however, at §§ 410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, respectively, in private practice. These regulations make it difficult for physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) to bill for the RTM services performed by the physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) they are supervising since the PTPP or OTPP must remain immediately available when providing direct supervision of PTAs and OTAs (even though we noted in the CY 2022 PFS final rule that PTPPs and OTPPs were intended to be among the primary billers of RTM services (86 FR 65116)). We designated the RTM codes as ''sometimes therapy'' codes (originally in the CY 2022 PFS final rule (86 FR 65116)), meaning that these services may be furnished outside a therapy plan of care when they are performed by physicians and certain NPPs where their State practice includes the provision of physical therapy, occupational therapy, and/or speech-language pathology services. Because we did not propose revisions to §§ 410.59 and 410.60 last year for OTPPs and PTPPs, we proposed to establish an RTM-specific general supervision policy at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow OTPPs and PTPPs to provide general supervision only for RTM services furnished by their OTAs and PTAs, respectively.

We also noted that Medicare requires each therapist in private practice to meet the requirements specified in our current regulations at §§ 410.59(c) and 410.60(c) to qualify under Medicare as a supplier of outpatient occupational therapy or physical therapy services. Given that occupational therapists (OTs) and physical therapists (PTs) who are not enrolled and working as employees of OTPPs or PTPPs do not meet these requirements, we believe they should continue to function under direct supervision of the OTPP or PTPP. This is consistent with the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 230.4.B, which states that in private practice, OTPPs and PTPPs must provide direct supervision of all services, including those furnished by OTs and PTs who are not yet enrolled in Medicare (even if they meet the other requirements for occupational therapists and physical therapists at 42 CFR part 484). As such, we proposed to retain the OTPP and PTPP direct supervision requirement for unenrolled PTs or OTs by clarifying that the RTM general supervision regulation at §§ 410.59(c)(2) and 410.60(c)(2) applies only to the OTA and PTA and does not include the unenrolled OT or PT. We solicited comment on this specific proposal as we want to know more about how this policy is now functioning with OTs and PTs who are not enrolled and our proposal to maintain this longstanding policy for direct supervision.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to allow PTs and OTs in private practice to provide general supervision for RTM services. Many commenters urged us to finalize our proposal.

Response: We appreciate the support for our proposed policy from the commenters.

Comment: Some commenters reported that the current direct supervision requirement makes it challenging to use PTAs or OTAs to deliver RTM services and stated that allowing general supervision of PTAs and OTAs in private practice settings provides a safe way for patients to receive RTM services.

Response: We appreciate the support for our proposed policy from the commenters.

Comment: Some commenters noted that our proposal aligns with the general supervision policy we finalized beginning in CY 2023 for RTM services furnished by physicians and other practitioners, while a few commenters noted that we did not propose to allow general supervision of PTAs and OTAs last year.

Response: We thank the commenters for their views and clarify that instead of the four proposed G-codes, two of which would encompass PTs, OTs, and SLPs in private practice, we finalized an alternate RTM general supervision policy to begin January 1, 2023. As such, we had not proposed a regulatory change for PTAs and OTAs employed in private practices of PTs and OTs.

Comment: One commenter supported our proposal to retain the OTPP and PTPP direct supervision requirement for unenrolled PTs or OTs. We did not receive any responses to our comment solicitation about how this policy now functions with OTs and PTs who are not enrolled.

Response: We appreciate the support for our proposed policy from the commenter.

After consideration of public comments, we are finalizing our proposal for RTM services to allow general supervision of OTAs and PTAs by OTs and PTs in private practice; and finalizing the proposal to continue the requirement for direct supervision of unenrolled PTs and OTs, including for RTM services. We are also finalizing the amendments to the corresponding regulation text at §§ 410.59 and 410.60 as proposed.

We believe this proposal will increase access to these remotely provided services performed by PTAs and OTAs under the general supervision furnished by PTPPs and OTPPs, and aligns the regulatory text at §§ 410.59 and 410.60 with the general supervision policy that we finalized for RTM services in the CY 2023 PFS final rule.

(b) General Supervision for PTs and OTs in Private Practice Comment Solicitation

Sections 1861(p) and 1861(g) (by cross-reference to section 1861(p)) of the Act describe outpatient physical therapy and occupational therapy services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary, including conditions relating to the health and safety of

individuals who are furnished services on an outpatient basis. The second sentence of section 1861(p) of the Act describes outpatient therapy services that are provided to an individual by a physical therapist or occupational therapist (in their office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations and differentiates the therapists that furnish these outpatient therapy services from those working for an institutional provider of therapy services. In regulations, we have specifically addressed these therapists, previously referred to as PTPPs and OTPPs, since 1999 (63 FR 58868 through 58870). Because we wanted to create consistent requirements for therapists and therapy assistants, we clarified in the CY 2005 PFS final rule with comment period (69 FR 66236, 66351 through 66354) that the personnel qualifications applicable to home health agencies (HHAs) in 42 CFR part 484 are applicable to all outpatient physical therapy, occupational therapy, and speech-language pathology services. Also, in the CY 2005 PFS final rule, we cross-referenced the qualifications for OTs and their OTAs and PTs and their PTAs for all occupational therapy and physical therapy services, respectively, including those who work in private practices, to 42 CFR part 484 by adding a basic rule at §§ 410.59(a) and 410.60(a), respectively. Under Medicare Part B, outpatient therapy services are generally covered when reasonable and necessary and when provided by PTs and OTs meeting the qualifications set forth at 42 CFR part 484. Services provided by qualified therapy assistants, including PTAs and OTAs, may also be covered by Medicare when furnished under the specified level of therapist supervision that is required for the setting in which the services are provided (institutions, and private practice therapist offices and patient homes).

In accordance with various regulations, the minimum level of supervision for services performed by PTAs and OTAs by PTs and OTs working in institutional settings is a general level of supervision (see Table A in the Report to Congress titled Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services at *https://www.cms.gov/Medicare/Billing/TherapyServices/Downloads/61004ptartc.pdf*). For example, 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an on-site supervisory visit at least once every 30 days. We noted that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 8, section 30.2.1 defines skilled nursing and/or skilled rehabilitation services as those services, furnished pursuant to physician orders, that, among other requirements, ''must be provided directly by or under the general supervision of these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.'' The same manual provision notes that in the SNF setting, skilled nursing or skilled rehabilitation personnel include PTs, OTs, and SLPs. However, since 2005 in the private practice setting, we have required direct supervision for physical and occupational therapy services furnished by PTAs and OTAs, requiring an OTPP or PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure(s). We finalized this direct supervision policy in the CY 2005 PFS final rule (69 FR 66354 through 66356)—changing it from personal supervision, which required the OTPP or PTPP to be in the same room as the therapy assistant when they were providing the therapy services. Under the current regulations §§ 410.59(c)(2) and 410.60(c)(2), all services not performed personally by the OTPP or PTPP, respectively, must be performed under the direct supervision of the therapist by employees of the practice. Subsequently, in the CY 2008 PFS final rule (72 FR 66328 through 66332), we updated the qualification standards at 42 CFR part 484 for OTs, OTAs, PTs, PTAs, along with those for speech-language pathologists (SLPs).

Over the last several years, interested parties have requested that we revise our direct supervision policy for PTPPs and OTPPs to align with the general supervision policy for physical and occupational therapists working in Medicare institutional providers that provide therapy services (for example, outpatient hospitals, rehabilitation agencies, SNFs and CORFs), to allow for the general supervision of their therapy assistants. Additionally, the interested parties have informed us that all-but-one State allows for general supervision of OTAs and at least 44 States allow for the general supervision of PTAs, via their respective State laws and policies.

We were considering whether to revise the current direct supervision policy for PTPPs and OTPPs of their PTAs and OTAs, to general supervision for all physical therapy and occupational therapy services furnished in these private practices, and solicited comments from the public that we may consider for possible future rulemaking. We were particularly interested in receiving comments regarding the possibility of changing the PTA and OTA supervision policy from direct supervision to general supervision in the private practice setting, and whether a general supervision policy could have implications for situations or conditions raised below:

- Because we want to ensure quality of care for therapy patients, could the general supervision policy raise safety concerns for therapy patients if the PT or OT is not immediately available to assist if needed? Do State laws and policies allow a PTA or OTA to practice without a therapist in a therapy office or in a patient's home?
- Could any safety concerns be addressed by limiting the types of services permitted under a general supervision policy?
- Would a general supervision policy be enhanced with a periodic visit by the PT or OT to provide services to the patient? If so, what number of visits or time period should we consider?
- Would a general supervision policy potentially cause a change in utilization? Would such a change in the supervision policy cause a difference in hiring actions by the PT or OT with respect to therapy assistants?

Interested parties have been requesting that CMS reconsider its supervision policies for occupational therapy or physical therapy services, and in light of experiences during the PHE for COVID–19, we may consider proposing a general supervision policy for all services furnished by OTAs and PTAs employed by a PTPP or OTPP in the future after reviewing the comments and supporting data in response to this comment solicitation. Therefore, we solicited public comment, along with supporting data, about the questions and concerns we highlighted above, for our consideration for possible future rulemaking. We were further interested in public comment regarding changing §§ 410.59(a)(3)(ii), 410.59(c)(2), 410.60(a)(3)(ii), and 410.60(c)(2) to allow for general supervision of OTAs and PTAs by the OTPP and PTPP, respectively, when furnishing therapy services. Additionally, we solicited public comment for our consideration for possible future rulemaking regarding any appropriate exceptions to allowing general supervision in the furnishing of therapy services.

We received public comments on this comment solicitation. The following is a summary of the comments we received.

Comment: Many commenters stated they supported general supervision of PTAs and OTAs in the private practice setting, as it would align with the supervision requirement of all other Medicare therapy settings and nearly all state practice acts for physical and occupational therapy. Other commenters stated that making the supervision requirement consistent across outpatient settings will reduce administrative burden and confusion and ease compliance for therapy services providers who work and manage staff in more than one type of setting.

Collectively, many commenters suggested that changing the Medicare minimum required supervision level in private practice from direct to general, for example, would: (a) increase access to therapy services for more patients, especially those in rural and underserved communities; (b) allow therapists and therapy assistants to work different or overlapping schedules to accommodate patient availability; (c) optimize resource allocation with more flexibility in scheduling time off for PTs/OTs when PTAs/OTAs are scheduled to work with Medicare patients; (d) remove the additional labor costs of onsite therapist staff during delivery of services by therapy assistants, and (e) eliminate the possibility of disruptions in patient care when the supervising therapist steps out of the practice office, even for a short period of time, as the therapy assistant must stop working, the commenter states that these disruptions can result in patient setbacks, delayed visits, and greater costs to Medicare.

Many commenters responded to our question as to whether a change to general supervision would raise safety concerns for therapy patients. Collectively, commenters did not believe there would be safety concerns with the change to general supervision; and many commenters also pointed out that they are unaware of safety concerns arising in the other Medicare settings where general supervision policies have been in place for many years, even though acuity levels were suggested by several commenters to be higher in SNFs and HHAs. Several other commenters stated that they were not aware of any *safety concerns* during the time PTAs/OTAs were treating patients while the PT/OT was off-site utilizing the direct virtual supervision flexibility through real-time audio and video technology during the COVID–19 PHE. One commenter also stated that they believe the existing structure of guidance from the House of Delegates of the American Physical Therapy Association, Medicare, and State law authorities on the PT–PTA relationship is sufficient to ensure patient safety under a general supervision policy.

Several commenters reported that State licensure practice acts include supervision policies for all settings, including when PTAs and OTAs treat patients in therapy offices or in patients' homes. Two commenters referred us to the Federation of State Boards of Physical Therapy for a comprehensive list of State supervision laws but listed out some of the latest trends in states' supervision requirements, including, for example—44 States require general supervision in all settings, New York and the District of Columbia are the only jurisdictions that require on-site supervision of PTAs in all settings, and five States expressly require a PT to be on-site when a PTA provides in-home care. These commenters noted that States are responsibly regulating supervision levels and that where a State has considered off-site supervision or in-home care as appropriate, CMS should not require additional standards.

Two commenters stated that Medicare regulations already limit the types of services permitted to be performed by PTAs and OTAs, for all settings not just private practice, that is, they may not provide evaluation services, make clinical judgments or decisions, or take responsibility for the service. One commenter stated that many States have added additional restrictions for PTAs and believes that State licensure and scope of practice requirements for PTAs determine what services can be safely provided by PTAs to patients, in and off the premises of each health care setting.

Commenters also noted that Medicare already requires the PT and OT to ''actively'' treat the patient at least once every 10 treatment days, per the progress note requirement. In addition, one commenter stated that many States also mandate that PTs provide periodic reevaluations or on-site or in-room supervisory visits of PTAs more frequently than Medicare does. Since Medicare and State laws already require periodic visits by the PT, one commenter asserted that additional requirements by CMS are not necessary.

In responding to our question as to whether a general supervision policy would cause a change in utilization of therapy services, Commenters mentioned a report by Dobson DaVanzo that they, along with several other rehabilitation organizations, commissioned to evaluate the financial impact of various provisions included in the Stabilizing Medicare Access to Rehabilitation and Therapy (SMART) Act, (H.R. 5536) in the 117 Congress.[41] As one issue, the report sought to predict whether the change to general supervision in the private practice setting would increase therapy utilization generally and whether a change in utilization of PTAs/OTAs versus PTs/OTs will occur, as part of the legislation. Using the report's data, the commenters stated that by making the supervision policy change—which they indicate replaces utilization of therapists with therapy assistants—Medicare could save up to $271.3 million (in 2021 dollars) over a 10-year period from 2022 to 2031. They stated this savings is due to the payment differential, the 15 percent reduction of the PFS amount—for services furnished in whole or in part by PTAs and OTAs that went into effect in CY 2022 per section 1834(v) of the Act.

Response: CMS will take these comments into consideration for possible future rulemaking.

After consideration of public comments in response to our comment solicitation for general supervision of PTAS and OTAs by PTs and OTs in private practice, we will take these comments into consideration for possible future rulemaking.

Additionally, we received public comments on issues that are considered out-of-scope of the proposals in this rule. As a result, CMS did not summarize or respond to those comments.

2. KX Modifier Thresholds

Formerly referred to as the therapy cap amounts, the KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018). These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). In the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2024, we proposed to increase the CY 2023 KX

[41] Dobson DaVanzo & Associates LLC. Impact on Medicare Spending of the Stabilizing Medicare Access to Rehabilitation and Therapy Act Assumptions and Methodology Final Technical Report Data, 2022.

modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022.[42] Multiplying the CY 2023 KX modifier threshold amount of $2,230 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent ($2,230 × 1.045), and rounding to the nearest $10.00 results in a proposed CY 2024 KX modifier threshold amount of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the CY 2024 2017-based MEI percentage increase), we would use such data, if appropriate, to determine the final CY 2024 MEI percentage increase and would apply that more recent MEI percentage increase to formulate the CY 2024 KX modifier threshold amounts in the CY 2024 PFS final rule. We received a more recent estimate of the CY 2024 2017-based MEI percentage increase of 4.6 percent which is greater than the MEI of 4.5 percent used for determining the proposed $2,330 each for the CY 2024 KX modifier threshold amounts; however, the MEI of 4.6 percent was not enough to formulate a change to the proposed KX modifier threshold amounts for CY 2024. Therefore, we are finalizing the CY 2024 KX modifier threshold amounts of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services as proposed. Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels would be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2024, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

(1) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(2) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(3) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(4) The services are furnished to treat a type of medical condition.

(5) The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceeds one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Through the use of the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied. (See the CY 2023 PFS final rule at 87 FR 69650 through 69651))

Comment: One commenter supported the change in the KX modifier threshold amounts for CY 2024, and thanked us for the confirmation.

Response: We appreciate the supportive remarks from the commenter.

Using the updated MEI of 4.6 in determining the CY 2024 KX modifier amounts, we are finalizing the CY 2024 KX modifier threshold amounts as proposed: $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services.

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals

During the CY 2022 PFS rulemaking, we adopted a regulation at § 410.72(d) that requires the services that RDs and nutrition professionals furnish to beneficiaries to be directly performed by them. This is based on the MNT regulations at subpart G, §§ 410.130—410.134. When developing this policy, we were only referring to MNT services. These MNT services are distinct from the DSMT services that RDs or nutrition professionals may furnish when they are or represent an accredited DSMT entity.

We note that the RD or nutrition professional, when named in or a sponsor of an accredited DSMT entity, may act as the DSMT certified provider, which is defined at section 1861(qq) of the Act as a physician or other individual or entity to which Medicare makes payment for other services. RDs and nutrition professionals may qualify as DSMT certified providers within the meaning of the statute since they provide and bill for MNT services. This is reinforced in our sub-regulatory manual provisions (Pub. 100–02, Chapter 15, section 300.2), which specifies that DSMT certified providers may bill and be paid for the entire DSMT program and further clarifies that the RD or nutrition professional is eligible to bill on behalf of an entire DSMT program (or entity) on or after January 1, 2002, after obtaining a Medicare provider number. In addition, section 1861(qq) of the Act requires that DSMT certified providers meet quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board. DSMT entities are required to meet the National Standards for Diabetes Self-management Education Programs (NSDSMEP) set of quality standards at § 410.144(b). DSMT entities are also required to be recognized or accredited by CMS Accreditation Organizations (AOs). There are currently two national DSMT AOs—the American Diabetes

[42] IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the MEI and other CMS market baskets.

Association (ADA) or the Association of Diabetes Care & Education Specialists (ADCES) (Medicare Program Integrity Manual, Pub. 100–08, chapter 10, section 10.2.4.B). The ADA and ADCES also review and approve the credentials of DSMT program instructors.

Interested parties have alerted us that the wording of § 410.72(d) has caused confusion for DSMT entities/suppliers and Part B Medicare Administrative Contractors (MACs) about whether RD or nutrition professionals must personally provide DSMT services. To alleviate any confusion, we believe a clarification is needed to distinguish between when a RD or nutritional professional is personally providing MNT services, in accordance with the MNT regulations, and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity, for example, registered nurses (RNs), pharmacists, or RDs other than the sponsoring RD. Under the NSDSMEP quality standards, the RD, RN, or pharmacist is permitted to provide the educational DSMT services on a solo basis, that is without a multi-disciplinary team; however, only the RD or nutrition professional, when enrolled as a Medicare supplier, in these accredited DSMT entities is authorized by section 1861(qq)(2)(A) of the Act to bill Medicare on behalf of the entire DSMT entity as the DSMT certified provider.

Consequently, we proposed to amend the regulation at § 410.72(d) to clarify that a RD or nutrition professional must personally perform MNT services. Additionally, we proposed to clarify that a RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. We proposed to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated their support for the proposal to clarify and revise § 410.72(d) for the enrolled RD or nutrition professional, when acting as the DSMT certified provider, may bill for, or on behalf of, the entire DSMT entity, regardless of which professional personally delivers each aspect of the services. Some commenters also supported the proposed regulatory text. One of these commenters appreciated that the revised text would provide clarity when Registered Dietitian Nutritionists (RDNs) bill for DSMT services to make sure they are complying with regulatory guidelines. Although two commenters recommended that in addition to mentioning RNs and pharmacists as additional professionals for whom the RD may bill for in DSMT that we include paraprofessionals in the examples as a means of aligning our proposal with the accreditation requirements. The commenters reasoned that ADCES and ADA Accreditation requirements include the use the paraprofessionals to deliver elements of the DSMT under the supervision of the RD, noting that many of the trained professionals have lived experience with diabetes.

Response: We thank the commenters for their comments and suggestions. We purposely limited the professionals we named in the proposed clarification of our policy to DSMT team members that the National Standards quality standards recognizes to provide services independently, without the supervision of the RD, RN, or pharmacist. This way, by naming the RD, RN, and pharmacist, it would encompass the paraprofessionals or other individuals who are being supervised in accredited ADA or ADCES DSMT entities.

After consideration of public comments, we are finalizing our proposal to revise § 410.72(d) to clarify that RDs and nutrition professionals can bill as or on behalf of a DSMT entity regardless of which professional furnished the actual services, but that they must directly provide the MNT services they bill for.

4. DSMT Telehealth Issues

(a) Distant Site Practitioners

Since 2006, RDs and nutrition professionals have been recognized as distant site practitioners for purposes of Medicare telehealth services under section 1834(m)(4)(E) of the Act. Section 1834(m)(4)(E) of the Act specifies that the practitioners listed at section 1842(b)(18)(C) of the Act, which include RDs and nutrition professionals as of 2006, can serve as distant site practitioners for Medicare telehealth services. Our regulations and sub-regulatory policies for Medicare telehealth services do not address scenarios involving the furnishing of DSMT services via telehealth when the actual services are personally furnished by individuals who provide them, for example, RNs, pharmacists, or other multidisciplinary team members, who are not recognized as telehealth distant site practitioners under the statutory definition. In keeping with the NSDSMEP quality standards, an RD is often part of a DSMT entity, and when they are, they can be considered a ''certified provider'' when they are enrolled in Medicare and intend to bill for the DSMT services, in accordance with the statutory provision at section 1861(qq)(2)(A) of the Act, which defines certified providers as physicians, or other individuals or entities designated by the Secretary, that, in addition to providing DSMT services, provides other items or services for which Medicare payment may be made. As we noted previously in this section of the final rule, there may be other RDs among the group or team of professionals, along with RNs and/or pharmacists, that are performing DSMT services in addition to the sponsoring or billing RD or nutrition professional functioning as the certified provider. Additionally, our Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 300.2 clarifies that these certified providers, including RDs or nutrition professionals, may bill for services of the DSMT entity. Since we allow RDs and other DSMT certified providers to bill on behalf of the DSMT entity when other professionals personally furnish the service in face-to-face encounters, we believe that this should also be our policy when DSMT is furnished as a Medicare telehealth service. To increase access to DSMT telehealth services, we proposed to codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity. This revision to our regulation will preserve access to DSMT services via telehealth for Medicare beneficiaries in cases where the DSMT service is provided in accordance with the NSDSMEP quality standards. We note that DSMT services are on the Medicare Telehealth Services List, and are subject to the requirements and conditions of payment under section 1834(m) of the Act and § 410.78 of our regulations, including originating site

and geographic location requirements, when they are in effect. See section II.D. for a discussion of Medicare telehealth policies.

(b) Telehealth Injection Training for Insulin-Dependent Beneficiaries

Currently, our manual instruction for Payment for Diabetes Self-Management Training (DSMT) in the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6, requires 1 hour of the 10-hour DSMT benefit's initial training and 1 hour of the 2-hour follow-up annual training to be furnished in-person to allow for effective injection training when injection training is applicable for insulin-dependent beneficiaries. This policy was clarified for 2019 to specify that in-person training only applies to a beneficiary for whom the injection training was applicable via CMS Transmittal 4173, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4173CP.pdf*.

We believe that, with the expansion of the use of telehealth during the PHE for COVID–19, there have been significant changes in clinical standards, guidelines, and best practices regarding services furnished using interactive telecommunications technology, including for injection training for insulin-dependent patients. We do not want our policies to prevent injection training via telehealth when clinically appropriate. Consequently, we proposed to revise our policy at § 410.78(e) to allow the 1 hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth. If finalized, we anticipate revising the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6 to reflect that flexibility.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Nearly half of the commenters submitting comments regarding our proposal for distant site practitioners expressed concerns about our proposed regulatory text for § 410.78(b)(2)(x) and the term distant site practitioner, not including outpatient hospitals, that bill on a UB–04 claim form using their NPI rather than a personal provider NPI, and pharmacies that enroll as suppliers of DSMT services. The commenters requested we include the term ''approved entity'' in the regulatory text and change the term ''report'' to ''bill for.'' Most of these commenters supported modifying the regulatory text to read as follows: Any distant site practitioner or approved entity who/that can bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity. One commenter stated ADA and ADCES accreditation data indicates that more than 1,200—or approximately 56 percent—of all accredited DSMT programs, operate out of the outpatient hospital setting. Similarly, more than 200—or approximately 11 percent—of all accredited DSMT programs are located within pharmacies, making up two-thirds of all DSMT programs. Five commenters expressed their support for including services for DSMT and MNT services furnished remotely by staff in outpatient hospitals to patients in their homes under section 1834(m) of the Act for payment of telehealth services see the provision in the Telehealth section at II.D. titled Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology. Another commenter asked that CMS clearly restate that accredited and recognized DSMT programs are eligible to bill Medicare Part B directly for DSMT services and may furnish and bill for DSMT services provided via telehealth, regardless of the provider type (RNs, pharmacists, registered dietitians, etc.) furnishing the service.

Response: Given that the pharmacy and outpatient hospital are recognized as certified providers of DSMT services per section 1861(qq) of the Act, they are recognized to bill for DSMT services they provide in-person, regardless of which professional furnishes the services. For purposes of telehealth, though, the current statute is clear at section 1834(m)(4)(E) of the Act, that only physicians and nonphysician practitioners listed at section 1842(b)(18)(C) of the Act qualify as distant site practitioners, so that area of Medicare law that does not include hospitals or pharmacies. However, we agree that the term ''bill for'' is more appropriate than ''report'' and will modify our proposed regulation text to reflect this change. We also want to clarify that CMS did not state that ''accredited and recognized DSMT programs are eligible to bill Medicare Part B directly for DSMT services and may furnish and bill for DSMT services provided via telehealth, regardless of the provider type (RNs, pharmacists, registered dietitians, etc.) furnishing the service'' since DSMT programs must qualify as a certified provider in accordance with the statute before they can bill for DSMT services. However, to the extent that the DSMT program qualifies as a certified provider of DSMT services and is a distant site practitioner specified in section 1834(m)(4) of the Act, that distant site physician or practitioner may bill for DSMT services furnished via telehealth and may do so on behalf of others who personally furnish the services as part of the DSMT entity.

Comment: Regarding our proposal on insulin injection-training to eliminate the regulatory prohibition on providing the full hours of DSMT via telehealth when clinically appropriate, all commenters were supportive. Although, a few commenters expressed concern about the definition of distant site practitioner that does not include all the DSMT multidisciplinary-team members that furnish injection-training in addition to RDs, including RNs and pharmacists. These commenters urged CMS to amend the proposed regulation text so as not to preclude certain practitioners from providing this important service via telehealth.

Response: We thank the many commenters for their support. Please refer to the previous response regarding distant site practitioners for DSMT furnished as Medicare telehealth services.

After consideration of public comments, we are doing the following: (a) finalizing our proposal on insulin injection-training that will allow the full initial 10-hours, or annual 2 hours, of DSMT services for insulin-dependent diabetics, via telehealth, when clinically appropriate, and we will reflect this change in our Medicare Claims Processing Manual, chapter 12, section 190.3. 6—Payment for Diabetes Self-Management Training (DSMT) as a Telehealth Service through our change management system; and, (b) finalizing our proposed regulatory text with a modification that replaces the term ''report'' with ''bill for'' so that the new text for § 410.78(b)(2)(x) will provide that any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

J. Advancing Access to Behavioral Health Services

1. Implementation of Section 4121(a) of the Consolidated Appropriations Act, 2023

a. Statutory Amendments

Section 4121(a) of Division FF, Title IV, Subtitle C of the Consolidated

Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022), Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program, provides for Medicare coverage of and payment for the services of mental health care professionals who meet the qualifications for marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals.

Specifically, section 4121(a)(1) of the CAA, 2023 amended section 1861(s)(2) of the Act by adding a new benefit category under Medicare Part B in new subparagraph (II) to include marriage and family therapist services (as defined in an added section 1861(lll)(1) of the Act) and mental health counselor services (as defined in an added section 1861(lll)(3) of the Act).

Section 4121(a)(2) of the CAA, 2023 added a new subsection (lll) to section 1861 of the Act, which defines marriage and family therapist services, marriage and family therapist (MFT), mental health counselor services, and mental health counselor (MHC). Section 1861(lll)(1) of the Act defines ''marriage and family therapist services'' as services furnished by an MFT for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service. Section 1861(lll)(2) of the Act defines the term MFT to mean an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which such individual furnishes marriage and family therapist services;
- Is licensed or certified as a MFT by the State in which such individual furnishes such services;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and
- Meets such other requirements as specified by the Secretary.

Section 1861(lll)(3) of the Act defines ''mental health counselor services'' as services furnished by a mental health counselor (MHC) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service. Section 1861(lll)(4) of the Act defining MHC as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under State law of the State in which such individual furnishes MHC services;
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in mental health counseling; and
- Meets such other requirements as specified by the Secretary.

Section 4121(a)(3) of the CAA, 2023 amended section 1833(a)(1) of the Act to add a new subparagraph (FF), which provides that, with respect to MFT services and MHC services under section 1861(s)(2)(II) of the Act, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L).

Section 1888(e)(2)(A)(ii) of the Act, as amended by section 4121(a)(4) of the CAA, 2023, excludes MFT and MHC services from consolidated billing requirements under the skilled nursing facility (SNF) prospective payment system. For further discussion about this exclusion of MFT and MHC services from SNF consolidated billing, see discussion in the FY 2024 SNF Prospective Payment System (PPS) proposed rule (88 FR 21316).[43] Section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners whose services can only be paid by Medicare on an assignment-related basis. MFTs, MHCs, and other practitioners described in section 1842(b)(18)(C) of the Act may not bill (or collect any amount from) the beneficiary or another person for any services for which Medicare makes payment, except for deductible and coinsurance amounts applicable under Part B. More information on assignment of claims can be found in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 1, Section 30.3.1.

We also noted that section 1861(aa)(1)(B) of the Act was amended by section 4121(b)(1) of the CAA, 2023 to add services furnished by MFTs and MHCs to the definition of rural health clinic services. See section III.B. of this final rule for discussion related to MFT and MHC services furnished in RHCs and FQHCs.

Additionally, section 1861(dd)(2)(B)(i)(III) of the Act was amended by 4121(b)(2) of the CAA, 2023 to require a hospice program to have an interdisciplinary team that includes at least one social worker, MFT or MHC. For further discussion about this amended requirement for hospice program interdisciplinary teams, see section III.O. of this final rule.

b. Proposed Changes to Regulations

Consistent with the changes to the statute described above, we proposed to create two new regulation sections at § 410.53 and § 410.54 to codify the coverage provisions for MFTs and MHCs, respectively.

Specifically, we proposed to define a marriage and family therapist at § 410.53 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;
- After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and
- Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

We noted that we are aware that there may be some States that require a number of hours of clinical supervised experience for MFT licensure that may be inconsistent with the statutory requirement in section 1861(s)(2) of the Act that requires at least 2 years of clinical supervised experience. We believe it could be possible for an MFT to have completed the required number of clinical supervised hours required for licensure in their State, but to have accomplished this in less than two years. Therefore, we proposed a requirement for MFTs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We stated in the proposed rule that we

[43] *https://www.govinfo.gov/content/pkg/FR-2023-04-10/pdf/2023-07137.pdf.*

believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers (CSWs) at § 410.73(a)(3)(ii) allow 2 years or 3,000 hours of supervised experience. Additionally, the statutory benefit category for both MFTs and CSWs is defined as services for the diagnosis and treatment of mental illnesses. As such, we believe it would be appropriate to provide similar flexibility in the required amount of clinical supervised experience for MFTs and CSWs. We stated in the proposed rule that we were also interested in public comments regarding States that have a supervised clinical hour requirement for MFT licensure that is less than 2 years.

We proposed to define ''Marriage and family therapist services'' at § 410.53(b)(1) as services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We also proposed at § 410.53(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

Lastly, we proposed at § 410.53(b)(2) that the following services do not fall under the Medicare Part B benefit category for MFT services:

- Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

Similarly, we proposed to define a mental health counselor at § 410.54 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;
- After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed. As previously explained for MFTs, and for the same reasons, we proposed a requirement for MHCs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers at § 410.73(a)(3)(ii) allows 2 years or 3,000 hours. The MHC statutory benefit category authorizes MHCs to furnish services for the diagnosis and treatment of mental illnesses as it does for CSWs. We stated in the proposed rule that we were also interested in public comments regarding States that have a supervised clinical hour requirement for MHC licensure that is less than 2 years.

We proposed to define ''mental health counselor services'' at § 410.54(b)(1) as services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We also proposed at § 410.54(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service.

We proposed at § 410.54(b)(2) that the following services do not fall under the Medicare Part B benefit category for MHC services:

- Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

We proposed to amend § 410.10 to add marriage and family therapist services and mental health counselor services to the list of included medical and other health services. We also proposed to amend § 410.150 to add marriage and family therapists and mental health counselors, to the list of individuals or entities to whom payment is made.

Currently, § 410.32(a)(2) lists the health care practitioners that may order diagnostic tests. Since this list currently includes CSWs and clinical psychologists (CPs), who are also authorized by statute to furnish services for the diagnosis and treatment of mental illnesses, we proposed to amend § 410.32(a)(2) to add MFTs and MHCs to the list of practitioners who may order diagnostic tests, as for the other non-physician practitioners, to the extent that the MFT or MHC is legally authorized to perform the service under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished.

We also proposed to codify in a new § 414.53 the payment amounts authorized under section 1833(a)(1)(FF) for MFT and MHC services. Additionally, we proposed to codify at § 414.53 the payment amount for clinical social worker (CSW) services as authorized under section 1833(a)(1)(FF) of the Act. As we reviewed our regulations to implement section 4121 of the CAA, 2023, we found that the payment amounts for CSWs are not yet codified under regulations. Specifically, we proposed to add that the payment amount for CSW, MFT, and MHC services is 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for clinical psychologist services under the PFS.

We also proposed to add MFTs and MHCs to the list of practitioners who are eligible to furnish Medicare telehealth services at the distant site. See section II.D. of this final rule for a discussion of this proposal.

Additionally, we proposed to allow Addiction Counselors who meet all of the applicable requirements (possess a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor; after obtaining such degree have performed at least 2 years (or, as proposed, 3,000 hours) of clinical supervised experience in mental health counseling; and licensed or certified as a MHC, clinical professional counselor, or professional counselor by the State in which the services are furnished) to enroll in Medicare as MHCs. That is, under this proposal, Addiction Counselors will be considered Mental Health Counselors and will be eligible to enroll and bill Medicare for MHC services if they meet these requirements. We understand there is variation in the terminology used for licensure across States for MHCs and MFTs and sought information pertaining to other types of professionals who may meet the applicable requirements for enrollment as mental health counselors. We noted that in past rulemaking, we have discussed the term 'mental health' to be inclusive of diagnosis and treatment of substance use disorders. For example, in the CY 2022 PFS final rule (86 FR 65061), we stated that SUD services are considered mental health services for the purposes of the expanded definition

of ''interactive telecommunications system.'' We proposed to apply that same interpretation for purposes of the mental health services included in the definition of MFT, MHC, and to clarify that the same interpretation applies for CSW, and CP services.

c. Coding Updates To Allow MFT and MHC Billing

In light of the new statutory benefits for MFTs and MHCs authorized by section 4121(a) of the CAA, 2023, we have considered whether updates to certain HCPCS codes are required in order to allow MFTs and MHCs to bill for the services described by those HCPCS codes. In the CY 2023 PFS final rule, we finalized new coding and payment for General Behavioral Health Integration services performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW serve as the focal point of care integration. In light of the new coverage under Medicare for MFT and MHC services for the diagnosis and treatment of mental illness, we proposed to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. We noted that MFTs and MHCs, like CSWs, are authorized by statute for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT or MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service. The code descriptor for HCPCS code G0323 is: *Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*

Lastly, we noted that consistent with the changes to valuation of CPT code 99484 in the Valuation of Specific Codes section (section II.E. of this final rule), which describes General BHI and is the crosswalk code used for valuation of HCPCS code G0323, we also proposed conforming updates to the valuation for work and PE inputs for HCPCS code G0323. See section II.E. of this final rule for further discussion of changes to the valuation for HCPCS code G0323.

We welcomed comments regarding any other HCPCS codes that may require updating to allow MFTs and MHCs to bill for the services described in the HCPCS code descriptor.

We received many public comments on these proposals to implement section 4121 of the CAA, 2023. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed broad support for our proposals to implement section 4121 of the CAA, 2023, and expressed appreciation that CMS is working to expand access to behavioral health services by allowing for qualified professionals to provide this vital care while others noted that the increased workforce would help to address shortages and needs in their communities.

Response: We thank the commenters for their support of our proposals to implement section 4121 of the CAA, 2023.

Comment: Many commenters expressed support for our proposal to allow either 2 years or 3,000 hours of clinical supervised experience. Several commenters provided detailed feedback regarding the amount of required clinical supervised experience for state licensure for MFTs and MHCs across States. A few commenters noted a small number of States that allow for licensure with less than 2 years and fewer than 3,000 hours. They stated that although most licensed and practicing MFTs and MHCs would meet the clinical supervised experience requirement as proposed, some would not and noted that those who obtained their supervised experience in a community mental health setting are more likely to accumulate the required number of hours of experience in less than 2 years. The commenters noted that some States differentiate between direct client contact versus other clinical activities and that some States require a specified number of direct contact hours. One commenter encouraged CMS to allow applicants who may not have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience before becoming licensed, but who instead provided an equivalent number of direct client contact hours to meet the supervised experience requirements and specified that they believed that 1,000 hours would be roughly equivalent to the proposed 2 years or 3,000 hours of clinical supervised experience. Other commenters expressed concern that ambiguity and discrepancies may exist in implementation across states as some states allow supervised clinical experience to count toward licensure requirements prior to completing their degree, and some states do not provide for clinical supervised experience requirements for licensure, and that licensure requirements can vary between clinicians with a master's or a doctoral degree. Some commenters requested that CMS allow for clinical supervised experience earned post-licensure to count toward the required amount for Medicare enrollment. A few commenters noted that ''clinical supervised experience'' was not defined and recommended that CMS be robust in its consideration of what constitutes such experience. Additionally, some commenters pointed out that California licensing laws for MFTs and MHCs consider some supervised clinical experience obtained during the progression toward academic degrees as supervised experience required for licensure and noted that while practicing MHCs and MFTs would generally meet the clinical supervised experience requirement as proposed, some individuals would not necessarily do so if CMS requires that all required supervised clinical experience occur following the granting of the academic degree. Some commenters also expressed that MFTs and MHCs who have been in practice for an extended period of time may have difficulty providing documentation of clinical supervised experience that occurred years or even decades ago. Some commenters requested that CMS consider accepting an attestation as evidence of having met the requirement for clinical supervised experience and others made a similar request for MFTs and MHCs who have not graduated within the last 5 years.

Response: We note that sections 1861(lll)(2) and1861(lll)(4) of the Act require that an MFT or MHC, after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy or mental health counseling. However, we wish to clarify that clinical

supervised experience earned after earning the required degree and licensure can count toward the required amount of clinical supervised experience for Medicare enrollment purposes. Regarding comments pertaining to States that differentiate between direct client contact versus other clinical activities and States that require a specified number of direct contact hours, we note that a total of 2 years or 3,000 hours of clinical supervised experience is required and we defer to State law and licensure requirements regarding specifics related to how many of these hours must be direct client contact. Similarly, regarding commenters' requests for CMS to define the term ''clinical supervised experience,'' we did not propose, and are not finalizing a definition of this term, but rather, defer to State law and licensure requirements regarding the nature of the 2 years or 3,000 hours of clinical supervised experience.

We thank the commenters for bringing the issue pertaining to clinical supervised experience for MFTs or MHCs in certain states, including California, to our attention. We note that sections 1861(lll)(2) and1861(lll)(4) of the Act require that an MFT or MHC, after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy or mental health counseling. As such, any clinical supervised experience would need to have occurred after obtaining the applicable master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which such individual furnishes marriage and family therapist services, or the applicable master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under State law of the State in which such individual furnishes MHC services, in order to count toward the required 2 years or 3,000 hours of clinical supervised experience. However, as noted above, clinical supervised experience earned after an individual obtains their licensure can count toward the required amount of clinical supervised experience for Medicare enrollment purposes.

Lastly, we note that the amount of clinical supervised experience required to be licensed as an MFT or MHC in certain states is the same as the required amount of clinical supervised experience that we are finalizing for Medicare enrollment purposes in this final rule (a total of 3,000 hours or 2 years). In a situation where an MFT or MHC is licensed in a state that requires a total of 3,000 hours or 2 years of clinical supervised experience after the completion of their degree as a requirement to be licensed as an MFT or MHC, no additional action is necessary for Medicare enrollment purposes and the Medicare Administrative Contractor (MAC) will validate the individual's license and clinical supervised experience during application processing.

Comment: Some commenters expressed concern regarding the statutory requirement that MFTs and MHCs be paid at 75 percent of the fee schedule rate and stated that the proposed regulations would prevent MFTs and MHCs from delivering services to hospital inpatients. A few commenters suggested that CMS consider add-on codes to more appropriately value the work, time, and effort of these practitioners, while others recommended that CMS consider further adjustments to the valuation of services used to treat mental health and SUDs under the PFS.

Response: The statutory benefit category for MFTs and MHCs does not prohibit MFTs and MHCs from delivering services to hospital inpatients. Rather, payment for MFT and MHC services furnished to hospital inpatients will be paid under the hospital inpatient prospective payment system as ''hospital inpatient services,'' consistent with section 1861(b) of the Act, instead of being paid as ''MFT or MHC services'' that are paid under the PFS. Additionally, the PFS payment amounts for MFT services and MHC services at 75 percent of the payment amount for a clinical psychologist is established in section 1833(a)(1)(FF) of the Act, which provides that, with respect to MFT services and MHC services under section 1861(s)(2)(II) of the Act, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist. We did not consider changing the valuation of services furnished by MFTs and MHCs in the proposed rule, but we welcome additional information for our consideration in the future.

Comment: Many commenters expressed support for our proposal to allow addiction counselors who meet all the applicable requirements of a MHC to enroll in Medicare as MHCs and bill Medicare for MHC services, noting that if finalized, this proposal will increase access to needed care for Medicare beneficiaries with SUDs. Several commenters requested for CMS to explicitly codify this inclusion at § 410.54 to ensure that these practitioners and Medicare beneficiaries are aware of this policy. Several commenters noted that in the Medicaid Managed Care Access Proposed Rule, when amending its regulations to specify MH and SUD instead of behavioral health, CMS stated, ''It is important to use clear, unambiguous terms in regulatory text.'' As such, the commenters noted they believe it was necessary for CMS to include ''addiction counselor or alcohol and drug counselor'' at §§ 410.54(a)(1) and (3); ''addiction counseling'' at § 410.54(a)(2); and ''substance use disorders'' at § 410.54(b)(1) in the final rule. Other commenters similarly recommended that CMS develop new guidelines (both regulatory and subregulatory) that use the phrase ''mental health'' or ''addiction'' services, rather than the more global ''behavioral health,'' noting that this is especially important for States in which addiction counselors and mental health counselors have distinct roles.

Response: We are finalizing our proposal to allow addiction counselors who meet all the applicable requirements of a MHC to enroll in Medicare as MHCs and bill Medicare for MHC services. We understand that some States certify addiction counselors with a Bachelor's degree; however, these individuals would not meet the education requirements for MHCs in the Medicare context. For Medicare purposes, an individual must possess a master's or doctor's degree to meet the definition of an MHC as defined at section 1861(lll)(4)(A) of the Act and § 410.54, which we are finalizing in this rule. While we are not finalizing changes to the regulation text at § 410.54 to refence addiction counselors, we note that for Medicare purposes, alcohol and drug counselors who furnish addiction counseling services for the diagnosis and treatment of mental illnesses, including substance use disorders, can enroll in Medicare and bill as MHCs, to the extent that they meet all of the statutory requirements regarding education, clinical supervised experience, and licensure. We are finalizing § 410.54 as proposed, and we refer readers to the discussion in our proposed rule on this topic (88 FR 52363).

Comment: One commenter noted that the requirements for MFTs and MHCs are not equivalent to the training that physicians must complete, noting that physicians complete 4 years of medical school plus 3 to 7 years of residency, including 10,000–16,000 hours of clinical training. The commenter stated

that MFTs and MHCs are an essential part of a physician led patient care team; however, they believe that they lack the requisite medical education, medication management training, and clinical training that is critical for the diagnosis and treatment of certain mental illnesses. As such, though commenters applauded CMS for requiring adherence to State law, they requested that the definitions of MFTs and MHCs have a specific additional reference to the requirement that they must adhere to State scope of practice requirements. The commenter also stated that the MFT or MHC should be licensed in the State in which the patient is receiving care, as well as the State in which the practitioner is located, to ensure that the patient has clear access to remedies should malpractice occur, especially with the increased use of telehealth in this space.

Response: We note that for Medicare telehealth services, 42 CFR 410.78(b)(1) requires that the distant site practitioner be ''licensed to furnish the [telehealth] service under State law.'' Therefore, any MHCs and MFTs who enroll in Medicare and furnish services would need to be licensed to furnish the service under State law. Additionally, we note that sections 1861(lll)(1) and (3) of the Act authorize MFTs and MHCs to furnish services for the diagnosis and treatment of mental illnesses which the MFT or MHC is legally authorized to perform under State law. We require that physicians and any practitioner who furnishes services under the Medicare program does so in accordance with their scope of practice. Therefore, MFTs and MHCs who furnish services under the Medicare program will also be required to adhere to the scope of practice in their respective State.

Comment: Several commenters requested clarification regarding variation in terminology used across States. Some commenters encouraged CMS to clarify that practitioners who meet the applicable requirements but are licensed by their State under a different title can also bill for these services and be recognized by Medicare for purposes of this policy. Other commenters recommended that CMS use the term Mental Health Professional (MHP) instead of Mental Health Counselor to be more inclusive of the types of professionals who may meet the applicable requirements for enrollment as a master's level mental health practitioner. They specifically requested that CMS recognize licensed psychological practitioners (Kentucky), licensed clinical psychotherapists (Kansas), licensed psychological associates (Texas), psychologist-masters (Vermont), and psychologists (West Virginia) as MHCs, or preferably as MHPs. Other commenters noted that Michigan has a licensure category for Licensed Professional Counselors (LPCs) and California uses the credential title Licensed Professional Clinical Counselor (LPCC) to describe the same or similar practitioner and noted that recognizing LPCs, LPCCs, and other functionally similar practitioners as MHCs for purposes of Medicare enrollment would increase access to these services. Another commenter advocated for psychologist associates or psychological associates to be included as mental health counselors. A few commenters expressed concern that the definitions of an MHC and MFT under the statute could open the door for master's level behavioral health professionals, who are not professional counselors, to qualify for Medicare reimbursement ''as counselors.'' The commenters stated that while they understand that it is not within CMS' authority to influence State occupational licensure requirements and the agency is beholden to the statute as passed by Congress, they are concerned with a growing trend of non-professional counselors, such as ''masters level psychologists,'' being granted the privilege to practice as counselors in some States.

Response: We note that while section 1861(lll)(4) of the Act uses the term ''mental health counselor,'' the statute defines this term as a clinical professional counselor or a professional counselor. Section 1861(lll)(4)(A) of the Act defines the term mental health counselor as an individual who possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes MHC services. Additionally, we proposed that addiction counselors who meet all applicable requirements for MHCs could enroll in Medicare as MHCs. In response to the comments received on the variation in nomenclature used across States for mental health counselors, we wish to make clear that individuals who meet all of the applicable statutory and regulatory qualifications for the mental health counselor benefit category for education and clinical supervised experience, but are licensed or certified by their State under a different title to furnish mental health counseling, are eligible to enroll in Medicare under the Part B ''mental health counselor'' statutory benefit category.

Comment: Commenters expressed support for our proposal to revise the code descriptor for HCPCS code G0323 to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service.

Response: We are finalizing our proposal to update the code descriptor for HCPCS code G0323, as proposed. The updated code descriptor for HCPCS code G0323 is: *Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*

Comment: One commenter urged CMS to update the code descriptors for all other HCPCS codes that are utilized by current Medicare behavioral health practitioners and requested that MFTs and MHCs be allowed to bill for services described in HCPCS code G0409 (*Social work and psychological services, directly relating to and/or furthering the patient's rehabilitation goals, each 15 minutes, face-to-face; individual (services provided by a CORF-qualified social worker or psychologist in a CORF*) pertaining to services directly relating to and/or furthering a patient's rehabilitation goals. The commenter also encouraged CMS to ensure that MFTs and MHCs are able to provide services and bill for them using applicable HCPCS codes even if the code descriptors do not address the provider types eligible to bill for these services, such as the two new G-codes for psychotherapy for crisis services, GPFC1 and GPFC2.

Response: As to MFTs and MHCs providing services and billing for them using applicable HCPCS codes even if the code descriptors do not address the provider types eligible to bill for these services, we note that most HCPCS codes do not specify in the code descriptor which practitioners may

furnish the service described, so CMS need not change code descriptors for most codes describing services for the diagnosis and treatment of mental illnesses in order for MFTs and MHCs to bill for them. As specified in sections 1861(lll)(1) and (3) of the Act, MFT services and MHC services include any services that are furnished by the MFT or MHC for the diagnosis and treatment of mental illnesses, that they are legally authorized to furnish under State law. Regarding the comment about HCPCS code G0409, which describes services provided by a CORF-qualified social worker or psychologist in a CORF, we thank the commenters for bringing this to our attention and note that this is something we may take into consideration for future rulemaking.

Comment: Several commenters urged CMS to use its authority to develop additional codes for substance use counseling that could be delivered by addiction counselors in office-based and community settings, similar to the services developed for community health workers, patient navigators, and peer support specialists in the proposed rule, and the services identified in the opioid treatment program regulations. A few commenters also suggested coding for psychoeducation activities for patients with SUD. Some commenters also urged CMS to work with Congress to authorize Medicare to cover addiction counselors who do not have master's degrees but have the appropriate training and supervision to deliver reasonable and necessary substance use disorder counseling services to Medicare beneficiaries. The commenters noted that allowing these additional substance use disorder counselors to serve Medicare beneficiaries, as many already do for Medicaid enrollees, aligns with CMS's objective to expand the workforce capacity to improve access to substance use disorder prevention, treatment, and recovery services, as outlined in its Behavioral Health Strategy.

Response: We thank the commenters for this feedback and the detailed suggestions about potential coding for substance use counseling and psychoeducation activities. We may consider this for future rulemaking. We thank the commenters for information regarding other types of professionals who furnish services for the treatment of SUDs, but who do not have a master's degree. We will keep this in mind as we consider ways to improve access to SUD treatment in the future. We note that the Medicare statute specifies the types of health care professionals that can enroll and bill the program directly for their services, and the services of the various recognized health care professionals are also defined in the statute. However, if a health care professional does not meet the statutory and regulatory requirements to enroll in Medicare, and bill and receive Medicare payment directly, they can instead explore whether they may work with a physician or other practitioner who is enrolled in the Medicare program to provide services incident to the billing practitioner's professional services in accordance with our regulation at § 410.26. This is a way in which individuals who do not meet the requirements to enroll in Medicare as MFTs or MHC, for example, addiction counselors and other professionals who do not have a master's or doctor's degree, may be able to participate in care furnished to Medicare beneficiaries.

Comment: Several commenters requested that CMS amend the regulations at 42 CFR 419.22 to add the services of MFTs and MHCs to the list of Medicare Part B services that are not paid for under the Hospital Outpatient Prospective Payment System (OPPS) (except when packaged as part of a bundled payment) in order to clarify that MHC and MFT services are excluded from payment under the OPPS. The commenters stated that the regulation at § 419.22 lists those services that are authorized by Medicare statute to be paid under other payment systems outside of the OPPS, such as the PFS, the Skilled Nursing Facility Prospective Payment System (SNF PPS) and, the End-Stage Renal Disease (ESRD) composite rate.

Response: We thank the commenters for bringing this to our attention. We proposed a number of changes to our regulations (88 FR 52361 through 52364) to implement the amendments made by section 4121 of CAA, 2023. Generally, these amendments added MFTs and MHCs as types of non-physician practitioners who can enroll in Medicare and bill independently for their professional services to diagnose and treat mental illnesses, and specified that payment is made for these services at 80 percent of the lesser of the actual charges for the services or 75 percent of the amount determined under the PFS for services of a clinical psychologist (CP). In proposing to implement section 4121 of CAA, 2023, we inadvertently did not address whether MFT and MHC services are excluded from payment under the hospital OPPS. Services paid under fee schedules or other payment systems, including the professional services of physicians and nonphysician practitioners, are not paid under the OPPS (see 69 FR 65685). The regulation at § 419.22 lists the hospital services excluded from payment under the OPPS, and includes among them the services of qualified psychologists, as defined in section 1861(ii) of the Act. Because MHC and MFT services are professional services of nonphysician practitioners for which payment is made under the PFS at 75 percent of the amount of payment for services of a psychologist, we believe that in implementing the amendments to the Act made by section 4121 of the CAA, 2023, we must also exclude these services from payment under the OPPS, effective January 1, 2024. Accordingly, we anticipate amending the regulation at § 419.22 to add the services of MFTs as defined in section 1861(lll)(1) of the Act and the services of MHCs as defined in section 1861(lll)(3) of the Act to the list of hospital services excluded from payment under the OPPS, at new paragraphs (w) and (x), respectively. These amendments to the regulation text will be addressed in the CY 2024 OPPS final rule which is expected to be issued on or around the same time as this final rule.

Comment: A few commenters requested that CMS update the definition of ''practitioner'' in the regulation text to enable MFTs and MHCs to opt out of the Medicare program and make use of private contracts with Medicare beneficiaries.

Response: We thank the commenter for bringing this to our attention. As noted above, we proposed a number of changes to our regulations (88 FR 52361 through 52364) to implement the amendments made by section 4121 of CAA, 2023. Generally, these amendments added MFTs and MHCs as types of non-physician practitioners who can enroll in Medicare and bill independently for their professional services to diagnose and treat mental illnesses, and specified that payment is made for these services at 80 percent of the lesser of the actual charges for the services or 75 percent of the amount determined under the PFS for services of a clinical psychologist (CP). In proposing to implement section 4121 of CAA, 2023, we inadvertently did not address the section of the regulation text pertaining to opting out of the Medicare program. We believe that in implementing the amendments to the Act made by section 4121 of the CAA, 2023, we must make a conforming change to § 405.400, which defines ''practitioner'' for opt-out purposes, to include MFTs and MHCs in the definition of ''practitioner,'' consistent with other practitioners listed in the regulation text who as authorized to furnish services for the diagnosis and

treatment of mental illnesses, such as clinical psychologists and clinical social workers. Accordingly, we are amending the regulation at § 405.400 to revise the definition of ''practitioner'' to include a marriage and family therapist and mental health counselor.

Comment: A few commenters requested that § 410.27, which permits certain hospital services to be furnished incident to a physician or nonphysician practitioner's service, be updated to expand the definition of ''nonphysician practitioner'' to include MFTs and MHCs.

Response: We thank the commenters for bringing this to our attention. As noted above, we proposed a number of changes to our regulations (88 FR 52361 through 52364) to implement the amendments made by section 4121 of CAA, 2023. Generally, these amendments added MFTs and MHCs as types of non-physician practitioners who can enroll in Medicare and bill independently for their professional services to diagnose and treat mental illnesses, and specified that payment is made for these services at 80 percent of the lesser of the actual charges for the services or 75 percent of the amount determined under the PFS for services of a clinical psychologist (CP). In proposing to implement section 4121 of CAA, 2023, we inadvertently did not address the section of the regulation text pertaining to therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service. We believe that in implementing the amendments to the Act made by section 4121 of the CAA, 2023, we must make a conforming change to § 410.27 to recognize MFTs and MHCs as a type of nonphysician practitioner. Accordingly, we are amending the regulation at § 410.27 to revise the definition of ''nonphysician practitioner'' to include MFTs and MHCs. This amendment to the regulation text at § 410.27 will be addressed in the CY 2024 OPPS final rule.

Comment: A few commenters stated that the regulatory exception to the physician self-referral law for assistance to compensate a nonphysician practitioner at § 411.357(x), defines ''nonphysician practitioner'' at § 411.357(x)(3) to include certain types of mental health practitioners, but the definition does not include marriage and family therapists or mental health counselors. The commenter asked that CMS expand the definition of ''non-physician practitioners'' to include marriage and family therapists and mental health counselors, which would permit a hospital to provide assistance to a physician to compensate such practitioners.

Response: The proposed rule focused on implementing the new benefit category for MFT and MHC services that permits them to enroll and bill independently under the Medicare program. The proposed rule addressed certain enrollment, billing and payment policies for MFTs and MHCs and the services they furnish, but did not address physician self-referral policies. We did not propose any changes to § 411.357(x) or any other physician self-referral regulation in the proposed rule. The change the commenter suggested falls outside the scope of the proposed rule. We thank the commenter for bringing this point to our attention and will take it into consideration for possible future rulemaking.

Comment: We received other comments that were outside the scope of the proposed rule.

Response: While we are not responding to comments that were outside the scope of the proposed rule in this final rule, we will take them into consideration for possible future rulemaking.

After consideration of the public comments, we are finalizing our proposals to implement section 4121 of the CAA, with some clarifications and modifications, as described above. In this final rule, we are clarifying that to the extent that addiction counselors and alcohol and drug counselors who furnish services for the diagnosis and treatment of mental illnesses, including substance use disorders, can meet all of the statutory and regulatory requirements regarding education, clinical supervised experience, and State licensure for MHCs, such counselors can enroll in Medicare as MHCs. We are also finalizing a clarification that individuals who meet the statutory and regulatory requirements for education and clinical supervised experience for MHCs, but are licensed to furnish mental health counseling in their State under a title other than mental health counselor, clinical professional counselor, or professional counselor, are eligible to enroll in Medicare as MHCs. We are also finalizing an amendment to § 405.400 to include MFTs and MHCs as practitioners who may opt out of Medicare; and will address amendments to §§ 419.22 and 410.27 in the CY 2024 OPPS final rule. We believe these policies to implement section 4121 of the CAA, 2023 will advance health equity by providing increased access to behavioral health services for Medicare beneficiaries.

d. Medicare Enrollment of MFTs and MHCs

Individuals who meet the applicable requirements as described in detail above in this section, and as finalized in this rule, will need to enroll in Medicare as MFTs and MHCs in order to submit claims for MFT services or MHC services, respectively, furnished to Medicare beneficiaries. Under § 424.510, a provider or supplier must complete, sign, and submit to the relevant MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532; 104 Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare requirements. We proposed, and are finalizing, that the MFT and MHC supplier types, like most nonphysician practitioner types, be subject to limited-risk screening under § 424.518.

Individuals who meet the MFT or MHC requirements in §§ 410.53 and 410.54 as finalized, would enroll in Medicare via the Form CMS–855I application (Medicare Enrollment Application—Physicians and Non-Physician Practitioners; OMB No. 0938–1355) and could begin submitting their enrollment applications after the publication of the CY 2024 PFS final rule. However, as the new benefit categories authorized by section 4121(a) of the CAA, 2023, do not take effect until January 1, 2024, MFT or MHC claims for MFT or MHC services furnished to Medicare beneficiaries with dates of service prior to January 1, 2024, will not be payable under Medicare Part B. MFTs and MHCs can visit *https://www.cms.gov/medicare/provider-enrollment-and-certification* for basic information on the provider enrollment process.

2. Implementation of Section 4123 of the CAA, 2023

Section 4123(a)(1) of the CAA, 2023, Improving Mobile Crisis Care in Medicare, amended section 1848 of the Act by adding a new paragraph (b)(12) regarding payment for psychotherapy for crisis services furnished in an applicable site of service. New subparagraph (A) of section 1848(b)(12) of the Act requires the Secretary to

establish new HCPCS codes under the PFS for services described in subparagraph (B) that are furnished on or after January 1, 2024. Subparagraph (B) of section 1848(b)(12) of the Act describes these services as psychotherapy for crisis services that are furnished in an applicable site of service. Section 1848(b)(12)(C) of the Act specifies that the payment amount for these psychotherapy for crisis services shall be equal to 150 percent of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), and any succeeding codes.

For purposes of this provision, subparagraph (D)(i) of new section 1848(b)(12) of the Act defines an applicable site of service as a site of service other than a site where the facility rate under the PFS applies and other than an office setting, while subparagraph (D)(ii) requires that the code descriptors for these new psychotherapy for crisis services be the same as the services identified (as of January 1, 2022) by HCPCS codes 90838 and 90840, and any succeeding codes, except that the new codes shall be limited to services furnished in an applicable site of service.

Therefore, consistent with the requirements described in new paragraph (12) of section 1848(b) of the Act, we proposed to create two new G-codes describing psychotherapy for crisis services furnished in any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting: HCPCS codes GPFC1 and GPFC2.

To identify the places of service that are assigned the non-facility rate, § 414.22(b)(5)(i) states that there are usually two levels of PE RVUs that correspond to each code paid under the PFS: facility PE RVUs and non-facility PE RVUs. Under § 414.22(b)(5)(i)(A), the facility PE RVUs apply to services furnished in a hospital, skilled nursing facility, community mental health center, hospice, ambulatory surgical center, or wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5), or for services furnished via telehealth under § 410.78 (though we note that special rules relating to the PHE for COVID–19 currently apply, and we include proposals regarding the place of service for telehealth services in section II.D. of this final rule). Under § 414.22(b)(5)(i)(B), the non-facility rate is paid in all other settings, including a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility. We provided the full list of places of service that are assigned a non-facility rate on the CMS website at *https://www.cms.gov/Medicare/Coding/place-of-service-codes*. We proposed that the two new G-codes describing psychotherapy for crisis services can be billed when the services are furnished in any non-facility place of service other than the physician's office setting. We also noted that in the CY 2022 PFS final rule (86 FR 65059), in our discussion of Medicare telehealth services where the patient's home is a permissible originating site for services furnished for diagnosis, evaluation, or treatment of a mental health disorder, we indicated that we define the term ''home'' broadly to include temporary lodging, such as hotels and homeless shelters (86 FR 65059). We clarified that, for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, that would qualify as the patient's home. For purposes of implementing section 1848(b)(12) of the Act, we proposed to use the same broad definition of the patient's home for purposes of these proposed G-codes describing psychotherapy for crisis services.

The new G-codes and their descriptors are:

- GPFC1 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes*); and
- GPFC2 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (List separately in addition to code for primary service)*).

As required by section 1848(b)(12)(C) of the Act, we proposed to establish a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), respectively. Specifically, we proposed to calculate the work, PE, and MP RVUs for HCPCS codes GPFC1 and GPFC2 by multiplying the work, PE, and MP RVUs for CPT codes 90839 and 90840, respectively, by 1.5.

We noted that section 4123(a)(2) of the CAA, 2023 amends section 1848(c)(2)(B)(iv) of the Act to include a waiver of budget neutrality providing that paragraph (b)(12) shall not be taken into account in applying PFS budget neutrality requirements under section 1848(c)(2)(B)(ii)(II) of the Act for 2024. Accordingly, we proposed to exclude expected expenditures for HCPCS codes GPFC1 and GPFC2 from the budget neutrality calculation for CY 2024 PFS ratesetting.

Additionally, section 4123(d) of the CAA, 2023 requires that the Secretary use existing communication mechanisms to provide education and outreach to providers of services, physicians, and practitioners with respect to the ability of auxiliary personnel, including peer support specialists, to participate, consistent with applicable requirements for auxiliary personnel, in the furnishing of psychotherapy for crisis services billed under the PFS under section 1848 of the Act, behavioral health integration services, as well as other services that can be furnished to a Medicare beneficiary experiencing a mental or behavioral crisis. We understand that there are varying definitions of the term ''peer support specialist.'' The Substance Abuse and Mental Health Services Administration (SAMHSA) defines a ''peer support specialist'' as a person who uses their lived experience of recovery from mental illness and/or addiction, plus skills learned in formal training, to deliver services to promote recovery and resiliency. The essential principles of peer support include shared personal experience and empathy, a focus on individual strengths, and supporting individuals as they work toward recovery pursuant to a person-centered plan of care. However, for Medicare payment purposes, we noted that the term auxiliary personnel is defined at § 410.26(a)(1) as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in

which the services are being furnished. We do not include definitions of any specific types of personnel who could be included under the definition of auxiliary personnel in our regulations and did not propose to do so in the proposed rule. We anticipate conducting this outreach and education through existing communications mechanisms as required by the CAA, 2023.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposals to implement section 4123 of the CAA, 2023. Some commenters noted that individuals who are in crisis should be able to access services wherever they are in need and commended CMS for enabling this flexibility through proposals included in the proposed rule. Other commenters stated that in light of the implementation of the 988-crisis system, it is particularly important to increase access to behavioral health services that can respond to a crisis in homes and communities and avoid law enforcement involvement.

Response: We thank the commenters for their support of our proposals to implement section 4124 of the CAA, 2023.

Comment: We received several comments on the proposal related to peer support specialists. Many commenters stated that psychotherapy is not within the scope of practice for peer support specialists. They stated that peer support specialists do provide engagement services, including education, support, and sharing lived experience to facilitate an individual participating in crisis psychotherapy effectively. The commenters described that peer support specialists are analogous to emergency medical technicians (EMTs) who are not medical clinicians but are specially trained to respond in emergency situations. Other commenters encouraged CMS to provide guidance and support that meaningfully encourages incorporation of peer support services, such as by training clinic staff on the value and role of peer services and ensuring that peer services are utilized in alignment with state scopes of practice for peers. One commenter requested that CMS update the regulatory definition of auxiliary personnel to specifically state that this includes, but is not limited to, peer support specialists and suggested using language from SAMHSA's national model standards.

Response: We thank the commenters for highlighting that furnishing psychotherapy is not within the scope of practice for peer support specialists. We did not make any proposals specific to peer support specialists as it pertains to section 4123 of the CAA, 2023. The CAA requires CMS to provide education and outreach to peer support specialists, to the extent that they can serve as auxiliary personnel, regarding psychotherapy for crisis services. Additionally, we wish to clarify that peer support specialists participating in the furnishing of any service as auxiliary personnel, including psychotherapy for crisis, must operate within their scope of the role of peer support specialists and meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We also note that we did not propose to specify any particular types of personnel in our regulatory definition of auxiliary personnel; the definition at § 410.26 currently references ''any individual,'' and we do not believe greater specificity is warranted at this time.

Comment: A few commenters urged CMS to consider paying for the existing code billed under Medicaid in many states, HCPCS code H2011 (*crisis intervention service per 15 minutes*), and to do so at rates that cover the cost of care, noting that there are limitations to the psychotherapy for crisis codes in that they require the services be provided by a licensed practitioner that can bill Medicare independently. Some of the commenters stated that much of this type of crisis work is done by a multidisciplinary team that does not always include someone who can independently bill under the Medicare program. They stated that the existing coding described by CPT codes 90839 and 90840, and the newly proposed codes which are based on the existing CPT codes, have the potential to create a barrier to care since they do not describe or include the resource costs of team-based care. Other commenters noted that SAMHSA's National Guidelines for Behavioral Health Crisis include mobile crisis teams as an essential component of a crisis system and specify that, to fully align with best practice guidelines, teams must ''incorporate peers within the mobile crisis team'' and requested that CMS create a pathway for peer support specialists to be reimbursed when they work with clinicians on mobile crisis teams. Other commenters recommended CMS create a code for ''Crisis Psychotherapy with engagement services'' and increase the payment by 40 percent with a modifier to indicate when the service is furnished by a two-person mobile crisis team. Other commenters requested adjustments for services furnished in rural areas, as well as additional payment for mileage, and some suggested that utilizing a Prospective Payment System (PPS) may be a more appropriate model for furnishing mobile crisis services. A few commenters requested that CMS consider whether it would be more appropriate to utilize a methodology similar to what it uses for establishing EMS/ambulance base rates and some commenters recommended that CMS consider expanding data collection and the testing of new payment and service delivery models for EMS providers to supplement mobile crisis response teams. Other commenters recommended that CMS create an add-on code for Mobile Crisis Services to bill up to two additional 30-minute blocks after the first 60 minutes of mobile crisis care, similar to the way HCPCS code 90839 (*Psychotherapy for crisis, first hour*) can be billed as the primary code with HCPCS code 90840 (*Psychotherapy for crisis, each additional 30 mins*). Some commenters noted that after 2 hours of Mobile Crisis Services, the patient should be transferred to the appropriate level of care.

Response: We note that the proposals for CY 2024 were specific to implementing section 4123 of the CAA, which focuses on payment for psychotherapy for crisis services furnished in an applicable site of service and specified that the payment amount for these psychotherapy for crisis services shall be equal to 150 percent of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), and any succeeding codes. However, regarding requests that CMS consider paying for other types of crisis care that is more comprehensive or team-based, we agree with commenters regarding the importance of beneficiary access to crisis services and we may consider this feedback for future rulemaking. Regarding the comment about an add-on code, we note that the proposed G codes are based on CPT codes 90839 (*Psychotherapy for crisis, first hour*) and 90840 (*Psychotherapy for crisis, each additional 30 mins*), and therefore, HCPCS codes GPFC1 and GPFC2 do allow for billing an add-on code for each

additional 30 minutes beyond the first hour.

Comment: A few commenters requested that CMS clarify that ''applicable sites of service'' includes services administered outside of a clinical setting by a mobile crisis response team, and in a crisis stabilization unit.

Response: In the CY 2024 PFS proposed rule (88 FR 52364), we proposed that the two new G-codes describing psychotherapy for crisis services can be billed when the services are furnished in any non-facility place of service other than the physician's office setting. We noted that the full list of places of service that are assigned a non-facility rate can be found on the CMS website at *https://www.cms.gov/Medicare/Coding/place-of-service-codes.*

Comment: One commenter requested that we clarify whether a co-pay would be applicable for these the newly proposed codes and noted that collecting a co-pay in this context would be difficult unless crisis psychotherapy is provided to a beneficiary with an existing professional relationship with the provider(s) furnishing the service.

Response: We note that the Part B coinsurance would apply for the new psychotherapy for crisis services, as mandated for Part B services by section 1833(a)(1) of the Act.

After consideration of public comments, we are finalizing our proposals to implement section 4123 of the CAA, 2023, as proposed. Specifically, we are finalizing two new G-codes to describe psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting) and establishing a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), respectively. As required by section 1848(b)(12)(C) of the Act, we proposed, and are finalizing, to establish a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), respectively.

We note that the codes GPFC1 and GPFC2 were placeholder codes and that the final code numbers will be G0017 and G0018. The new G-codes and their descriptors are:

- G0017 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes*); and
- G0018 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (List separately in addition to code for primary service)*).

3. Implementation of Section 4124 of the Consolidated Appropriations Act, 2023 (CAA, 2023)

Section 4124 of the CAA, 2023, Ensuring Adequate Coverage of Outpatient Mental Health Services under the Medicare Program, establishes Medicare coverage and payment for intensive outpatient services for individuals with mental health needs when furnished by hospital outpatient departments, community mental health centers, RHCs, and FQHCs, effective January 1, 2024. Please see the discussion of our implementation of section 4124 in the CY 2024 Outpatient Prospective Payment System (OPPS) final rule, section VIII. Payment for Partial Hospitalization and Intensive Outpatient Services.

4. Health Behavior Assessment and Intervention (HBAI) Services

The current Health and Behavior Assessment and Intervention codes (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, and 96171) were created by the CPT Editorial Panel during its September 2018 meeting. The CPT Editorial Panel deleted the six previous HBAI CPT codes and replaced them with nine new CPT codes. As discussed in the CY 2023 PFS final rule (87 FR 69541), the HBAI range of CPT codes are intended to be used for psychological assessment and treatment, when the primary diagnosis is a medical condition. A health behavior assessment under these HBAI services is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation, and adherence to medical treatment. HBAI services are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions. The HBAI codes apply to services that address psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. According to the CPT prefatory language in the CPT 2023 Professional Edition, the patient's primary diagnosis is physical in nature and the focus of the assessment and intervention is on factors complicating medical conditions and treatments. The HBAI codes capture services related to physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health related risky behaviors, and adjustment to physical illness.

In light of the new benefit categories authorized by section 4121(a)(2) of the CAA, 2023, which authorize MFTs and MHCs to furnish services for the diagnosis and treatment of mental illness, this prompted us to consider whether MFTs and MHCs could furnish and bill for HBAI services. Additionally, we re-examined whether CSWs could furnish and bill these HBAI codes given that their statutory benefit category also authorizes them to furnish services for the diagnosis and treatment of mental illnesses. We noted that prior to the passage of the CAA, 2023, which authorized benefit categories for MFTs and MHCs, there was previously a National Coverage Determination (NCD) that stated, the CPT codes 96156, 96158, 96159, 96164, 96165, 96167 and 96168 may be used only by a Clinical Psychologist (CP), (Specialty Code 68). However, we noted that this NCD was retired on December 8, 2022.[44]

Like CPs, who can currently bill Medicare for HBAI services, CSWs, MFTs, and MHCs have the education and training to address psychosocial barriers to meet the needs of patients with physical health conditions. In accordance with State law and scope of practice, CSWs, MFTs, and MHCs can assess, diagnose, and treat psychological and/or psychosocial behaviors associated with physical health conditions. Interested parties have informed us that like CSWs, MHCs and MFTs can play a key role in a multidisciplinary team approach that leads to successful outcomes in patient care, including offering integrated care within hospitals and medical practices where patients are diagnosed with

[44] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57754&ver=12&=.*

physical health conditions. For example, mental health professionals such as MHCs and MFTs facilitate ''behavioral management and reinforcement, guided problem-solving, supporting patients in setting realistic and attainable goals, and teaching relaxation strategies for managing diabetes-related stressors.'' [45] In this role, mental health professionals such as CSWs, MHCs, and MFTs help patients manage mental health symptoms associated with a physical health condition. Moreover, according to the National Cancer Institute at the National Institutes of Health, mental health professionals can also provide emotional and social support to assist cancer patients in reducing ''levels of depression, anxiety, and disease and treatment-related symptoms among patients.'' [46] Therefore, we proposed to allow the HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs. We noted that in order for payment to be made under Medicare for HBAI services furnished to a beneficiary, the HBAI services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, in accordance with section 1862(a)(1)(A) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposal to allow HBAI services and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs. One commenter requested that we allow HBAI services to be billed by occupational therapists during the mental health workforce shortage.

Response: We appreciate the support expressed in the comments. HBAI services have historically not been designated as therapy services, therefore occupational therapists cannot furnish these services. As such, we are not recognizing these codes as therapy services at this time.

After consideration of public comments, we are finalizing our proposal to allow the HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs.

5. Adjustments to Payment for Timed Behavioral Health Services

There is an ongoing behavioral health crisis in the United States, which has been exacerbated by the COVID–19 pandemic, the overdose crisis,[47] and worsening behavioral healthcare workforce shortages.[48] Public comments received in response to the CY 2023 PFS proposed rule described practices that furnish treatment for behavioral health conditions experiencing difficulty recruiting and retaining behavioral health clinicians and expressed concern that people are experiencing unprecedented delays in receiving medically necessary services across care settings. Commenters described workforce shortages nationwide that, combined with increasing demand for behavioral health care services, have limited Medicare beneficiary access to these vital services. Prior to the pandemic, the Health Resources and Services Administration (HRSA) projected shortages of seven selected types of behavioral health providers by 2025.[49] As of March 31, 2023, HRSA designated more than 6,635 health professional shortage areas for mental health, with more than one-third of Americans living in these shortage designations.[50] Additionally, according to SAMHSA's guide on *Addressing Burnout in the Behavioral Health Workforce Through Organizational Strategies,* staffing shortages, and high turnover rates place enormous demands on the workforce, jeopardizing the provision of care, especially to underserved individuals.[51] The behavioral health workforce experiences high levels of work-related stress, relatively low salaries, and full caseloads; these combined factors place individuals working in the behavioral health field at high risk for experiencing burnout.[52] Over 50 percent of behavioral health providers report experiencing burnout symptoms. The rate of burnout will likely increase, given the continued growth in the number of people seeking behavioral health care, behavioral health staffing, and retention challenges.[53]

In CY 2023 PFS rulemaking, we sought comment on how we can best help ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS. We described that as part of our review of our payment policies and systems, we understand that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to PE. In the CY 2018 PFS final rule (82 FR 52999), we discussed feedback we received from some interested parties suggesting that, for codes with very low direct PE inputs, our methodology for allocating indirect PE does not produce a differential between facility and nonfacility PE RVUs that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. We stated that primary therapy and counseling services available to Medicare beneficiaries for the treatment of behavioral health conditions, including substance use disorders, are among the services most affected by our methodology. For example, we stated at the time that, for the most commonly reported psychotherapy service (CPT code 90834), the difference between the nonfacility and facility PE RVUs was only 0.02 RVUs, which seemed unlikely to represent the difference in relative PE resource costs in terms of administrative labor, office expense, and all other expenses incurred by the billing practitioner for 45 minutes of psychotherapy services when furnished in the office setting versus the facility setting. We agreed with these interested parties that the site of service differential for these services produced by our PE methodology seems unlikely to reflect the relative resource costs for the practitioners furnishing these services in nonfacility settings. For example, we believe the 0.02 RVUs, which translated at the time to approximately $0.72, was unlikely to

[45] Powell PW, Hilliard ME, Anderson BJ (2014). Motivational interviewing to promote adherence behaviors in pediatric type 1 diabetes. *Curr Diab Rep.* 2014;14(10):531. 10.1007/sll892-014-0531-z.

[46] National Cancer Institute at the National Institutes of Health, (nd). ''Stress and Cancer'' *https://www.cancer.gov/about-cancer/coping/feelings/stress-fact-sheet.*

[47] *https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/.*

[48] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[49] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[50] Health Resources and Services Administration, Health Workforce Shortage Areas, *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[51] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf.*

[52] Kelly, R.J., Hearld, L.R. Burnout and Leadership Style in Behavioral Health Care: a Literature Review. *J Behav Health Serv Res* 47, 581–600 (2020). *https://doi.org/10.1007/s11414-019-09679-z.*

[53] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep22-06-02-005.pdf.*

reflect the relative administrative labor, office rent, and other overhead involved in furnishing the 45-minute psychotherapy service in a nonfacility setting. Consequently, we modified our PE methodology to establish a minimum nonfacility PE RVU for certain outlier codes with very low direct PE inputs as compared to work RVUs, most of which are primarily furnished by behavioral health professionals. We finalized a policy to implement only one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes over a 4-year transition period, beginning with CY 2018. We stated that we recognized that this change in the PE methodology could significantly impact the allocation of indirect PE RVUs across all PFS services (82 FR 53000).

In light of increasing patient needs for behavioral health services and continued workforce shortages, we have been examining a number of dynamics in our processes for developing values for behavioral health services under the PFS. We continue to consider approaches to ensuring that the relative values we establish for these services accurately reflect the resources involved in furnishing them, especially since any potential systemic undervaluation could serve as an economic deterrent to furnishing these kinds of services and be a contributing factor to the workforce shortage.

Interested parties have long raised concerns regarding the valuation of services that primarily involve person-to-person interactions with beneficiaries, particularly those services that are comprised of conversational interactions rather than physical interactions, because these services require minimal equipment and supplies compared to other services, and therefore, valuation is based almost entirely on the practitioner's work. Because the physician/practitioner work RVU is developed based on the time and intensity of the service, the issues regarding the valuation of these types of services are particularly pronounced for services that are billed in time units (like psychotherapy codes) that directly reflect the practitioner time inputs used in developing work RVUs, compared to other services that are not billed in time units in which work RVUs are based on estimates of typical time, usually based on survey data. For example, a 2016 report by the Urban Institute entitled *Collecting Empirical Physician Time Data* [54] (the Urban Institute report) reviewed empirical time estimates for 60 services paid under the PFS with relative values developed based on time estimates derived from survey data (as opposed to actual reported time). The Urban Institute report suggested that there may be systemic overestimations of times for these services within the PFS, which would lead to overvaluation of these services and, by implication, undervaluation of other services.

The dynamic described by the Urban Institute report can lead to systemic undervaluation for some kinds of time-based codes for several, interrelated reasons. First, overestimates of time for some kinds of codes compared to other kinds of codes results in ''implied intensity'' (that is the ratio of work RVU/per minute, sometimes referred to by the AMA RUC as intra-service work per unit of time, or IWPUT) that is artificially low. This is important since we understand that the implied intensity is used as part of the AMA RUC review of survey data to contextualize the credibility of data and the resulting recommended work RVUs compared to codes with similar times. CMS' review of the RUC recommendations similarly utilizes implied intensity as important contextual information in order to assess the relative values assigned to particular services.

The second reason this dynamic could result in potential undervaluation of certain services is that time-based codes that describe one-on-one time with the patient are highly unlikely to become more efficient over multiple years. In contrast, surgical procedures tend to become more efficient over the years as they become more common, professionals gain more experience with them, improved technology is deployed, and other general operational improvements are implemented. Meanwhile, 45 minutes of psychotherapy remains static in terms of efficiency since, by definition, it requires 45 minutes of time, personally spent by the billing professional, one-on-one with the patient. Moreover, even if there were efficiencies that reduced the time required to furnish therapy services, the services would then be reported with time-based codes with lower total values. Additionally, in contrast to services such as procedures that utilize clinical staff, no part of the one-on-one therapy service can be performed by clinical staff working with the billing professional. This means that any overestimations in the initial estimates of time used to established work times and values, as discussed previously, are likely compounded over time as there are gains in efficiencies for some services in terms of time, clinical staff delegation, and improved technology, but no such gains for other services.

For many professionals who provide a heterogenous range of services paid under the PFS, this phenomenon may not have a significant overall impact on their Medicare PFS payments. However, this phenomenon would have an outsized impact on Medicare PFS payments for professionals who predominantly furnish services involving person-to-person interactions with patients that are reported and valued in time-based units. It would not be logical to assume that the marketplace ignores this dynamic, since the opportunity for increased revenue generation through efficiency for timed, one-on-one services is limited as compared to services for which there are multiple avenues to gain efficiencies.

We also recognized that, while this underlying valuation dynamic may create distortion of increasing magnitude over time, the quickly changing needs of Medicare beneficiaries relative to behavioral health also likely contribute to systemic distortion. This is especially the case as beneficiaries rely on behavioral health professionals for ongoing care of chronic and acute mental health needs. In other words, at the same time that the intensity of the work involved in furnishing services to Medicare beneficiaries increases, the work RVUs assigned to these services may be initially undervalued relative to other services that are valued based on potentially inflated time data, and therefore, may not accurately reflect the current relative resource costs associated with these services.

One approach to curb the impact of this dynamic would be to conduct more frequent revaluations of these kinds of services, including timed psychotherapy services. However, our current valuation process relies primarily, as noted, on times reported through survey data of professionals who furnish these services and assessment by the RUC of those survey data. We believe that survey results from the professionals that currently provide behavioral health services, including physicians, psychologists, and social workers could reflect the increased intensity of the work due to changes in the complexity of care for beneficiaries, but would be unlikely to address any relative undervaluation of work estimates. We are interested in working with the broader community, including the AMA RUC, to address these specific concerns over the long term.

[54] *https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-relative-value-units_0.pdf.*

However, given the emerging need for access to behavioral health care and the continuing difficulties in behavioral health workforce capacity, we believe it would be appropriate to take immediate steps to improve the accuracy of the valuation of these services until we can develop systemic solutions to longstanding process limitations. Consequently, we proposed to address the immediate need for improvement in valuation for timed psychotherapy services in such a way that considers the policy we initially finalized in the CY 2020 PFS final rule (84 FR 62856) in order to address valuation distortions for primary and longitudinal care through implementation of an add-on code for office/outpatient E/M services that involve inherent complexity, and which we proposed to reestablish in this rule. Our implementation of that policy is discussed in section II.F. of this final rule. Like E/M visits that are furnished for primary and longitudinal care, we believe that the psychotherapy codes similarly describe treatment that is ongoing or longitudinal, and therefore, we believe it is appropriate to address the need for improvement in valuation for timed psychotherapy services based on the valuation for the inherent complexity add-on code for office/outpatient E/M services.

We proposed to apply an adjustment to the work RVUs for the psychotherapy codes payable under the PFS. We proposed to base this adjustment on the difference in total work RVUs for office/outpatient E/M visit codes (CPT codes 99202 through 99205 and 99211 through 99215) billed with the proposed inherent complexity add-on code (HCPCS code G2211) compared to the total work RVUs for visits that are not billed with the inherent complexity add-on code. This resulted in an approximate upward adjustment of 19.1 percent for work RVUs for these services, comparable to the relative difference in office/outpatient visits that are also systemically undervalued absent such an adjustment, which we proposed to implement over a 4-year transition. In making significant adjustments to RVUs in past rulemaking, we have implemented such changes using a 4-year transition, noting that a transition period allows for a more gradual adjustment for affected practitioners. We proposed to apply this adjustment to the following time-based psychotherapy codes that describe one-on-one time with the patient that are significantly unlikely to become more efficient over multiple years: CPT code 90832 *(Psychotherapy, 30 minutes with patient);* CPT code 90834 *(Psychotherapy, 45 minutes with patient);* CPT code 90837 *(Psychotherapy, 60 minutes with patient);* 90839 *(Psychotherapy for crisis; first 60 minutes);* CPT code 90840 *(Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service);* CPT code 90845 (*Psychoanalysis*); 90846 (*Family psychotherapy (without the patient present), 50 minutes*); CPT code 90847 (*Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes*); CPT code 90849 (*Multiple-family group psychotherapy*); CPT code 90853 (*Group psychotherapy (other than of a multiple-family group*) and newly proposed HCPCS codes GPFC1 and GPFC2 ((*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting).* We did not propose to include CPT codes 90833, 90836, and 90838 in this list of codes for which we would make the adjustment because these are add-on codes for psychotherapy that is performed with an E/M visit and under our proposal described at section II.F. of this final rule, E/M codes will be eligible to be billed with HCPCS code G2211. Therefore, the psychotherapy codes that are performed with an E/M visit will already be eligible for an adjustment to account for the resources costs involved in furnishing longitudinal care. We stated we believe that implementing an adjustment to the work RVUs for psychotherapy services concurrent with implementation of HCPCS code G2211 will help address distortions that may occur within our valuation process that may otherwise result in understated estimates of the relative resources involved in furnishing psychotherapy services. We recognized that many other services share some similarities with these psychotherapy services. For example, there are other services that are reported in time units. Likewise, there are other codes that primarily describe conversational interactions between medical professionals and beneficiaries. However, we believe that these services are unique because neither technology nor clinical staff can be utilized to increase efficiency, and because these services represent the significant majority of services furnished by certain types of professionals. We stated that if finalized, the implementation of this proposal for CY 2024, concurrent with the proposal to implement the inherent complexity add-on code, if finalized, would also mitigate any negative impact in valuation for psychotherapy services based on redistributive impacts if we were to finalize only the inherent complexity add-on code for E/M visits without proposing and finalizing any adjustments for psychotherapy. We welcomed comments on this proposal, including and especially how the PFS valuation processes for these services and other services with similar characteristics can be improved in the future in order to mitigate the kinds of distortions previously described.

Additionally, as noted above in this section, in the CY 2018 PFS final rule (82 FR 52999), we identified a set of outlier codes for which we believed it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection of the resources involved in furnishing these services. For each of the outlier codes, we compared the ratio between indirect PE RVUs and work RVUs that result from the application of the standard methodology to the ratio for a marker code, which was CPT code 99213. The finalized change in the methodology then increased the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios. We stated we believed this approach reflected a reasonable minimum allocation of indirect PE RVUs, but that we did not have empirical data that would be useful in establishing a more precise number. We finalized implementation of one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes. We stated that we recognized that this change in the PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services and finalized that we would implement this change over a 4-year transition, beginning in CY 2018 and ending in CY 2021. We welcomed comments on whether we should consider further adjustments to the nonfacility indirect PE for the identified outlier codes. Specifically, we requested comment on whether this minimum value adjustment to the indirect PE for certain services sufficiently accounted for the resources involved in furnishing these services, or whether we should consider further adjustments, such as applying 50 percent of the calculated minimum value for nonfacility indirect PE values for these services, and whether we should consider implementing further changes using a similar 4-year transition.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed increase, and expressed appreciation that CMS recognized the limitations associated with the valuation of time-based services that must be performed directly by the clinician that offers no opportunity to become more efficient over time. Some commenters stated that the proposed changes will help close the access gap to behavioral health services by expanding the behavioral health workforce and paying more accurately for behavioral health services.

Response: We thank the commenters for their support of this proposal.

Comment: Many commenters requested that CMS also increase the values for other similar services. Some commenters stated they believe that the increase should also be applied to the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838), noting that not doing so would further exacerbate the lack of pay-parity and result in rank order anomalies. The commenters also stated that if finalized, this policy would have the unintended consequence of devaluing the work of psychiatrists when compared to psychologists, social workers, and other mental health professionals, thereby further discouraging psychiatrist participation in Medicare, while also reducing access for patients to what has been shown to be one of the most effective treatments, combined psychotherapy and medication management. These commenters also referenced our statement in the CY 2012 PFS rule final rule that, ''. . .we believe that the work involved in furnishing the psychotherapy add-on CPT codes is very similar to the work of furnishing the stand-alone psychotherapy CPT codes'' and that the work itself is the same regardless of the professional degree held by the clinician, with the same constraints due to the time-based nature of the codes and the fact that the clinician, and not their clinical staff, must provide the care. Many commenters requested that the increase also be applied to the HBAI services, as well as the psychological and neuropsychological testing services.

Response: We thank the commenters for this feedback. After consideration of the comments received, we are finalizing the 19.1 percent increase to the work RVUs for the standalone psychotherapy codes, transitioned over the course of 4 years, as proposed. Additionally, we are finalizing to apply the same increase to the work RVUs for the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838), as we agree with the commenters and our statement in past rulemaking that the work involved in furnishing the psychotherapy add-on CPT codes is very similar to the work of furnishing the stand-alone psychotherapy CPT codes, and therefore, agree that it is appropriate to apply the increase to the psychotherapy codes billed as an add-on to E/M visit in addition to the standalone psychotherapy codes. We do not wish to discourage psychiatrist participation in Medicare and believe that applying this increase to the work RVUs for all of the psychotherapy codes, whether billed with an E/M visit or as a standalone service, will avoid the relativity issues the commenters raised. In addition to finalizing the increase to the work RVUs for the standalone psychotherapy codes and the psychotherapy codes that are billed as an add-on to an E/M visit, we are also finalizing the proposed increase to the work RVUs of the codes describing HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168), as we believe that these codes are similar to the psychotherapy services in that these codes are also timed services and are generally provided person-to-person without support from clinical staff. Regarding the request to apply the proposed increase to the work RVUs of the codes describing psychological and neuropsychological testing services, we believe psychological and neuropsychological testing services are distinct from psychotherapy and HBAI services with regard to the nature of the work in that they are not necessarily timed services that are provided without assistance from clinical staff, and therefore, do not fit the same criteria as the services addressed in the proposed rule. We welcome additional feedback on the valuation of the psychological and neuropsychological testing services, and we may consider updates to the valuation of these services in future rulemaking.

Comment: The RUC acknowledged the emerging need for access to behavioral health care and the continuing difficulties in behavioral health workforce capacity, but stated they did not believe that a systematic percentage increase to the psychotherapy services would appropriately address this issue and would negatively exacerbate the relativity to other services paid under the PFS. They stated that distortions and rank order anomalies would result if finalized as proposed. For example, they noted that if these increases are implemented for CPT code 90837 (*Psychotherapy, 60 minutes with patient),* the fully transitioned work RVU in 2028 will be higher than the work RVU for CPT code 90838 (*Psychotherapy, 60 minutes with patient when performed with an evaluation and management service*), when reported with a CPT code 99213 office visit.

Response: We welcome RUC review and recommendations on the valuation for these services, however, we reiterate our concerns described in the proposed rule that survey results from the professionals that currently provide behavioral health services, including physicians, psychologists, and social workers, could reflect the increased intensity of the work due to changes in the complexity of care for beneficiaries, but would be unlikely to address any relative undervaluation of work estimates due to the longstanding systematic undervaluation of this type of work. Additionally, as noted above, we are finalizing to apply the 19.1 percent increase to the work RVUs for the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838), transitioned over the course of 4 years, in order to avoid any rank order anomalies within the psychotherapy code family.

Comment: A few commenters suggested that as an alternative to the proposed increase, CMS create a separate G-code for psychiatry services with an RVU equivalent to the RVU for HCPCS code G2211 that could be used by qualified mental health professionals (that is, psychologists and social workers) as an add-on to stand-alone psychotherapy, similar to the way the CPT code 90785 (*Interactive Complexity*) is used.

Response: While an add-on G-code could serve to address the issues we cited in the proposed rule, we believe that building the proposed increase into the valuation of these services would more directly address the systematic undervaluation of these services. Unlike HCPCS code G2211 and CPT code 90785, which are meant to be billed only in certain specified circumstances, we believe that the issues we describe in the proposed rule apply the psychotherapy services uniformly.

Comment: A few commenters expressed concern that the proposed increase is insufficient, especially recognizing that many of the practitioners who bill these codes, including Clinical Social Workers, and as of January 1, 2024, Marriage and Family Therapists and Mental Health Counselors, are only reimbursed at 75 percent of the PFS rate. The commenters recommended that CMS consider

further adjustments to the ratesetting methodology, pending legislative change. The commenters noted that a more substantial increase would further the goal of bringing more mental health and SUD practitioners into the Medicare program. One commenter recommended that CMS consider ways to either mitigate the impact of behavioral health payment increases on other services by spreading budget neutrality adjustment over longer time horizons, or suggested that Congress should appropriate additional, permanent funding for behavioral health services within the PFS.

Response: We will continue to evaluate how we can ensure that these services are valued accurately, but we believe that the final increase of 19.1 percent to the work RVUs for psychotherapy services and psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838) is sufficient. We based this adjustment on the valuation for the inherent complexity add-on code that will be used with office/outpatient E/M services to address valuation distortions for primary and longitudinal care, and since the psychotherapy codes similarly describe treatment that is ongoing or longitudinal, we believe that it is appropriate to address the need for improvement in valuation for timed psychotherapy services based on the valuation for the inherent complexity add-on code for office/outpatient E/M services.

Regarding ways to mitigate the impact of these increases on other services, we note that we are implementing these changes over a 4-year transition, as we have done when making significant adjustments to RVUs in past rulemaking. We believe that this transition period will allow for a more gradual budget neutrality adjustment for affected practitioners. Regarding practitioners such as CSWs, MFTs, and MHCs being paid at 75 percent of the PFS rate for services of a clinical psychologist, we note that this is a requirement specified in section 1833(a)(1)(FF) of the Act.

Comment: Some commenters supported finalizing the proposal but recommended that CMS view the adjustment as a temporary stopgap and consider long-term solutions to code valuation moving forward. Another commenter urged CMS to implement RVU accuracy assessments annually, or at least more frequently.

Response: We reiterate that we are interested in working with the broader community, including the AMA RUC, to address these specific concerns regarding valuation and RVU accuracy over the long term.

Comment: One commenter stated that the market rate for out-of-network mental health care far exceeds Medicare rates and suggested that CMS should conduct a review and issue a report comparing out-of-network billing rates to Medicare rates and determine if the current code valuation process reflects the market. The commenter went on to suggest that accordingly, CMS should make changes to the RUC/RVU system so it more closely values behavioral healthcare at market rates. The commenter also noted that CMS should recognize that it has historically undervalued these rates for decades and it will take time and incentives to grow the workforce.

Response: We thank the commenter for this feedback. We note that we are trying to address potential historical undervaluation of certain mental health services in this rule. We will continue to evaluate how we can make sure that these services are valued accurately and may consider these comments regarding market rates for future rulemaking.

After consideration of the public comments, we are finalizing our proposal to apply an upward adjustment of 19.1 percent to the work RVUs for the standalone psychotherapy services, in addition to the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838) and the codes describing HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168), and we are finalizing our proposal to implement this adjustment over a 4-year transition.

6. Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) Bundle (HCPCS Codes G2086–G2088)

In the CY 2023 PFS final rule (87 FR 69772 through 69774), we finalized a modification to the payment rate for the non-drug component of the bundled payment for episodes of care under the Opioid Treatment Program (OTP) benefit to base the rate for individual therapy on a crosswalk to CPT code 90834 *(Psychotherapy, 45 minutes with patient),* which reflects a 45-minute psychotherapy session, instead of a crosswalk to CPT code 90832 *(Psychotherapy, 30 minutes with patient),* as was our current policy at the time. We received public comments urging us to consider adopting this modification for other bundled payments for SUD under the PFS, such as the bundled rate for office-based SUD treatment, to reflect the complexity of treating these patients and ensure that there is consistent and sufficient access to counseling for SUD across settings of treatment. The commenters noted that some patients who are prescribed buprenorphine in non-OTP settings will have similarly complex care needs requiring more intensive therapeutic care, and that by recognizing the appropriate complexity and intensity of the services in setting the rates, CMS can incentivize more office-based practices to offer these services and build out the treatment teams that deliver this care.

In the CY 2020 PFS final rule (84 FR 62673 through 62677), we finalized the establishment of bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We stated that for the purposes of valuation of HCPCS codes G2086 (*Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month)* and G2087 (*Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month),* we assumed two individual psychotherapy sessions per month and four group psychotherapy sessions per month, and noted that we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. We were persuaded by the public comments received in response to the CY 2023 PFS proposed rule requesting that these codes be priced consistent with the crosswalk codes used to value the bundled payments made for OUD treatment services furnished at OTPs, as beneficiaries receiving buprenorphine in settings outside of OTPs may have similarly complex care needs as compared to beneficiaries receiving OUD treatment services at OTPs. In order to update the valuation for HCPCS codes G2086 and G2087, we proposed to increase the current payment rate to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 *(Psychotherapy, 45 minutes with patient),* rather than CPT code 90832 *(Psychotherapy, 30 minutes with patient).* The current work RVU assigned to CPT code 90834 is 2.24, compared to the work RVU assigned to CPT code 90832, which is 1.70, which results in a difference of 0.54 work RVUs. Because the bundled payments

described by HCPCS codes G2086 and G2087 include two individual psychotherapy sessions per month, we proposed to add 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087, which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087. We noted that as described above, we also proposed to update the work RVUs assigned to CPT code 90834. We noted in the proposed rule that if our proposal to update the work RVUs for the standalone psychotherapy codes were finalized, CPT code 90834 would be assigned a work RVU of 2.35. We stated that in that case, our update to HCPCS codes G2086 and G2087 would also reflect the updated work RVUs for 90834 and would result in a work RVU of 8.36 for HCPCS code G2086 and a work RVU of 8.19 for HCPCS code G2087.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for this proposal. Commenters stated that they agreed that the proposed increase more accurately reflects the cost, time, and effort of delivering these services. Commenters stated that by making the proposed adjustment, CMS will help to increase access to office-based SUD treatment and meet beneficiaries where they are and noted that the proposed increased payment rate will also enable more auxiliary personnel to participate in interdisciplinary teams, further ensuring that beneficiaries have the full range of services and supports they need. Some commenters stated that the proposed payment increase will help ensure that the complex care needs of patients receiving in-office treatment for SUDs are addressed and that the complexity of delivering office-based SUD treatment is accurately reflected.

Other commenters expressed support for actions to facilitate access to substance use disorder treatment, including medications for Opioid Use Disorder, like buprenorphine, noting that the U.S. is in the midst of a drug overdose epidemic and that according to the Centers for Disease Control and Prevention, 106,699 people died from a drug overdose in 2021, a 14 percent increase from 2020.[55] The commenters described that in-office treatment for SUDs can also enable patients to receive care for co-occurring conditions.

Response: We thank the commenters for their support of this proposal. We agree that the proposed increase more accurately reflects the cost, time, and effort of delivering office-based SUD services. We aim to ensure that beneficiaries have access to the full range of services needed, especially in light of the drug overdose epidemic referenced in the comments. After consideration of the public comments, we are finalizing as proposed to increase the payment rate for HCPCS codes G2086 and G2087 to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 *(Psychotherapy, 45 minutes with patient),* rather than CPT code 90832 *(Psychotherapy, 30 minutes with patient).*

7. Comment Solicitation on Expanding Access to Behavioral Health Services

In recent years, we have made efforts to undertake rulemaking and establish policies to expand access to behavioral health services, consistent with the CMS Behavioral Health Strategy, which aims to strengthen quality and equity in behavioral health care; improve access to substance use disorders prevention, treatment, and recovery services; ensure effective pain treatment and management; improve mental health care and services; and utilize data for effective actions and impact.[56] We continue to be interested in hearing feedback regarding ways we can continue to expand access to behavioral health services. For example, we welcomed feedback regarding ways to increase access to behavioral health integration (BHI) services, including the psychiatric collaborative care model; whether we could consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness; intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule; and how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties. Additionally, we solicited comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated.

We welcomed comments from the public on these topics as well as any other ways we might consider expanding access to behavioral health services for Medicare beneficiaries.

We received public comments in response to these comment solicitations. The following is a summary of the comments we received and our responses.

Comment: We received many detailed comments on these topics. Commenters provided feedback regarding potential ways to expand implementation of the psychiatric collaborative care model (CoCM) and suggestions to support technical assistance and increased payments for CoCM.

In response to our comment solicitation regarding whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, several commenters encouraged CMS to enable wider implementation under Medicare of the Safety Planning Intervention (SPI) and the Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) and expressed that the current payment mechanisms are not sufficient, noting that the lack of adequate payment mechanisms and suitable billing codes for these interventions are barriers that are essential to address. The commenters noted that EDs are not the only care setting where there is need and opportunity to enhance suicide prevention, but that elevated suicide risk is particularly prevalent among ED patients. One commenter noted that a designated code for SPI would make it significantly easier to document that SPI was furnished, including in quality reporting and value-based payment programs. Commenters also cited that multiple trials have found FCI to reduce improve outcomes and specifically, to reduce suicide attempts and deaths, but noted that despite the effectiveness of these interventions, they are underutilized.

Regarding settings of care where IOP services are furnished, commenters described that IOP services are most commonly delivered in freestanding community-based SUD treatment facilities and suggested that CMS create coding that would enable IOP to be delivered in these settings.

[55] *https://www.cdc.gov/drugoverdose/deaths/index.html.*

[56] *https://www.cms.gov/cms-behavioral-health-strategy.*

Commenters also suggested a variety of ways to improve psychiatrist participation in Medicare and many cited low and disparate reimbursement rates as a significant barrier.

Response: We thank the commenters for the many detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

8. Request for Information on Digital Therapies, Such as, but not Limited to, Digital Cognitive Behavioral Therapy

The widespread adoption and use of software technologies, including, but not limited to digital therapeutics, is creating new ways to treat patients. In recent years, the Food and Drug Administration (FDA) has reviewed and cleared several mobile medical applications (''apps'') that have been shown to demonstrate a reasonable assurance of safety and effectiveness for addressing a variety of health conditions including sleep disorders disturbances and substance use disorders. These breakthrough devices include apps for depression and anxiety. Our understanding is that these mobile medical apps generally require a prescription or referral from a clinician and are used for specific medical purposes rather than general wellness and education.

As technologies have evolved, we have sought public comment and expanded Medicare payment under Part B for use of technologies in remote monitoring of treatment and physical health. Beginning in 2018, CMS began making separate payment for the services described by CPT code 99091, which paid for collection and interpretation of physiologic data digitally stored and/or transmitted to the practitioner. Beginning in 2019, we began paying for additional new remote physiologic monitoring (RPM) codes.

We have continued to improve and expand payment for remote treatment and monitoring in subsequent years. In 2022, we began paying for a new class of CPT codes (98975, 98980, and 98981) for Remote Therapeutic Monitoring (RTM) in addition to RPM, which enabled reimbursement of monitoring of non-physiologic data, to help ensure Medicare beneficiaries have access to these services. RTM is currently limited to monitoring respiratory system status, musculoskeletal status, and therapy adherence, or therapy response (87 FR 69647). However, we continue to add, clarify, and refine payment for RTM codes.

In the CY 2023 PFS final rule (87 FR 69645), we finalized a new RTM code for supply of a device for cognitive behavioral therapy monitoring (CPT Code 989X6 *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily)*) *recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days).* In that rule, we noted specialty societies indicated the technologies for this service are still evolving, and as a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. We accepted the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. We stated we would work with Medicare Administrative Contractors (MACs) to better understand the devices and device costs they encounter as they review claims for payment for the new cognitive behavioral monitoring code.

For both RPM and RTM codes, the device used must meet the FDA definition of a device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). As we continue to gather information on how remote monitoring services are used in clinical practice and experience with coding and payment policies for these codes, we requested information on the following areas to improve our understanding of the opportunities and challenges related to our coverage and payment policies, as well as claims processing, as we consider the need for further practitioner education, program instructions, and guidance, or potential future rulemaking regarding these services.

- How do practitioners determine which patients might be best served by digital therapeutics? How do practitioners monitor the effectiveness of prescribed interventions, such as, but not limited to, for their patients on an ongoing basis once the intervention has begun?
- We sought comment and real-life examples where digital cognitive behavioral therapy or other digital enabled therapy services are used by clinicians, and how the technology is imbedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital cognitive behavioral therapy?
- What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health?
- What are effective models for distribution/delivery of digital therapeutics, such as prescription digital mental health therapy products to patients? What best practices exist to ensure that patients have the necessary support and training to use applications effectively?
- What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate for and/or recommended standard of care in the delivery of these services?
- How are data that are collected by the technology maintained for recordkeeping and care coordination?
- What information exists about how an episode of care should be defined, particularly in circumstances when a patient may receive concurrent RTM or digital CBT services from two different clinicians engaged in separate episodes of care?
- We noted in previous rulemaking that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected. We sought information on the type and frequency of circumstances that involve multiple medical devices and multiple clinicians. How might allowing multiple, concurrent RTM services for an individual beneficiary affect access to health care, patient out-of-pocket costs, the quality of care, health equity, and program integrity?
- Do interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981? What impediments may exist to using these codes for digital CBT?
- In the past, commenters generally supported the concept of a generic RTM device code, and offered a wide variety of possible use cases, including where FDA approved devices and devices that have gone through other premarket pathways exist for the purpose of monitoring various conditions that do not meet the current scope of the existing RTM codes.

++ What are the advantages and disadvantages of a generic RTM device code, versus specific RTM codes?

++ Would generic device codes undermine or stall progress toward a wider set of specific codes that would provide less ambiguity on reimbursement?

++ How might generic RTM codes for supply of a device be valued given the broad array of pricing models?

- What scientific and clinical evidence of effectiveness should CMS consider when determining whether digital therapeutics for behavioral health are reasonable and necessary?
- What aspects of digital therapeutics for behavioral health should CMS consider when determining whether it fits into a Medicare benefit category, and which category should be used?
- If CMS determines the services fit within an existing Medicare benefit category or if other coverage requirements are met, what aspects of delivering digital cognitive based therapy services should be considered when determining potential Medicare payment? Under current practice models, are these products used as incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?
- Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?
- What strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services?
- What are some potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with State behavioral health privacy requirements?

We received public comments in response to our request for information on Digital Therapies, such as, but not limited to, digital Cognitive Behavioral Therapy. The following is a summary of the comments we received and our responses.

Comment: We received many detailed comments in response to our Request for Information on digital therapies, such as, but not limited to, digital Cognitive Behavioral Therapy. Some commenters stated that CMS has existing authority to pay for two types of digital therapeutics: those that meet the definitions of durable medical equipment (DME) and those that are used incident to a physician service, assuming other relevant criteria are met. The commenters suggested that CMS should continue to use their authority to code and pay for digital therapeutics that are cleared by the FDA consistent with other prescription medical devices that fall under these existing benefit categories, and that are reasonable and necessary for the treatment of illness or injury. Additionally, the commenters stated that regarding coding and payment under the PFS for digital therapeutics that are furnished incident-to a physician's service, they noted that there are new coding proposals shown in the public agenda for the September 2023 CPT Editorial Panel meeting to allow for reporting of digital CBT (dCBT) and remote therapeutic treatment and other digital therapeutics as incident-to services. These commenters stated that such coding would provide an appropriate mechanism to facilitate coverage when furnished incident-to a healthcare practitioner's service and stated that if such coding is not adopted, they would encourage CMS to use its authority to adopt such coding under the HCPCS system where CMS would establish a separate set of G-codes to account for when digital therapeutic devices are acquired by a Medicare enrolled practitioner, and that practitioner then furnishes that device to a patient and manages their treatment.

Response: We thank the commenters for their detailed feedback on this topic. In the CY 2023 PFS final rule (87 FR 69645 through 69649), we accepted the RUC's recommendation to contractor price CPT code 98978, a PE-only code that describes provision of a monitoring device for CBT and noted that we would work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment for the services described by this code. Additionally, we note that the existing codes described by CPT codes 98978, 98980, and 98981 allow for the billing of remote therapeutic monitoring services, including monitoring patient adherence and therapy response for use with cognitive behavioral therapy. In response to the commenters' statement that there are new coding proposals shown in the public agenda for the September 2023 CPT Editorial Panel meeting to allow for reporting of digital CBT (dCBT) and remote therapeutic treatment and other digital therapeutics as incident-to services, we note that we routinely rely on the CPT coding process as a critical part of how services, including those involving emerging technologies, that might be paid under the PFS are understood and provided by medical professionals. While we do not always rely on CPT exclusively, we look forward to reviewing any forthcoming codes and potential recommendations for the valuation of such codes through our standard annual processes. Additionally, we continue to be interested in any feedback from interested parties on this topic, including feedback from interested parties about any potential codes that we would review under those processes and considerations we might need to take into account for future rulemaking to improve the accuracy of coding and payment under the Medicare PFS. For example, we welcome nominations for potentially misvalued codes and refer to the public nomination process outlined in section II.C. of this final rule, which can be used to help us identify codes that should be prioritized for review through the RUC process as well as resource costs involved in furnishing reasonable and necessary care to Medicare beneficiaries that are not accurately reflected under existing coding and payment policies. In some specific cases, of course, we have identified the need to develop G-codes as part of proposals to improve accuracy of payment for services paid under the PFS.

In response to the comments regarding DME, we note that for a digital therapeutic item to be designated as DME it must meet the Medicare definition of DME. DME is defined in section 1861(n) of the Act and Medicare regulations at 42 CFR 414.202, and means equipment furnished by a supplier or a home health agency that meets the following conditions: (1) Can withstand repeated use; (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) Is primarily and customarily used to serve a medical purpose; (4) Generally is not useful to an individual in the absence of an illness or injury; and (5) Is appropriate for use in the home. All five of these conditions must be met in order for equipment to be classified as DME.

K. Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') In the CY 2023 PFS final rule

(87 FR 69663 through 69688), we identified certain clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act.

The regulation at § 411.15(i)(3)(i) includes examples of services for which payment can be made under Medicare Parts A and B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related to the clinical success of, certain other covered services (hereafter in this section, ''inextricably linked to other covered services'').

Recognizing that there may be other instances where covered services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, in the CY 2024 PFS proposed rule we proposed to codify other instances where dental services are inextricably linked to other covered services such that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act (88 FR 52371 through 52384). At the same time, we continue to recognize that there are dental services that are not, or currently not evidenced to be, inextricably linked to other covered services. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act, except when, due to the patient's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act will apply.

In the CY 2023 PFS final rule (87 FR 69682, 69685, 69687), we also established a process for the public to submit additional dental services that may be inextricably linked to other covered services for our consideration and review and finalized a policy to permit payment for certain dental services, such as dental examinations and necessary treatment, prior to or contemporaneously with the treatment of head and neck cancers, beginning in CY 2024. The process for the public to submit comments is discussed below.

In the CY 2024 PFS proposed rule, we proposed to codify in section § 411.15(i)(3)(i)(A) additional policies to permit payment for certain dental services that are inextricably linked to other covered services. We also proposed to make non-substantive technical changes to improve the clarity of the regulation text (88 FR 52740).

b. Other Medical Services for Which Dental Services May Be Inextricably Linked

In the CY 2023 PFS final rule, we discussed whether we should specify that payment can be made under Medicare Parts A and B for certain dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures, or other surgical procedures. We stated that we remain committed to exploring the inextricable link between dental and covered services associated with immunosuppressant therapy, joint replacement surgeries, and other surgical procedures and that we welcomed continued engagement with the public to review the clinical evidence to determine whether certain dental services were inextricably linked to other covered services (87 FR 69668 and 69680 through 69686).

We partnered with researchers at the Agency for Healthcare Research and Quality (AHRQ) to consider the relationship between dental services and specific covered services and reviewed available clinical evidence regarding the relationship between dental services and medical services in the treatment of cancer using chemotherapeutic agents, which may lead to more clinically severe infections and often involve immunosuppression in patients.[57] [58] The AHRQ report [59] regarding dental services and the link between medical services is available at *https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/rapid-response-chemotherapy-dental.pdf*. For example, it is generally understood that many chemotherapeutic agents used in the treatment of cancer target rapidly proliferating cells (which include those cells found in healthy tissue, like the oral mucosa). This targeting of rapidly reproducing cells in the oral mucosa can lead to the development of oral mucositis, which can negatively affect individuals with periodontitis and other dental conditions more severely, especially when exposed to higher doses/duration of chemotherapy.[60] Another example of a dental-related issue resulting from covered services that are immunosuppressive in nature is medication-related osteonecrosis of the jaw (MRONJ). MRONJ may occur as an adverse effect when patients with cancer receive specific covered services, such as high-dose antiresorptive and/or antiangiogenic drug therapy (for example, high doses of bisphosphonates or drugs like denosumab used to treat osteoporosis) or bone-modifying therapy in conjunction with their chemotherapy regimen. Patients with existing dental disease are most at risk for developing MRONJ secondary to bone-modifying therapy. MRONJ complicates the cancer treatment and can reduce survival rates up to 3 years post-treatment.[61] Dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[62] Further, AHRQ noted that there is abundant worldwide experience and related standards of care in the management of patients whose medical conditions require chemotherapy regimens that induce immunosuppression and that this experience has led to an understanding of how improved dental care potentially can reduce the incidence of serious infections and improve overall patient outcomes.

The AHRQ examined the effects of dental care prior to treatment on the success of medical services for patients receiving chemotherapy regimens (primary medical service) in the treatment of cancer (primary medical illness). As part of this analysis, AHRQ identified 26 primary research studies, seven systematic reviews, and five practice guidelines that outline the benefits and harms of pre-treatment dental services and their effects on cancer chemotherapy regimens. The

[57] Immunosuppression describes an impairment of the cells of a patient's immune system and a reduction in their ability to fight infections and other diseases.

[58] National Cancer Institute. NCI Dictionary of Cancer Terms. 2019. Available at *https://www.cancer.gov/publications/dictionaries/cancer-terms*.

[59] Hickam DH, Gordon CJ, Armstrong CE, Coen MJ, Paynter R, Helfand M. The Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy for Cancer. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC021. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/10.23970/AHRQEPCRAPIDDENTALCANCER*.

[60] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573-0002.2017.03*.

[61] Corraini, P., Heide-Jørgensen, U., Schiødt, M., Nørholt, S. E., Acquavella, J., Sørensen, H. T., & Ehrenstein, V. (2017). Osteonecrosis of the jaw and survival of patients with cancer: a nationwide cohort study in Denmark. Cancer medicine, 6(10), 2271–2277. *https://doi.org/10.1002/cam4.1173*.

[62] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573-0002.2017.03*.

studies were selected using specific inclusion criteria: a sample of patients beginning cancer treatment within 2 months; targeted dental services occurring prior to cancer treatment; outcomes data, such as rates of serious adverse events, quality of life, cancer relapse rates, mortality, or adherence to cancer treatment; and a minimum sample size of 10 patients.

The 26 primary research studies identified by AHRQ included prospective cohort studies, retrospective cohort studies, randomized controlled trials, and registry-based studies. From this group of studies, AHRQ found evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the covered services, as well as requiring fewer emergency treatments.[63] [64] There was further evidence found in systematic reviews that showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[65] They note that treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (often life-threatening) bacterial and fungal infections, and that the route of entry of these offending bacteria can be the mouth. AHRQ also analyzed several clinical practice guidelines that supported a dental evaluation/treatment before initiating chemotherapy so that any oral complications could be mitigated prior to initiating care to treat the cancer.[66] [67] [68]

[63] Watson EE, Metcalfe JE, Kreher MR, *et al.* Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397–e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[64] Owosho AA, Liang STY, Sax AZ, *et al.* Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668.*

[65] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, *et al.* Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328.*

[66] Elad S, Cheng KKF, Lalla RV, *et al.* MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2020 Oct 1;126(19):4423–31. doi: *https://dx.doi.org/10.1002/cncr.33100. PMID: 32786044.*

[67] Yarom N, Shapiro CL, Peterson DE, *et al.* Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270–90. doi: *https://dx.doi.org/10.1200/JCO.19.01186. PMID: 31329513.*

[68] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

c. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we stated that we believed there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on the basis that dental services are inextricably linked to other covered services (87 FR 69686). In order to ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we finalized an annual public process, including notice and comment rulemaking, whereby interested parties can submit recommendations for other clinical scenarios for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3)(i).

Through this process, we stated that we would review clinical evidence to assess whether there is an inextricable link between certain dental and covered services because the standard of care for that medical service is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69685). We also stated that, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services (87 FR 69666). As such, we requested that documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to other covered services. Specifically, we requested that the medical evidence should:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to other covered services; and

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient) (87 FR 69686).

We stated that interested parties should submit medical evidence to support, for the recommended clinical scenario, the inextricable link between certain dental services and other covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686, 69687).

We stated that we intended to use the PFS annual rulemaking process to discuss public submissions when considering whether the recommended dental services associated with certain clinical scenarios should be considered outside the scope of the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to other covered services. We believe that public feedback is important, especially when considering Medicare payment for dental services that may benefit the clinical outcomes for certain covered services. We believe that using our annual notice and comment rulemaking process to discuss submitted recommendations will allow the public to comment and submit further medical evidence to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit

Medicare payment for the dental services. Under the public process established in the CY 2023 PFS final rule, recommendations received by February 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. The deadline for submissions for potential consideration for CY 2024 rulemaking was February 10, 2023. We received eight submissions from various organizations on or before February 10, 2023. We received one submission after the deadline that presented nominations for covered services that have already been addressed by this payment policy.

Submissions included recommendations for payment under Medicare Parts A and B of dental services prior to covered services associated with the treatment of cancer (chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, bone-modifying agents or antiresorptive therapy), total joint arthroplasty, all cardiovascular procedures, diabetes treatment, treatment for sickle-cell anemia and hemophilia, and systemic autoimmune diseases. Additionally, many submissions recommended that CMS refine certain terminology surrounding previously finalized policies, specifically around whether payment can be made for dental services furnished during and after the performance of certain covered services.

Several submissions recommended that Medicare make payment under Parts A and B for dental services prior to covered services associated with the treatment of patients with leukemia and lymphoma, as well as other cancers. Most submitting organizations stated that, by examining and addressing the oral health of the patient prior to the initiation of chemotherapy in the treatment of cancer, with or without radiation, oral complications could be appropriately addressed or prevented that would improve the clinical success of the overall cancer treatment. Submissions also recommended Medicare payment under Parts A and B for dental services before, during, and after CAR T-cell therapy and other lymphodepleting covered services (lymphodepleting therapy involves a short course of chemotherapy that targets T-cells, preconditioning the body prior to enhance treatments like CAR T-cell therapy). These submissions stressed the need to detect and monitor dental issues early to avoid the increased risk of related infections and complications.

Most submissions stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of antiresorptive and/or antiangiogenic drug therapy used to help manage the treatment of cancer. Several recommended that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated, such as blood and solid tumor cancers and metastatic cancers associated with the risk of osteonecrosis of the jaw. These submissions recommended payment of dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. One provided references that support the provision of dental services to prevent, or as part of treatment for MRONJ. Another submission stated that the risk of MRONJ is significantly greater in patients receiving antiresorptive therapy in connection with cancer treatment compared to patients receiving antiresorptive therapy for osteoporosis.[69] However, the submitter stated that the combination of poly-pharmaceutical management of cancer patients and related immunosuppression are risk factors for MRONJ without exposure to antiresorptive agents and that it would be difficult to identify a single medication as the etiologic agent for MRONJ in case reports or mini-case series. The submitter stated that prevention of MRONJ would be the clinical gold standard.

One submission also recommended that Medicare make payment under Parts A and B for dental services prior to all cardiovascular procedures. In their view, the provision of dental services to reduce the risk of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. They cited a literature review supporting the need for screening and treatment for oral/dental infections before cardiac surgery. This submission did not recommend dental services prior to a specific cardiovascular procedure; rather, it recommended dental services prior to all cardiovascular procedures. The literature review they cited (which we discuss in section II.K.3. of this final rule) noted that there was a mixture of medical literature to support the performance of dental services prior to all cardiac procedures in part because such cardiovascular procedures are more urgent or emergent than elective.

One submission recommended that Medicare make payment under Medicare Parts A and B for dental services prior to joint replacement surgeries, specifically total knee and hip arthroplasty. The submitting organization stated that providing dental services prior to or contemporaneously with joint replacement surgeries may result in more rapid healing and quicker rehabilitation, especially if a known dental infection could be addressed and potentially prevent surgical and rehabilitation complications for the patient. However, the submission acknowledged that there is no consensus on whether performing dental services prior to joint replacement surgeries improves the clinical outcomes of the medical service or whether it is typical in practice to furnish dental services before joint replacement procedures.

Other submissions recommended Medicare make payment for dental services for patients diagnosed with a specific condition(s), such as patients with poorly controlled diabetes mellitus or individuals living with sickle cell disease (SCD) or hemophilia.

Submissions also recommended Medicare payment for dental services for persons affected by systemic autoimmune disease. They argued that dental services are essential for medical treatment for individuals at much higher risk of advanced dental decay, dental loss, and/or gum disease. They stated that reducing oral infection of the mucosa, teeth, and gums; oral inflammation; and tooth loss through consistent oral management reduces the systemic impact that these dental conditions have on a patient's systemic autoimmune disease. One submission stated that oral health disparities

[69] We note that antiresorptive therapy for cancer is the parenteral administration of bisphosphonates and denosumab, also called osteoclast inhibitors, for the purpose of reducing the frequency of skeletal complications (for example, fractures) in patients with multiple myeloma and in those with bone metastases from solid tumors. Per FDA label, they are administered parenterally and in doses that exceed those typically used for patients with osteoporosis. (Only two bisphosphonates, pamidronate and zoledronic acid, and the single monoclonal antibody, denosumab, have the cancer indication).

Antiresorptive therapy for osteoporosis is typically for the postmenopausal female patient, for the purpose of reducing the risk of skeletal fracture (for example, vertebral, hip) in those patients who have a high fracture risk. They are typically dosed orally, at dosages that have significant supportive efficacy and safety data. Parenteral administration of bisphosphonates is available for osteoporosis for patients that are unable to take an oral preparation, at significantly lower dosages.

For example, the dosage difference for zoledronic acid between the two indications would be as follows: cancer (for example, multiple myeloma, bone metastases) at 4 mg IV every 3 to 4 weeks compared with osteoporosis at 5 mg every 12 months.

disproportionately affect members of racial or ethnic minority groups, which they offered is most pronounced in populations aged 65 and older. Another presented their proposal to bridge the gap in health equity and to improve the health outcomes for those ages 65 and older living with autoimmune diseases.

We thanked all those who submitted recommendations for clinical scenarios for which they believe Medicare payment for dental services will be consistent with the policies we codified and clarified in the CY 2023 PFS final rule at § 411.15(i)(3)(i), under which Medicare payment may be made for dental services when they are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services (hereafter in this section, ''inextricably linked to other covered services''). We continued to encourage interested parties to engage with us regularly and to submit recommendations for our consideration of additional clinical scenarios where dental services may be inextricably linked to other covered services. As stated earlier, interested parties should provide evidence to support or refute that at least one of the three criteria listed above for submissions is met. Furthermore, submissions should focus on the inextricably linked relationship between dental services and other medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status, and whether it is not clinically advisable to move forward with the primary medical service without performing certain dental services. We remind readers once again that, to be considered for purposes of CY 2025 PFS rulemaking, submissions through our public process for recommendations on payment for dental services should be received by February 10, 2024, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Interested parties should include the words ''dental recommendations for CY 2025 review'' in the subject line of their email submission to facilitate processing. We continue to stress to submitters that recommendations must include at least one of the types of evidence listed earlier when submitting documentation to support the inextricable link between specified dental services and other covered services. We further note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

2. Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

Under our current policy, we have identified several clinical scenarios where dental services are inextricably linked to other covered services that is covered by Medicare, such that Medicare payment for the dental services is not precluded by section 1862(a)(12) of the Act. After further review of current medical practice, and through internal and external consultations and consideration of the submissions received through the public process established in the CY 2023 PFS final rule (87 FR 69669), we believe there are additional circumstances that are clinically similar to the scenarios we codified in our regulation at § 411.15(i)(3)(i) as examples of clinical scenarios under which Medicare payment may be made for certain dental services because they are inextricably linked to other covered medical services.

As described in the CY 2024 PFS proposed rule, in the case of the proposed primary-covered services, we believe that dental services are inextricably linked to, and substantially related and integral to the clinical success of, the proposed covered services because such dental services serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services, including infection (88 FR 52374 through 52380). Additionally, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services or if the dental services are considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment. As such, we believed the certain dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, the following medical services, and we proposed that the statutory dental exclusion would not apply:

(1) Chemotherapy when used in the treatment of cancer;

(2) CAR T-Cell therapy, when used in the treatment of cancer; and

(3) Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

As such, we proposed to revise our regulation at § 411.15(i)(3)(i)(A) by adding to the list of clinical scenarios in which Medicare Part A and B payment is permitted for dental or oral examinations performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

a. Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer

In the CY 2024 PFS proposed rule, we discussed clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of chemotherapy services. We stated that there is an inextricable link between certain dental and chemotherapy services when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the chemotherapy services when used in the treatment of cancer (88 FR 52377). Chemotherapy services, when used in the treatment of cancer, cause immunosuppression which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn leads to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) such that the standard of care would be to not

proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of chemotherapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment. Therefore, we believed the dental services are integral and inextricably linked to the chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply.

We proposed to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we proposed to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered chemotherapy when used in the treatment of cancer; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer. We solicited comments on all aspects of this proposal.

Additionally, we noted that we proposed that payment is permitted for dental services that are inextricably linked to chemotherapy used in the treatment of cancer with or without the use of other therapy types, including radiation therapy in the treatment of cancer. That is, this provision is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies. We solicited comment on this aspect of the proposal.

As discussed in section II.K.2. of this final rule, we received submissions through the public process and comments on the CY 2023 PFS proposed rule requesting that Medicare payment should be permitted under Parts A and B for dental services when medical services that cause immunosuppression are being provided to treat a variety of medical conditions.

Commenters asserted that immunocompromised patients are at an increased risk of serious infection that can lead to severe conditions (87 FR 69683). We stated that we agreed with commenters that individuals who are immunocompromised may be prone to serious infection, and that we will continue to consider feedback and the clinical literature provided by interested parties to determine whether there are other clinical scenarios, such as the initiation of immunosuppressive therapies, where Medicare payment should not be excluded for dental services under section 1862(a)(12) of the Act, because the services are inextricably linked to other covered services.

In the CY 2023 PFS final rule (87 FR 69681) and as discussed in section II.K.2. of this final rule, we stated that we were finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer. We stated that removing infections in the oral cavity is necessary to prepare patients for treatment and is inextricably linked to the clinical success of treatment for cancers of the head and neck. There is significant and abundant worldwide experience and research regarding the care of patients whose medical conditions require chemotherapy regimens that induce acute immunosuppression.[70] [71] The treatment of a broad range of malignancies often requires chemotherapeutic agents that, in turn, suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (potentially life-threatening) infections. The route of entry of the offending pathogens can be the mouth.[72] [73] [74] Therefore, individuals receiving chemotherapy treatment for cancer who become immunosuppressed may be more susceptible to infection and other adverse events with serious consequences for the patient. We understand that medical services used in cancer treatment, such as chemotherapy, induce immunosuppression. As such, we believe that cancer patients being treated with chemotherapy represent an acutely impacted, immunocompromised patient population due to the nature of the effects of such chemotherapy treatment. If dental or oral infections are left undetected or untreated in these patients, serious complications may occur, negatively impacting the clinical success of the medical services and outcomes for the patients. Moreover, the immunosuppression induced by the chemotherapy medical services in cancer treatment increases the likelihood and intensity of complications for the patient that could potentially jeopardize or impact the ability to complete the totality of the treatment across a normal course of treatment.[75] [76] If an oral or dental infection is not properly diagnosed and treated prior to and/or during the chemotherapy in the treatment of cancer, which suppresses the immune system, there may be an increased risk for local and systemic infections from odontogenic sources. Furthermore, the successful completion of that treatment could be compromised. Additionally, if such an infection is not treated, then there is an increased likelihood of morbidity and mortality resulting from the spreading of the local infection to sepsis.[77] [78]

Individuals undergoing chemotherapy services used in the treatment of cancer who become immunosuppressed by the treatment may also experience oral mucositis, which often facilitates the entry of oral bacteria into the body, potentially increasing the risk of infection for the patient and compromising the chemotherapy

[70] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329.* PMID: 32166855.

[71] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896.* PMID: 25024068.

[72] Mirowski GW, Bettencourt JD, Hood AF. Oral infections in the immunocompromised host. Semin Cutan Med Surg. 1997 Dec;16(4):249–56. doi: *https://dx.doi.org/10.1016/s1085-5629(97)80013-2.* PMID: 9421215.

[73] Greenberg MS, Cohen SG, McKitrick JC, et al. The oral flor as a source of septicemia in patients with acute leukemia. Oral Surg Oral Med Oral Pathol. 1982 Jan;53(1):32–6. PMID: 6948251.

[74] King A, Irvine S, McFadyen A, et al. Do we overtreat patients with presumed neutropenic sepsis? Postgrad Med J. 2022 Nov;98(1165):825–9. doi: *https://dx.doi.org/10.1136/postgradmedj-2021-140675.* PMID: 34611037.

[75] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329.* PMID: 32166855.

[76] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896.* PMID: 25024068.

[77] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[78] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May;2007 15(5):491–496. [PubMed: 17139495].

regimen. The risk of mucositis and potential complications to the clinical success of medical services for cancer treatment is similar to the risk for patients receiving Hematopoietic Stem Cell Transplants (HSCT) and bone marrow transplants,[79] [80] for which we finalized payment for certain dental services prior to these medical services (87 FR 69677). These potential complications, resulting from the combined immunosuppression and mucositis caused by the chemotherapy services, present a risk to the patient and the success of the medical chemotherapy regimen unless mitigated by the provision of dental services. Additionally, as described previously, evidence found in systematic reviews showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[81]

Moreover, as described in section II.K.2. of this final rule, dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[82] Additionally, as discussed in section II.K.2. of this final rule, research studies support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the medical services, as well as requiring fewer emergency treatments.[83] [84]

Consequently, we believe that the evidence supports that the standard of care is such that one would not proceed with the chemotherapy when used in the treatment of cancer without performing the dental services because the covered services would or could be significantly and materially compromised, such that clinical outcomes of the chemotherapy treatment could be compromised absent the provision of the inextricably linked dental services.

As described in the CY 2023 PFS final rule (87 FR 69685), we noted that evidence to support the linkage between the dental and covered services could include information demonstrating that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to clear the patient of an oral or dental infection; or, in instances where a known oral or dental infection is present, the standard is such that the medical professional would not proceed with the medical service until the patient received the necessary treatment to eradicate the infection. Our review of relevant clinical practice guidelines demonstrated that multiple professional societies recommend the performance of dental services prior to the initiation of or during chemotherapy.[85] [86] For instance, the United Kingdom published a guideline for dental evaluation and treatment before and after treatments for head and neck cancer (5th edition of the UK Multi-Disciplinary Guidelines for Head and Neck Cancer), based on guidance from the National Institute for Health and Care Excellence (NICE) and expert recommendations: ''Preventive oral care must be delivered to patients whose cancer treatment will affect the oral cavity, jaws, salivary glands and oral accessibility.'' [87] Additionally, as described in the CY 2023 PFS final rule (87 FR 69680), several commenters provided data regarding the treatment of head and neck cancer that illustrated that conditions such as oral mucositis or osteonecrosis of the jaw that occur during the treatment may compromise the clinical success of the primary medical service (chemotherapy for the treatment of head and neck cancer), potentially leading to multiple hospitalizations, including systemic infections or fatal sepsis, if dental infections remained untreated.

We believe chemotherapy used in the treatment of cancer causes acute immunosuppression, causing significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn may lead to serious and imminent risks to the success of the primary medical procedures and treatments. These treatment-induced complications, including possible infection, prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause the inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of the Medicare covered chemotherapy, when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently, the dental services facilitate the successful completion of the prescribed course of treatment, and therefore, the dental services are integral and inextricably linked to these medical services, and the statutory dental exclusion would not apply.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to chemotherapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of chemotherapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and

[79] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May, 2007 15(5):491–496. [PubMed: 17139495].

[80] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[81] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116*. PMID: 36115328.

[82] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions—a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

[83] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397–e405. doi: *https://dx.doi.org/10.1200/OP.20.00107*. PMID: 32609586.

[84] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003*. PMID: 29580668.

[85] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

[86] American Academy of Pediatric Dentistry. Dental management of pediatric patients receiving immunosuppressive therapy and/or head and neck radiation. The Reference Manual of Pediatric Dentistry. Chicago, Ill.; 2022:507–16.

[87] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered services.

In the CY 2024 PFS proposed rule, we also solicited comment on whether we should consider radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) as medical services that may be inextricably linked to dental services (88 FR 52377). We stated that we do not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as for cancer patients receiving chemotherapy since radiation specifically targets malignant cells and has more targeted and localized effects on the body as compared to system-wide immunosuppression effects of chemotherapy for cancer treatment. However, we solicited comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore, payable under Medicare Parts A and B.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal that Medicare Parts A and B payment may be made for dental services, such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with Medicare-covered chemotherapy when used in the treatment of cancer and urged CMS to finalize this policy as proposed. Commenters included individuals, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, health centers, and health insurance companies, among others. Many commenters expressed the view that payment for dental services in the proposed additional circumstances could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. Commenters also stated that they believe that these updates will have a direct and meaningful impact on the lives of many Medicare beneficiaries. Many commenters also stated that they believe that these revisions would serve to promote health equity and increase access to medically necessary services for vulnerable members of the Medicare population. The commenters asserted that underserved populations generally do not have access to the necessary oral health services required for successful outcomes and will help address persistent inequities in cancer outcomes. Commenters also stated that they believed payment for dental services in these circumstances may ensure that poor oral health in these circumstances does not further complicate the treatment of these covered medical conditions, may generate cost savings for vulnerable patients, and may also help with their candidacy for further interventions such as allogeneic stem cell transplant.

Commenters stated that standard of care in many cancer centers includes a comprehensive oral exam prior to starting therapy.[88] Commenters also noted that the National Cancer Institute recommends that cancer patients receiving high-dose chemotherapy, stem cell transplants, or radiation therapy should have an oral care plan in place before treatment begins to mitigate the risk of oral complications [89] that administering chemotherapy before providing dental treatment when an identifiable oral or dental infection is present does not align with the established standard of care. Commenters also supported the proposed clarification that payment may be made for dental and oral health treatments and ancillary services prior to or during cancer treatment regardless of the cancer's primary or metastatic status, site of origin, or initial treatment modality. Several commenters expressed support and appreciation for proposing to permit Medicare payment for dental services in scenarios where patients are receiving chemotherapy as a single modality, regardless of whether chemotherapy is used in combination with other cancer therapies. Commenters noted that if the policy were to only apply in cases where chemotherapy is the only treatment, they were concerned that such an application of the policy would increase health disparities between cancer treatments.

Response: We agree with commenters that there is evidence to support that certain dental services serve to mitigate the substantial risk to the clinical success of the medical services due to the severity of complications that can be caused by the dental infection. We also agree that administering chemotherapy before providing dental treatment when an identifiable oral or dental infection is present does not align with the established standard of care, and that the dental services are considered to be an essential clinical requirement before moving forward with the primary medical procedure.

We further agree with commenters that Medicare payment for dental services should not be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies, as chemotherapy services when used in the treatment of cancer, either as a single modality or in conjunction with other therapy types, can cause immunosuppression which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn lead to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) such that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of chemotherapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently, the dental services facilitate the successful completion of the prescribed course of treatment. As such, we believe the dental services are integral and inextricably linked to the chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply

[88] Yong CW, Robinson A, Hong C. Dental Evaluation Prior to Cancer Therapy. Front Oral Health. 2022 Apr 18;3:876941. *doi: 10.3389/froh.2022.876941.* PMID: 35510226; PMCID: PMC9058061.

[89] *https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq.*

and are finalizing this aspect of the proposal.

Comment: Several commenters requested that Medicare provide payment for dental and oral examinations performed as part of a comprehensive workup for Medicare beneficiaries with cancer prior to the administration of single modality radiation therapy, outside of usage in the treatment of head and neck cancer. Commenters suggested that radiation, although usually not systemic, also has a powerful cytotoxic effect, though commenters noted that radiation may have a less damaging impact on the immune system because it is not systemic and does not cause immunosuppression. Commenters stated that radiation does have to travel through areas of healthy cells to treat the tumor, so healthy cells through which the radiation travels and nearby cells can be affected. Commenters also stated that the radiation may directly damage the immune system, the skeletal system, or bone marrow, causing neutropenia. Commenters stated that, for example, radiation near the axilla following treatment of a solid breast cancer tumor, can damage lymph nodes which are part of the immune system, leading to risk of infection in the arm and lymphedema.

Commenters further suggested that patients with a diagnosis of leukemia, lymphoma, or multiple myeloma scheduled for a stem cell or, bone marrow transplant receive total body radiation (TBI) prior to the transplant (conditioning process), which then causes neutropenia and related immunosuppression. The commenters noted that because the radiation conditioning process kills stem cells, patients are temporarily unable to replace the neutrophils that fight infection, potentially leaving the patients at higher risk for oral and systemic infections such as dental infections.

Response: We appreciate the suggestion that single modality radiation therapy should be included in the list of covered medical services. However, we do not believe that the evidence submitted by commenters is sufficient to demonstrate an inextricable linkage between dental services and the success of single modality radiation therapy during the treatment of certain cancers (other than head and neck cancer). In cases of single modality radiation (other than when utilized for treatment of head and neck cancer), we are not convinced that the radiation treatment necessary to treat the individual's underlying medical condition requires the performance of certain dental services and that those dental services would serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services. While single modality radiation may create medical complications for the patient, we do not believe that dental services would serve to mitigate the substantial risk to the success of the radiation or is an essential clinical requirement before moving forward with the primary medical procedure, and therefore, that an inextricable linkage between the covered medical services and the provision of dental services can be established. However, we note that in instances, for example, where patients with a diagnosis of leukemia, lymphoma, or multiple myeloma scheduled for a stem cell or, bone marrow transplant receiving total body radiation (TBI) prior to the transplant (conditioning process) pretreatment for transplantation, Medicare Parts A and B payment may be made for dental services, such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, an organ transplant, including hematopoietic stem cell transplant, are currently included in the examples listed at § 411.15(i)(3)(i).

However, we continue to encourage additional public discussions and engagement on issues relating to Medicare payment for certain dental services that do not fall within the exclusion under section 1862(a)(12) of the Act through the finalized public process as described in section described in section II.K.1.c. above in this final rule and welcome additional public submissions regarding single modality radiation. We continue to seek medical evidence that certain dental services are so integral to medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act and that such dental services are inextricably linked to other covered services.

Moreover, we note that MACs retain the flexibility to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i)(3). We further note that the finalized policies outlined in this section of the final rule would not prevent a MAC from making a determination that payment can be made for dental services in accordance with the regulation at § 411.15(i)(3)(i) in other circumstances not specifically addressed within this final rule and the finalized amendments to that regulation.

After consideration of the public comments, clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research, we are finalizing amendments to our regulation at § 411.15(i)(3)(i) to add chemotherapy in the treatment of cancer as an additional example of a clinical scenario under which payment can be made under Medicare Parts A and B, under the applicable payment system, for certain dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. We are finalizing, with modifications, an amendment to § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, chemotherapy in the treatment of cancer to the list of examples of dental services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B for dental services.

b. Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer

After consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of CAR T-cell therapy, in the CY 2024 PFS proposed rule we proposed that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy, and that these services also represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures (88 FR 52377 to 52379). We stated that we believe there is an inextricable link between dental and CAR T-cell therapy when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical

services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the CAR T-cell therapy when used in the treatment of cancer.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present a substantial risk to the success of the (CAR) T-cell therapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with (CAR) T-cell therapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services. As such, in the CY 2024 PFS proposed rule, we proposed to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A) (88 FR 52379). Specifically, we proposed to amend the regulation to include a dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered CAR T-cell therapy when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, CAR T-cell therapy when used in the treatment of cancer. We solicited comments on all aspects of this proposal.

We also solicited comment on whether we should add as an example of dental services for which payment may be made under Medicare Parts A and B other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-cell therapy for cancer treatment. Commenters submitting through the public process for consideration in CY 2024 rulemaking specifically stated that CAR T-Cell therapies constituted lymphodepleting therapies, and we believe there may be other immunotherapies that may have a similar lymphodepletion component, but we received no specific information regarding such therapies. Evidence submitted by the public through the finalized public submission process indicates that treatment-induced immunosuppression may also occur with lymphodepleting medical services, and that complications caused by the treatment-induced immunosuppression, including possible infection, may prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. However, we requested comment on what specific medical services also involve lymphodepletion and should be considered in addition to CAR T-cell therapy. We also requested additional information regarding how dental infections/conditions might impact those specific services. We noted that if we receive compelling clinical evidence, we may finalize in the CY 2024 PFS final rule additional clinical scenarios, such as dental services prior to other types of specific lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer and the standard of care would be to not proceed with the medical services without having first complete the dental services, where payment could be made under Medicare Part A or Part B. We solicited comment on whether there is a significant quality of care detriment if certain dental services are not provided prior to these other types of lymphodepleting medical services, and if so, we requested a description of that systematic evidence. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal that Medicare Parts A and B payment may be made for dental services, such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with Medicare-covered CAR–T cell therapies when used in the treatment of cancer and urged CMS to finalize this policy as proposed. Commenters included individuals, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, health centers, and health insurance companies, among others.

Many commenters expressed that payment for dental services in the proposed additional circumstances could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. Commenters also stated that they believe that these updates will have a direct and meaningful impact on the lives of many of Medicare beneficiaries. Many commenters also stated that they believe that these revisions would serve to promote health equity and increase access to medically necessary services for vulnerable members of the Medicare population. The commenters asserted that underserved populations generally do not have access to the necessary oral health services required for successful outcomes and will help address persistent inequities in cancer outcomes. Commenters also stated that they believed payment for dental services in these circumstances may ensure that poor oral health in these circumstances does not further complicate the treatment of these covered medical conditions, may generate cost savings for vulnerable patients, and may also help with their candidacy for further interventions such as allogeneic stem cell transplant.

Commenters stated that standard care in many cancer centers includes a comprehensive oral exam, which is a requirement prior to starting CAR T-cell therapy. Commenters noted that proceeding with CAR T-cell prior to dental treatment services when a known oral or dental infection is present is not the accepted standard of care, as the presence of the infection could jeopardize the outcome of the treatment. Commenters further stated that CAR T-cell medical services cause a patient to be immunosuppressed, such that an untreated oral or dental infection could complicate or compromise the clinical outcome of the CAR T-cell medical service. For those reasons, the commenters supported CMS' proposal and urged finalization of the proposed policy.

Response: We agree with commenters that there is evidence to support that dental services serve to mitigate the substantial risk to the success of the medical services due to the severity of complications caused by the primary medical services, including increased risk of infection and potential sepsis. We also agree that the standard of care for chemotherapy, when used in the treatment of cancer, would be compromised absent the provision of certain dental services and that the dental services are considered to be an essential clinical requirement before moving forward with the primary medical procedure.

Additionally, we agree with commenters that CAR T-cell therapy causes immunosuppression, which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn leads to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) such that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of CAR T-cell therapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment. Therefore, we believe that the dental services that are inextricably linked to, and substantially related and integral to the clinical success of, CAR T-cell in the treatment of cancer are not subject to the exclusion under section 1862(a)(12) of the Act and that payment can be made under Medicare Parts A and B, under the applicable payment system, for such dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. We are finalizing, with modifications, an amendment to § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with CAR T-cell therapy in the treatment of cancer to the list of examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B. We are finalizing this aspect of the proposal.

Comment: A few commenters provided feedback and requested that CMS evaluate whether dental services may be inextricably linked to the clinical success of other immunotherapies that may have a similar lymphodepleting component as CAR T-cell therapies. However, the commenters noted that at this time they were unable to supply medical or clinical evidence to support this potential addition to this policy. The commenters encouraged CMS to continue to consider whether dental services may be inextricably linked to the clinical success of other immunotherapies that may have a similar lymphodepleting component as CAR T-cell therapies. One commenter submitted research related to the usage of rituximab as a first-line treatment for non-Hodgkin's lymphoma and discussed the impacts the advent of rituximab had on treatment outcomes for patients with diffuse large B cell lymphoma (DLBCL) compared with the pre-rituximab era.[90]

Response: We thank the commenters for their suggestion and submission of studies related to the connection between the clinical success of other immunotherapies that may have a lymphodepleting component and the provision of dental services. While the clinical trials appeared to show a positive impact of rituximab on survival outcomes when treating aggressive B-cell lymphomas, the research did not provide concrete evidence regarding the connection between the provision of dental or oral services and outcomes for immunotherapies such as Rituximab. We continue to welcome further evidence on the impact of dental services on clinical scenarios involving monoclonal antibodies. Additionally, while some commenters noted that there is limited evidence to establish that dental services may be inextricably linked to the clinical success of other lymphodepleting therapies, we will continue to consider this and other suggestions as we consider potential future rulemaking through research of clinical studies and related materials. We reiterate that as described in section II.K.1.c. of this final rule, documentation submitted for the purposes of this payment policy should include medical evidence to support that certain dental services are inextricably linked to other covered services. Materials submitted should demonstrate that dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act but rather that such dental services are inextricably linked to other covered services, and therefore, are instead substantially related and integral to that primary medical service. Details regarding the public submission process are available in the CY 2023 PFS final rule (87 FR 69669 through 69670).

Moreover, we reiterate that MACs have the flexibility to determine on a claim-by-claim basis whether certain dental services for beneficiaries receiving other immunotherapies that may involve a lymphodepleting component are subject to the exclusion on payment for dental services under section 1862(a)(12) of the Act and § 411.15(i). We further note that the finalized policies outlined in this section of this final rule would not prevent a MAC from determining on a case-by-case basis that payment can be made for certain dental services in other circumstances not specifically addressed within this final rule and § 411.15(i)(3)(i), including as that regulation is amended by this final rule.

c. Dental Services Inextricably Linked to Administration of High-Dose Bone-Modifying Agents (Antiresorptive Therapy) When Used in the Treatment of Cancer

In the CY 2024 PFS proposed rule, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, we proposed to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A) (88 FR 52379). We stated that we believe that there is an inextricable link between dental and administration of high-dose bone-modifying agents (antiresorptive

[90] Mohammed R, Milne A, Kayani K, Ojha U. How the discovery of rituximab impacted the treatment of B-cell non-Hodgkin's lymphomas. J Blood Med. 2019 Feb 27;10:71–84. *doi: 10.2147/JBM.S190784*. PMID: 30881167; PMCID: PMC6398399.

therapy) when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, we proposed to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered the administration of Medicare-covered high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer. We solicited comments on all aspects of this proposal.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further proposed that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported Medicare payment for dental services, such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Commenters included individuals, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, health centers, and health insurance companies, among others. Many commenters expressed the view that payment for dental services in the proposed additional circumstances could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. Commenters also stated that they believe that these updates will have a direct and meaningful impact on the lives of many of Medicare beneficiaries. Many commenters also stated that they believe that these revisions would serve to promote health equity and increase access to medically necessary services for vulnerable members of the Medicare population. The commenters asserted that underserved populations generally do not have access to the necessary oral health services required for successful outcomes and will help address persistent inequities in cancer outcomes. Commenters also stated that they believed payment for dental services in these circumstances may ensure that poor oral health in these circumstances does not further complicate the treatment of these covered medical conditions and may generate cost savings for vulnerable patients.

Commenters recommended that Medicare provide payment for dental exams and related preventative services before initiating bone directed therapy using bisphosphonates and denosumab and urged CMS to finalize this policy as proposed. Commenters noted that there is no effective treatment for bisphosphonate-induced osteonecrosis, but preventative dental exams and management decrease risk of osteonecrosis of the jaw in cancer patients receiving these therapies, which can in turn jeopardize the successful completion of the treatment for cancer. Commenters stated that research shows that osteonecrosis of the jaw is a preventable condition, and that care coordination and preventative services can result in improved outcomes and in lower incidence of osteonecrosis of the jaw for cancer patients receiving bisphosphonate therapy. Commenters expressed appreciation for the inclusion of clinical guidelines as the rationale for coverage in the proposed rule, which state that cancer patients should receive an oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) prior to initiating the administration of high-dose bone modifying agents (antiresorptive therapy) when used in the treatment of cancer to reduce complications and manage modifiable risk factors. Commenters stated that the dental-related complication to certain immunosuppressive cancer treatments, such as high-dose antiresorptive and/or antiangiogenic drug therapy can be serious, particularly medication-related osteonecrosis of the jaw (MRONJ), which can complicate cancer treatment and lead to reduced survival rates post-treatment. Commenters noted that patients with existing dental disease pose the greatest risk for developing MRONJ secondary to bone-modifying therapy and recommended that the dental infection be addressed prior to the start of care, so as to facilitate the successful completion of the treatment. Commenters further stated that from a clinical standpoint, prevention of MRONJ is the gold standard and emphasized the importance of a multidisciplinary, coordinated approach that includes pretreatment dental management in minimizing the risk of MRONJ and supported CMS's proposal to expand Medicare coverage and payment for dental examinations prior to, as well as diagnostic and treatment services to eliminate an oral or dental infection prior to or at the same time as, the administration of high-dose bone modifying agents.

Response: We agree with commenters that there is evidence to support that dental services serve to mitigate the substantial risk to the success of the medical services due to the severity of complications caused by the primary medical services as well as minimize the risk of infection and therefore the dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of the medical service and are substantially related and integral to the covered medical service of administration of high-dose bone modifying agents in the treatment of cancer. As such, we are finalizing our proposal that Medicare Part A and Part B payment can be made for certain

dental services such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. We believe that the standard of care for that medical service would be compromised absent the provision of dental services, and that the dental services are considered to be an essential clinical requirement before moving forward with the primary medical procedure.

Comment: A few commenters asked that we clarify the term ''high-dose'' bisphosphonate therapy and provide guidance regarding what this phrase means so as to minimize potential confusion with respect to this policy.

Response: For the purposes of Medicare payment for dental services inextricably linked to other covered services, the term ''high-dose'' bisphosphonate therapy refers to the usage of bisphosphonate therapy when used in the treatment of cancer. In general, for patients undergoing treatment for cancer, currently, intravenous formulations have FDA label indication for patients with multiple myeloma or bone metastases from solid tumors. We believe that the particular dosage may be adjusted for various clinical situations, so setting a defined high-dose dosage at a particular level may inadvertently exclude certain patient populations (such as renal-impaired patients who are receiving a particular dose). We also recognize that there may also be variation in dosage interval for the bisphosphonates varying between three, four, and perhaps twelve weeks of therapy. As such, we believe that ''high-dose'' bisphosphonate therapy to which dental care may be inextricably linked would be defined as intravenous bisphosphonate therapy for the treatment of multiple myeloma and bone metastases of solid tumors. For example, ICD–10 codes for related conditions could include those that reflect multiple myeloma and bone metastases from a primary solid tumor (for example, breast, prostate), such as C90 Multiple myeloma and malignant plasma cell neoplasms, C90.0 Multiple myeloma, C90.00 Multiple myeloma not having achieved remission, C90.01 Multiple myeloma in remission, C90.02 Multiple myeloma in relapse, C79.5 Secondary malignant neoplasm of bone and bone marrow, C79.51 Secondary malignant neoplasm of bone or C79.52 Secondary malignant neoplasm of bone marrow.

From the evidence provided and reviewed, we note there are FDA approved defined intravenous dosages and intervals (with adjustment for renal impairment) for the use of some bisphosphonates for metastatic bone lesions and multiple myeloma, and we would not expect that oral regimens of these or other bisphosphonates would be commonly prescribed for these purposes.[91] [92] However, other dosage forms, when used for these purposes, possibly in an off-label manner, could be considered by the MACs on a case-by-case basis. Additionally, we would be open to reviewing evidence in the future of other applicable dosage forms. Currently, oral regimens have indications for osteoporosis and Paget's disease, which are not included in the list of clinical examples at § 411.15(i).

After consideration of the public comments, clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research, we are finalizing amendments to our regulation at § 411.15(i)(3)(i) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment of cancer are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B, under the applicable payment system, for such dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. We are also finalizing an amendment to § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment of cancer to the list of examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B.

[91] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021113s008lbl.pdf.*

[92] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021223s028lbl.pdf.*

d. Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer

In the CY 2024 PFS proposed rule, we proposed to clarify and codify that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as for the medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment (88 FR 52380).

Specifically, we proposed to amend our regulation at § 411.15(i)(3)(i)(A) to allow for payment under Medicare Parts A and Part B for:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported Medicare payment for dental services, such as dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with treatments for head and neck cancers. Commenters included individuals, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, health centers, and health insurance companies, among others. Many commenters expressed the view that payment for dental services in the proposed additional circumstances could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. Commenters also stated that they believe that these updates will have a direct and meaningful impact on the lives of many of Medicare

beneficiaries. Many commenters also stated that they believe that these revisions would serve to promote health equity and increase access to medically necessary services for vulnerable members of the Medicare population. The commenters asserted that underserved populations generally do not have access to the necessary oral health services required for successful outcomes and will help address persistent inequities in cancer outcomes. Commenters also stated that they believed payment for dental services in these circumstances may ensure that poor oral health in these circumstances does not further complicate the treatment of these covered medical conditions and may generate cost savings for vulnerable patients.

Commenters described that treatment for head and neck cancer generally refers to a group of cancers that originate in or metastasize to various areas of the head and neck, with the mucosal surfaces of the oral cavity, pharynx and larynx being most common and stated that these cancers are often grouped together because they share common risk factors, symptoms, and treatment approaches.

Commenters noted, particularly for patients undergoing radiation therapy for any head and neck cancer, the importance of thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. The commenters stated that cleaning and preparation work for radiation therapy is critical to the clinical success of radiation therapy. Commenters provided evidence that described the connection between the provision of dental services prior to, during, and after the treatment for head and neck cancer and the reduction of risk of complications that may jeopardize the success of the treatments and simultaneously result in improved outcomes for the patient.

Response: We thank the commenters for their support. We agree that head and neck cancer generally refers to a group of cancers that originate in or metastasize to areas of the head and neck, which could include the mucosal surfaces of the oral cavity, pharynx and larynx and acknowledge that these cancers are often grouped together because they share common risk factors, symptoms, and treatment approaches. We also agree that the medical services necessary to diagnose and treat the underlying head and neck cancer may require the performance of certain dental services, which in turn serve to mitigate the substantial risk to the success of the medical services because of the risk of infection and of the occurrence and severity of complications that are caused by the primary medical services. Additionally, we agree that the standard of care for treatment for head and neck cancer would be compromised absent the performance of certain dental services, and that dental services are considered to be an essential clinical requirement before moving forward with the primary medical procedure. As such, we are finalizing our proposal that Medicare Part A and Part B payment can be made for certain dental services when furnished prior to or contemporaneously with the treatment of head and neck cancer.

Comment: Several commenters requested that Medicare payment be permitted for patients undergoing single modality radiation therapy for any head and neck cancer, as the commenters note that it is important that those patients receive a thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. Commenters provided evidence and stated that cleaning and preparation work for radiation therapy is also critical to the clinical success of radiation therapy, including the preparation of a fluoride carrier to protect teeth in an ongoing fashion. Commenters supplied research and further stated that due to the chronic dental side effects of head and neck radiotherapy and the risk of osteoradionecrosis with dental extractions after treatment, curative treatment for the underlying cancer may be delayed until dental care can be completed and that those delays would be eliminated if dental care could be addressed prior to the initiation of radiation treatment. Commenters also noted that in some radiation oncology treatments, masks utilized for treatment must fit on patients' faces correctly when receiving radiology and suggested that if the mask fits improperly due to issues related to dental care, treatment for the underly cancer is delayed until dental care can be completed. Commenters asserted that dental care to address these issues would facilitate the successful completion of the radiology treatment for head and neck cancer.

Response: We agree that in the case of head and neck cancers, single modality radiation therapy uniquely impacts the dental and oral tissues such that the provision of certain dental services before or during the single modality treatment are linked to improved outcomes, including the reduction of the risk of infection. As such, we are finalizing our proposal that Medicare Part A and Part B payment can be made for certain dental services furnished before or during single modality radiation therapy when used in the treatment of head and neck cancer even when used as the single treatment modality and not in combination with any other therapy types.

Comment: Many commenters requested that Medicare payment be permitted after direct treatment is completed for patients undergoing treatment for head and neck cancer. The commenters suggested that dental evaluations to identify, address, and rectify potential oral complications are necessary to ensure the success of the treatments and to improve quality outcomes for the patient in the period after the direct treatment for head and neck cancer. Commenters supplied clinical studies and research that demonstrate that the side effects encountered by patients undergoing treatment, such as radiotherapy, chemotherapy or combination treatment with concurrent systemic agents, for head and neck cancers, can include, but are not limited to: infection, mucositis, hyposalivation, dysphagia, osteoradionecrosis, and radiation-related caries.[93] [94] [95] [96] [97] [98] [99]

[93] National Cancer Institute. Head and Neck Cancers. Updated May 25, 2021. Available at *https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet* Accessed August 8, 2023.

[94] Pisani, P., Airoldi, M., Allais, A., Aluffi Valletti, P., Battista, M., Benazzo, M., Briatore, R., Cacciola, S., Cocuzza, S., Colombo, A., Conti, B., Costanzo, A., Della Vecchia, L., Denaro, N., Fantozzi, C., Galizia, D., Garzaro, M., Genta, I., Iasi, G. A., Krengli, M., Landolfo, V., Lanza, G.V., Magnano, M., Mancuso, M., Maroldi, R., Masini, L., Merlano, M.C., Piemonte, M., Pisani, S., Prina-Mello, A., Prioglio, L., Rugiu, M.G., Scasso, F., Serra, A., Valente, G., Zannetti, M., and Zigliani, A. (2020). Metastatic disease in head & neck oncology. Acta Otorhinolaryngologica Italica,40(SUPPL. 1), S1–S86. *https://doi.org/10.14639/0392-100X-suppl.1-40-2020.*

[95] Pisani, P., Airoldi, M., Allais, A., Aluffi Valletti, P., Battista, M., Benazzo, M., Briatore, R., Cacciola, S., Cocuzza, S., Colombo, A., Conti, B., Costanzo, A., Della Vecchia, L., Denaro, N., Fantozzi, C., Galizia, D., Garzaro, M., Genta, I., Iasi, G. A., Krengli, M., Landolfo, V., Lanza, G.V., Magnano, M., Mancuso, M., Maroldi, R., Masini, L., Merlano, M.C., Piemonte, M., Pisani, S., Prina-Mello, A., Prioglio, L., Rugiu, M.G., Scasso, F., Serra, A., Valente, G., Zannetti, M., and Zigliani, A. (2020). Metastatic disease in head & neck oncology. Acta Otorhinolaryngologica Italica,40(SUPPL. 1), S1–S86. *https://doi.org/10.14639/0392-100X-suppl.1402020.*

[96] Epstein, J.B., Thariat, J., Bensadoun, R.J., Barasch, A., Murphy, B.A., Kolnick, L., Popplewell, L. and Maghami, E. (2021). Oral complications of cancer and cancer therapy. CA: Cancer Journal for Clinicians, 62(6). 400–422. *https://doi.org/10.3322/caac.21157.*

[97] Palmier N.R., Ribeiro, A.C.P, Fonseca, J.M., Salvajoli, J.C., Vargas, P.A., Lopes, M.A., Brandao,

Commenters noted that these oral toxicities may be acute (developing during active treatment) or late onset (manifesting several months after treatment is complete) with some latent complications of radiotherapy linked to permanent tissue damage, as well as damage to bony structures, tissues, and salivary glands. Commenters noted that current data show approximately 30 percent of head and neck cancer patients develop radiation caries within 12 months following completion of radiotherapy.[100]

Commenters also stated that the oral health of cancer patients undergoing radiation therapy in the treatment of head and neck cancer are uniquely impacted by the primary medical services intended to treat the underlying cancer. Commenters stated that patients undergoing radiotherapy experience an overall deterioration of dental and periodontal health, as well as chronic effects of radiotherapy, such as mucosal pain and recurrent infection, salivary gland dysfunction, and osteoradionecrosis, all of which are caused by the primary treatments for cancer. Commenters noted that these oral complications caused by the treatment for head and neck cancer can be either acute or chronic and can manifest within months of the final treatments and potentially persist through the end of life. Commenters stated that managing oral complications of head and neck cancer therapy can be very costly and create a financial burden for patients, offering that ongoing treatment for complications caused by treatment can range from approximately $4,000–$35,000 for osteoradionecrosis and between $5,000–$30,000 for management of oral mucositis in cancer patients undergoing radiotherapy, stating that some researchers attribute this high cost both to the resource-intensive settings in which management of oral complications typically takes place and the complex needs of cancer patients including enteral and parenteral feedings, febrile neutropenia, and frequency of hospitalizations.[101] [102]

Additional commenters stated that, in general, medical standards of cancer care include routine follow-up, supplemental, or secondary treatments for symptom management and long-term management of overall health for head and neck cancer patients, and that oral and dental care should be incorporated into clinical cancer care protocols for pre-, intra- and post-treatment, especially for diagnoses or therapies known to cause oral complications. The commenters asserted that access to medically necessary dental services post-radiation positively impact patient quality of life and mitigate some of the resource-intensive treatment of advanced oral sequelae of head and neck cancer and its treatment. These commenters requested that CMS expand Medicare payment to include medically necessary dental services occurring postradiotherapy for beneficiaries with a diagnosis of head and neck cancer.

Several commenters asked CMS to adopt a definition of ''during'' or ''contemporaneously with'' in the treatment of head and neck cancer that recognizes the patient-specific clinical decisions that occur in this specific patient population. The commenters suggested that the definition of ''during'' or ''contemporaneously with'' for head and neck cancer should encompass a clinically recognized recovery phase for targeted head and neck cancer treatment, which the commenters noted they believe would advance the goals of the Medicare program without violating the statutory dental exclusion.

Response: We appreciate the commenters' thoughtful and evidence-based feedback regarding the link between medically necessary diagnostic and treatment services for head and neck cancer and the unique circumstances surrounding the ongoing oral complications that following treatment for head and neck cancer. While we did not propose to add to our regulation that Medicare Parts A and B payment is permitted for medically necessary diagnostic and treatment services to address dental or oral complications after radiation, chemotherapy, and/or surgery when used in the treatment of head and neck cancer, we are persuaded by evidence provided by commenters that treatment for head and neck cancer uniquely causes additional significant and acute (developing during active treatment) dental and/or oral complications for the patient, including increased risk of infection even after the direct treatment for head and neck cancer has ended. The research submitted by commenters indicates that radiation therapy causes an increased occurrence of caries, mucositis, osteoradionecrosis, and other severe complications. Commenters provided persuasive arguments, clinical guidelines, and research to substantiate that the provision of dental services with the treatment for head and neck cancer leads to improved healing and improved quality outcomes for the treatments, including the reduction of incidence of infection, and without the provision of dental services, the final outcome of the treatment for head and neck cancer may be jeopardized. We are also convinced that the standard of care for the treatments for head and neck cancer would be compromised absent the provision of dental services to address the oral complications caused by the primary treatment. Additionally, we are convinced by the evidence submitted by commenters that the provision of certain dental services after direct treatments for head and neck cancers supports that certain dental services would result in clinically significant improvements in quality and safety outcomes for the patient.

The research submitted by commenters demonstrates varying post-treatment dental needs for individuals receiving treatment for head and neck cancer (HNC), stemming from the acute (developing during active treatment) and chronic complications caused by the treatment for the HNC. For example, mucositis may be caused by either radiation therapy or chemotherapy. According to the National Cancer Institute, mucositis caused by chemotherapy will heal by itself, usually within 2 to 4 weeks if there is no infection. Mucositis caused by radiation therapy usually lasts 6 to 8 weeks, depending on the duration of

T.B. and Santos-Silva, A.R. (2017). Radiation-related caries assessment through the International Caries Detection and Assessment System and the Post-Radiation Dental Index. Oral Surgery Oral Medicine Oral Pathology Oral Radiology, 124(6), 542–7. *https://doi.org/10.1016/j.oooo.2017.08.019.*

[98] National Institute for Dental and Craniofacial Research. (2009). Oral Complications of Dental Treatment: What the Dental Team Can Do (NIH Publication No. 09–4372). National Institutes of Health. 2023. *https://www.nidcr.nih.gov/sites/default/files/2017-09/oral-complications-cancerdental-team.pdf.* Accessed August 11, 2023.

[99] PDQ® Supportive and Palliative Care Editorial Board. PDQ Oral Complications of Chemotherapy and Head/Neck Radiation. Bethesda, MD: National Cancer Institute. Updated October 21, 2022. Available at *https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oralcomplications-hp-pdq.* Accessed August 11, 2023. [PMID: 26389320].

[100] Pedroso, C.M., Miglioratti, C.A., Epstein, J.B., Ribeiro, A.C.P., Brandao, T.B., Lopes, M.A., Fernando de Goes, M. and Santos-Silva, A.R. (2022). Over 300 radiation caries papers: Reflections from the rearview mirror. Frontiers in Oral Health, 3. *https://doi.org/10.3389/froh.2022.961594.*

[101] Sroussi, H.Y., Epstein, J.B., Bensdoun, R.J., Saunders, D.P., Lalla, R.V., Migliorati, C.A., Heaivilin, N. and Zumsteg, Z.S. (2017). Common oral complications of head and neck cancer radiation therapy: mucositis, infections, saliva change, fibrosis, sensory dysfunctions, dental caries, periodontal disease, and osteoradionecrosis. Cancer Medicine,6(12). 298–2931. *https://doi.org/10.1002/cam4.1221.*

[102] Elting, L.S. and Chang, Y.C. (2019). Costs or oral complications of cancer therapies: Estimates and a blueprint for future study. Journal of the National Cancer Institute Monographs,2019(53). *https://doi.org/10.1093/jncimonographs/lgz010.*

treatment.[103] Additionally, complications such as dropped head syndrome (DHS) can occur from 3 months to 30 years after radiation therapy for HNC patients.[104] Current research highlights the long-term dental service needs for individuals treated for HNC. Patients who underwent radiation therapy reported oral complications and challenges within six months after treatment, such as dry mouth, sticky saliva, difficulty swallowing solid foods, and changes in taste.[105] A systematic review revealed that certain treatment-related issues persisted beyond 12 months, including dry mouth, sticky saliva, difficulties with social eating, fatigue, and physical functioning,[106] all of which may benefit from ongoing monitoring and dental support in the first year following treatment and beyond. Moreover, access to expert oral healthcare is critical for both HNC patients and survivors, as issues related to mobility and sensory disturbances can persist permanently.[107] A systematic review indicated that dental caries occurs in approximately 29 percent of post-radiotherapy HNC patients. Furthermore, the risk of developing dental caries within two years of head and neck radiotherapy is approximately 37 percent; studies with a higher proportion of patients treated with chemotherapy, in addition to radiotherapy, had an increased incidence of dental caries.[108] Based on the evidence provided by commenters, we believe that most oral complications may arise within 24 months of the completion of direct treatment. However, we recognize that some oral complications may persist beyond such a window. We continue to seek feedback from the public and interested parties on our continued interest in understanding how the timing of medical treatment and oral health care might illustrate an inextricable linkage.

For example, we believe that dental services may be warranted in the case of a patient with locoregionally advanced head and neck cancers treated with surgery followed by radiation therapy, or definitive radiation therapy, with or without adjuvant chemotherapy, and the oral cavity is within the radiation treatment field. We considered the clinical scenario of a 75-year-old patient who is a non-smoker, that presents with a single enlarged 2 cm level 2 [upper lateral neck] right lymph node. The ensuing work-up discovers human papilloma virus (HPV) positive squamous cell carcinoma in the neck node with a right base of tongue primary tumor. The patient has intact dentition. The patient is treated with definitive chemoradiation for both the primary tumor and the regional metastatic neck disease. The patient is followed regularly by the dentist during and after treatment to assist with management of the oral mucositis and xerostomia [dry mouth] and to monitor the dentition. The oral services provided after the direct treatment for head and neck cancer serve to address any complications that may arise from the primary treatment itself. In this scenario, we believe that Medicare Parts A and B payment may be made for dental services inextricably linked to the treatment for head and neck cancer, such as dental or oral examination to monitor for oral and dental complications such as oral mucositis and xerostomia, as well as evaluate for changes in dentition and identification and the elimination of an oral or dental infection. We note that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to address oral complications caused by the treatment for head and neck cancer. Therefore, we believe that such additional services would not be inextricably linked to, and substantially related and integral to, the clinical success of, the treatment for head and neck cancer. As such, no Medicare payment would be made for the additional services that are not immediately necessary prior to addressing the oral complications caused by the treatments for head and neck cancer.

We also considered another case in which a 65-year-old patient, who is a long-term smoker, presents with multiple level 2 and 3 [upper and mid lateral neck] enlarged left lymph nodes. The ensuing work-up discovers human papilloma virus (HPV) negative squamous cell carcinoma in the neck nodes, but no defined primary origin of tumor, and no distant metastases. The patient has generally poor dentition and undergoes extraction of several vulnerable teeth by an oral surgeon prior to beginning the cancer treatment. The patient is treated with a left modified radical neck dissection [surgery to remove the cancerous lymph nodes in the neck with some of the surrounding tissue] followed by radiation therapy to the neck and the aerodigestive mucosa [nose, mouth and throat lining] from the nasopharynx [back of the nose] to the larynx [voice box]. The patient declined adjuvant chemotherapy. The patient is followed by the dentist during and after treatment to assist with management of the oral mucositis and xerostomia [dry mouth] and to monitor the remaining dentition. Again, the oral services provided after the direct treatment for head and neck cancer serve to address the unique oral complications that were a result of the primary treatment itself. In this scenario, we believe that Medicare Parts A and B payment may be made for dental services inextricably linked to the treatment for head and neck cancer, such as medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of treatment, and, after direct treatment, dental or oral examination to monitor for oral and dental complications such as oral mucositis and xerostomia, as well as evaluate for changes in dentition and identification and the elimination of an oral or dental infection resulting from the treatment for head and neck cancers. We note that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to address oral complications caused by the treatment for head and neck cancer. Therefore, we believe that such additional services would not be inextricably linked to, and substantially related and integral to the clinical success of, the treatment for head and neck cancer. As such, no Medicare

[103] PDQ® Supportive and Palliative Care Editorial Board. PDQ Oral Complications of Chemotherapy and Head/Neck Radiation. Bethesda, MD: National Cancer Institute. Updated <04/26/2019≤. Available at *https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-pdq.* Accessed 10/12/2023. [PMID: 26389169]

[104] Brook I. Late side effects of radiation treatment for head and neck cancer. Radiat Oncol J. 2020 Jun;38(2):84–92. doi: 10.3857/roj.2020.00213. Epub 2020 Jun 25. PMID: 33012151; PMCID: PMC7533405.

[105] Lalla RV, Treister N, Sollecito T, Schmidt B, Patton LL, Mohammadi K, Hodges JS, Brennan MT; OraRad Study Group. Oral complications at 6 months after radiation therapy for head and neck cancer. Oral Dis. 2017 Nov;23(8):1134–1143. doi: 10.1111/odi.12710. Epub 2017 Aug 3. PMID: 28675770; PMCID: PMC6218933.

[106] So WK, Chan RJ, Chan DN, Hughes BG, Chair SY, Choi KC, Chan CW. Quality-of-life among head and neck cancer survivors at one year after treatment—a systematic review. Eur J Cancer. 2012 Oct;48(15):2391–408. doi: 10.1016/j.ejca.2012.04.005. Epub 2012 May 12. PMID: 22579456.

[107] Sroussi HY, Epstein JB, Bensadoun RJ, Saunders DP, Lalla RV, Migliorati CA, Heaivilin N, Zumsteg ZS. Common oral complications of head and neck cancer radiation therapy: mucositis, infections, saliva change, fibrosis, sensory dysfunctions, dental caries, periodontal disease, and osteoradionecrosis. Cancer Med. 2017 Dec;6(12):2918–2931. doi: 10.1002/cam4.1221. Epub 2017 Oct 25. PMID: 29071801; PMCID: PMC5727249.

[108] Moore C, McLister C, Cardwell C, O'Neill C, Donnelly M, McKenna G. Dental caries following radiotherapy for head and neck cancer: A systematic review. Oral Oncol. 2020 Jan;100:104484. doi: 10.1016/j.oraloncology.2019.104484. Epub 2019 Nov 28. PMID: 31786391.

payment would be made for the additional services that are not immediately necessary prior to address the oral complications caused by the treatments for head and neck cancer.

As described by evidence submitted by the commenters, the treatment of head and neck cancer causes oral complications caused by the primary medical treatment itself and increases the risk of infection after the direct treatment. Treatments for head and neck cancers are demonstrated to cause infection, caries, mucositis, and osteoradionecrosis, among other complications and jeopardize successful outcomes for the treatments. We are convinced that the provision of dental services in the context of treatments for head and neck cancers for the complications of the medical treatment is inextricably linked to the primary medical treatment. This is not only because such services lead to improved healing and improved quality outcomes, and because without the provision of dental services, the final outcome of the treatment for head and neck cancer may be jeopardized, but especially because the treatment itself is the direct cause of the acute oral/dental complications requiring the dental intervention. As demonstrated by evidence submitted by commenters, these complications may occur after some passage of time following the primary medical treatment. In other words, the treatment of head and neck cancer directly causes the oral complications, which may emerge after the treatment is completed. Treatments for head and neck cancers may cause infection, caries, mucositis, and osteoradionecrosis, among other complications, that may occur over months post-treatment. Based on persuasive information presented by commenters, we believe addressing and rectifying these direct consequences of the primary medical treatment for head and neck cancer aligns with the standard of care for treatment of head and neck cancers, would result in improved clinical outcomes for the patient, and is inextricably linked to the treatment.

Therefore, we believe that there is a direct connection between the primary treatment and the dental and oral complications caused by the treatment for head and neck cancer itself, including those that occur after the direct treatments for cancer. As such, we believe that these dental services should be considered not subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to, and substantially related and integral to the clinical success of, the treatment for head and neck cancer, because the dental services serve to mitigate the substantial risk to the success of the medical services due to the severity of complications caused by the primary medical services and the standard of care for the medical service would be compromised. Consequently, we are clarifying that for the purposes of treatment for head and neck cancer, treatment may include dental services required in the period following direct treatment for the head and neck cancer.

Final Action Statement

As described in the sections above, we are revising § 411.15(i)(3)(i) to add to the list of clinical scenarios under which Medicare Part A and B payment is permitted for dental or oral examinations performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. We are also adding a new § 411.15(i)(3)(i)(E) to permit Part A and B payment for dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, radiation, chemotherapy, and/or surgery when used in the treatment of head and neck cancer. The policies we are finalizing take into account commenters' feedback and information provided in clinical literature, such as peer reviewed publications or clinical guidelines supported by clinical evidence, supporting the inextricable link between dental services and certain covered medical services. We anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100–02) to reflect the final changes. Additionally, we intend to issue educational and outreach materials to inform billing and payment for any policies finalized in the final rule. Moreover, we believe that the process we finalized for CY 2023, as described above in section II.K.1.c. of this final rule, to engage with interested parties and review their recommendations regarding the inextricable link between dental services and certain covered medical services will continue to serve the need expressed by commenters for continued engagement on these issues. Additionally, we intend to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for certain dental services that do not fall within the preclusion or exclusion under section 1862(a)(12) of the Act and related topics. We also continue to partner with researchers at the Agency for Healthcare Research and Quality (AHRQ) and other entities to consider and study the relationship between dental services and specific covered medical services, to review available clinical evidence regarding the relationship between dental services and specific covered medical services, and to identify other potential instances in which dental services are inextricably linked to other covered services. Furthermore, we remain open to adjusting and revising these finalized policies through future rulemaking and/or additional guidance as necessary. We appreciate the thoughtful questions raised by commenters and remain committed to continued engagement.

3. Dental Services Integral to Covered Cardiac Interventions

In the CY 2023 PFS final rule, we finalized a policy to permit payment for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered cardiac valve replacement or valvuloplasty procedures; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the cardiac valve replacement or valvuloplasty procedure (87 FR 69675).

We recognized that, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement or valvuloplasty procedure, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves and the surrounding cardiac muscle tissues involved with the surgical site and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient (87 FR 69667).[109] Specifically, we noted that the replaced valve is also at risk of being a seeding source for future endocarditis.

[109] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834-7819.1991.tb00724.x.*

Endocarditis can carry a high risk of mortality for these patients and eliminating an infection prior to or contemporaneously with the procedure would be important for preventing future endocarditis related to the new valve (87 FR 69678).

We also concluded that an oral or dental infection could present a substantial risk to the success of organ transplants, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We stated that we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services (89 FR 69667).

We encouraged the public to use the public submission process finalized in the CY 2023 PFS final rule to identify additional clinical scenarios and related medical evidence to support an inextricable link between specified dental services and other covered medical services.

Through the submission process, an interested party has encouraged CMS to consider extending Medicare payment to include dental services to eliminate infection prior to all cardiovascular procedures, as the mitigation of risks of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. This submission noted that the current standard of care does not conclusively require dental evaluation, diagnosis, or treatment services prior to certain cardiac procedures, perhaps in part because such cardiac procedures are often performed on a more urgent or emergent basis where there is not an opportunity to consider the possible presence of dental infection. Moreover, the submission noted that much of the scientific literature is inconclusive as to whether pre-operative dental treatments impact postoperative surgical outcomes in cardiovascular surgery, including cardiac valve procedures.[110] A systematic literature review by Cotti *et al.* found that, based upon expert opinion, there is general agreement on the need for screening and treatment of oral/dental infections in patients who are to undergo cardiac surgery (although no standardized clinical guidelines or protocols exist to outline the screening process, in terms of either dental treatment options and/or timing of such procedures in relation to the planned cardiac intervention).[111] The authors convened an expert panel from six Italian scientific societies (including cardiologists, cardiac surgeons, and dental specialists) to establish a consensus on early screening and resolution of dental or periodontal infections prior to cardiac surgery, that they intended would result in a standardized protocol for evaluating oral infections and dental treatments for cardiac patients to be used in the interventional preparation phase by both dental and cardiac teams.[112] The authors noted, however, the lack of scientific evidence on the risk-to-benefit ratio for perioperative dental treatment in patients undergoing cardiovascular surgery.

We believe, after further review of current medical practice, through consultations with interested parties (including commenters on last year's final rule and those commenting on current topics) and our medical officers, and through evidence submitted through the public submission process we established in the CY 2023 PFS final rule, that there may be additional circumstances that are clinically similar to examples we codified in our regulation at § 411.15(i)(3)(i) where Medicare payment for dental services could be made under other clinical circumstances where the dental services are inextricably linked to a covered cardiac medical service(s).

To gain further understanding of any potential relationship between dental services and specific covered cardiac medical services, we again partnered with researchers at the AHRQ to review available clinical evidence regarding the relationship between dental services and covered cardiac medical services, including implantation of ventricular assist devices, artificial pacemakers, implantable defibrillators, synthetic vascular grafts and patches, and coronary and vascular stents. This AHRQ report [113] is available at *https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/rapid-response-cardio-dental.pdf.*

As stated in their report, the available evidence does not permit conclusions regarding the effect of pre-treatment dental care for preventing downstream infections related to any of these devices. They noted that professional society guidelines endorse the provision of patient education on routine oral hygiene practices but have not recommended other pre-treatment dental care prior to insertion of these devices. They also noted that professional society guidelines recommend ongoing routine dental examinations for some patients treated with cardiovascular devices.

Nonetheless we solicited comment to identify additional cardiac interventions (that is, specific medical services) where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty. We note that, in order to consider whether certain dental services are inextricably linked to other covered services, we need to identify specific medical services for which there is clinical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to other covered service(s). We encourage interested parties to use the public submission process to submit recommendations and relevant clinical evidence for establishing this connection. In section II.K. of this final rule, we have described the various types of documentation to support recommendations through this process. We considered, and solicited comment on, whether the following cardiac interventions are examples of specific medical services for which dental services are inextricably linked to clinical success: implantation of electronic devices in the heart, such as pacemakers, cardioverter defibrillators, and monitors. We also considered, and solicited comment on, whether the following procedures would be considered examples of specific medical services for which dental services are inextricably linked to their clinical success: the placement of intracardiac or

[110] Lockhart, P.B., DeLong, H.R., Lipman, R.D., Estrich, C.G., Araujo, M.W.B. and Carrasco-Labra, A. (2019). Effect of dental treatment before cardiac valve surgery: Systematic review and meta-analysis. Journal of the American Dental Association,150(9). 739–747. *https://doi.org/10.1016/j.adaj.2019.04.024.*

[111] Cotti, E., Cairo, F., Bassareo, P.P., Fonzar, F., Venturi, M., Landi, L., Parolari, A., Franco, V., Fabiani, C., Barili, F., Di Lenarda, A., Gulizia, M., Borzi, M., Campus, G., Musumeci, F., and Mercuro, G. (2019). Perioperative dental screening and treatment in patients undergoing cardiothoracic surgery and interventional cardiovascular procedures. A consensus report based on RAND/UCLA methodology. International Endodontic Journal,53. 186–199. *https://doi.org/10.1111/iej.13166.*

[112] *Ibid.*

[113] Hickam DH, Gordon CJ, Armstrong CE, Paynter R. The Efficacy of Dental Services for Reducing Adverse Events in Those Undergoing Insertion of Implantable Cardiovascular Devices. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC020. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/10.23970/AHRQEPCRAPIDDENTALCARDIO.*

intravascular foreign material, such as a stent or for hemodialysis, or for a vascular access graft, whereas you would not proceed with the medical service without having first completed a dental evaluation and/or treatment as determined necessary. We solicited comment on whether preoperative and perioperative dental services are inextricably linked to any other covered cardiac interventions as supported by clinical evidence.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters urged us to permit payment for dental screenings and, when clinically justified, medically necessary dental treatment that a patient may need in order to undergo, or to avoid complicating or compromising certain covered cardiac procedures, that is, pacemaker insertion or replacement, insertion or replacement of implantable cardioverter defibrillator, transcatheter aortic valve replacement, aortic valve surgical procedure, mitral valve replacement, endovascular stent repair or replacement, cardiac assist procedures, and other cardiac valve procedures. These commenters asserted that a large number of epidemiological investigations describe an association between periodontal disease (PD) and cardiovascular diseases (CVD). They reasoned that as CVD is clearly influenced by inflammation, and as treatment of PD would reduce both oral and systemic inflammation, it is logical to assume that treatment of PD would reduce overall inflammatory burden and hence the risk of CVD. As such they drew a parallel with our payment policy finalized last year for cardiac valve replacement and valvuloplasty where they stated the risk of infection posed to beneficiaries is similar. Other commenters stated that dental services should be covered for interventional cardiovascular procedures, another for device closure of intracardiac defects and stent implants, other commenters stated generally that dental services should be covered for cardiovascular disease patients, one commenter wrote to say they were not opposed to coverage of dental services to find and eradicate infection prior to the additional cardiac procedures about which we requested information.

Response: As we described above, based on clinical evidence for cardiac valve replacement and valvuloplasty, we believed that without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to or contemporaneous with the procedure, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves and the surrounding cardiac muscle tissues involved with the surgical site and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient. Commenters did not assert an inextricable linkage between dental services and any covered cardiovascular service. They did cite studies for the proposition that CVD and stroke are influenced by inflammation and that as treatment of periodontal disease would reduce both oral and systemic inflammation, then it is logical to assume that treatment of periodontal disease would reduce overall inflammatory burden and hence the risk of cardiovascular disease and ischemic stroke. One study cited suggested that there may be associations between periodontal disease and cardiovascular issues.[114] Another study cited found that periodontitis treatment can improve surrogate measurements of cardiovascular health.[115] Commenters did not offer clinical evidence to support that dentally sourced infections can cause serious complications at the site of intracardiac or intravascular stents and devices, or that dental services to eradicate such dentally sourced infections is so integral to clinical success of the intracardiac or intravascular stents and devices that they are inextricably linked.

Comment: One commenter stated that most clinical guidelines do not recommend prophylactic dental procedures before undergoing subsequent cardiovascular procedures or device implantations. In contrast, the commenter continued, other guidelines counsel the value of optimal oral health hygiene and antibiotic prophylaxis to avoid infective endocarditis in patients with congenital heart disease and/or prior prosthetic valve implant. They summarized that current evidence might not support a role for pre-treatment dental care for preventing downstream infections related to the implantation of ventricular assist devices, artificial pacemakers, implantable cardioverter defibrillators, synthetic grafts, and patches, or coronary and vascular stents. However, the commenters noted that as evidence and guidelines continue to evolve—especially as increasing emphasis is placed on both health equity and high-quality outcomes that conserve scarce health care resources—it may prove appropriate for CMS to determine dental services are inextricably linked to certain cardiovascular therapies in the future.

Response: We will continue to monitor the evolution of guidelines and the production of evidence showing specific cardiovascular services for which dental services are inextricably linked to their clinical success.

Comment: Another commenter stated that they do not believe that dental evaluation and treatment are absolutely necessary prior to performing stents and vascular access grafts for hemodialysis. They relayed that clinicians report that while completing dental care before such a procedure is a laudable goal, they would proceed with placing the stent or graft without having this completed and do not believe dental services are inextricably linked to the procedures.

Response: We thank the commenter for their perspective and sharing of clinical insight. After consideration of public comments, we are not expanding the examples in the regulation at § 411.14(i)(3)(i) to include additional cardiac procedures at this time but will continue to consider public submissions through the public process discussed above in section II.K.1.c. of the final rule, of specific medical services in the future. Submissions should include clinical evidence that certain dental services are so integral to their clinical success that the standard of care for that cardiovascular intervention would be compromised or require the dental services to be performed in conjunction with the covered cardiovascular intervention services.

4. Request for Comment on Dental Services Integral to Specific Covered Services To Treat Sickle Cell Disease (SCD) and Hemophilia

Payment for Dental Services for Individuals Living With SCD

Interested parties using the public submission process we finalized in the CY 2023 PFS final rule urged us to propose to provide that payment can be made for dental services for individuals living with SCD.

These submissions provided information and references supporting

[114] Peruzzi M, Covi K, Saccucci M, Pingitore A, Saade W, Sciarra L, Cristalli MP, Miraldi F, Frati G, Cavarretta E. Current knowledge on the association between cardiovascular and periodontal disease: an umbrella review. Minerva Cardiol Angiol. 2022 Mar 25. doi: 10.23736/S2724–5683.22.06022–7. Epub ahead of print. PMID: 35332749.

[115] Sanz M, Del Castillo AM, Jepsen S, Gonzalez-Juanatey JR, D'Aiuto F, Bouchard P, Chapple I, Dietrich T, Gotsman I, Graziani F, Herrera D, Loos B, Madianos P, Michel JB, Perel P, Pieske B, Shapira L, Shechter M, Tonetti M, Vlachopoulos C, Wimmer G. Periodontitis and Cardiovascular Diseases. Consensus Report. Glob Heart. 2020 Feb 3;15(1):1. doi: 10.5334/gh.400. PMID: 32489774; PMCID: PMC7218770.

prevention of dental infection among individuals with SCD to reduce need for more extensive procedures that may result in bleeding complications and require hospitalization. They also provided information detailing increased dental caries and periodontal disease in people with SCD,[116] many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life.

We note that the decisions we make through the public submissions and the rulemaking process regarding whether payment is permitted for certain dental services are not in terms of a coverage decision. Rather, we are considering whether payment can be made for certain dental services in a particular clinical scenario because, in accordance with § 411.15(i)(3)(i), the dental services would be ''inextricably linked to, and substantially related and integral to the clinical success of a certain covered medical service'' such that they are not subject to the statutory preclusion on payment for most dental services under section 1862(a)(12). If we determine that certain dental services provided in a specific clinical scenario do meet the criterion in § 411.15(i)(3)(i), then payment can be made for the dental services.

We solicited comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. We solicited comment identifying such covered services for SCD and whether an inextricable link is supported by clinical evidence as described in section II.K.1.c. of this final rule.

We received public comments on these requests for comment. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported coverage for dental services as inextricably linked to covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. The commenters also recommended that we extend coverage for dental services to patients living with SCD or hemophilia for 2024. Other commenters urged us to add SCD as a covered indication for treatment of dental services that are integral to the outcomes for Medicare beneficiaries with SCD.

Another commenter urged us to expand coverage and payment of dental services for individuals with SCD presenting with pain crises in the jaw, mouth, or face and in the case of a dental abscess stated that better access to dental services will help to improve quality of life for individuals with SCD and reduce overall costs to the healthcare system by allowing for more appropriate treatment options and a reduction in length of hospital stay. This commenter provided references.[117] [118] [119] [120] [121] One commenter questioned the clinical basis for adding SCD, and hemophilia, as predicates for medically necessary dental benefits since there are relatively few cases of SCD and hemophilia in the Medicare population.

Response: We thank commenters for their feedback. After consideration of public comments, we are not expanding the examples under § 411.15(i)(3)(i) to include additional covered medical services for SCD or hemophilia at this time but will continue to consider public submissions through the public process discussed above at section II.K.1.c. of the final rule, of specific medical services in the future. The information commenters provided did not support finding that dental services are inextricably linked to a covered medical service for SCD or that the standard of SCD care would be compromised or require dental services to be performed in conjunction with hydroxyurea therapy or other treatment for SCD. One reference cited concluded in part that good access to oral health care might be as important for SCD as it is for diabetes mellitus, but more research is needed.[122] In order for us to find that dental services are inextricably linked to, and substantially related and integral to the clinical success of hydroxyurea therapy or other treatments for SCD, we would need clinical evidence to demonstrate that the standard of care would be not to proceed with the other covered services without providing the dental services in conjunction with the hydroxyurea therapy or other treatment for SCD. We welcome additional public submissions by the February 10 deadline for consideration in PFS rulemaking for CY 2025. Submissions should include medical evidence and supporting literature addressing why dental services are inextricably linked to hydroxyurea therapy or other covered treatment for SCD. Specifically, we request that the medical evidence should support the inextricable link between certain dental services and other covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario; and/or

(3) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686, 69687).

Payment for Dental Services for Individuals Living With Hemophilia

Interested parties also urged us to propose a policy to permit payment for dental services for individuals living with hemophilia. They noted that periodic dental care reduces the risks of dental complications requiring haemostatic therapy (such as tooth extractions that may require clotting factor treatment) or oral surgeries requiring clotting factor replacement therapy.[123] [124] [125]

We noted that many submitters, using the public submission process we

[116] Kakkar M, Holderle K, ShethM, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia. 2021 Oct22; 2021:5556708. Doi: 10.1155/2021/5556708. PMID: 34721900; PMCID: PMC8556080.

[117] Basati MS. Sickle cell disease and pulpal necrosis: a review of the literature for the primary care dentist. Prim Dent J. 2014 Feb;3(1):76–9. *doi:10.1308/205016814812135922.*

[118] Chekroun M, Chérifi H, Fournier B, Gaultier F, Sitbon IY, Ferré FC, Gogly B. Oral manifestations of sickle cell disease. Br Dent J. 2019 Jan 11;226(1):27–31. *doi: 10.1038/sj.bdj.2019.4.*

[119] Hsu LL, Fan-Hsu J. Evidence-based dental management in the new era of sickle cell disease: A scoping review. J Am Dent Assoc. 2020 Sep;151(9):668–677.e9. *doi: 10.1016/j.adaj.2020.05.023.*

[120] Bedrouni M, Touma L, Sauvé C, Botez S, Soulières D, Forté S. Numb Chin Syndrome in Sickle Cell Disease: A Systematic Review and Recommendations for Investigation and Management. Diagnostics (Basel). 2022 Nov 24;12(12):2933. *doi:10.3390/diagnostics12122933.*

[121] Mestoudjian P, Steichen O, Stankovic K, Lecomte I, Lionnet F. Sickle cell disease, a benign cause of numb chin syndrome. Am J Med. 2008 Oct;121(10):e1. *doi: 10.1016/j.amjmed.2008.05.028.*

[122] Hsu LL, Fan-Hsu J. Evidence-based dental management in the new era of sickle cell disease: A scoping review. J Am Dent Assoc. 2020 Sep;151(9):668–677.e9. *doi: 10.1016/j.adaj.2020.05.023.*

[123] Raso S, Napolitano M, Sirocchi D, Siragusa S, Hermans C. The important impact of dental care on haemostatic treatment burden in patients with mild haemophilia. Haemophilia. 2022 Nov;28(6):996–999. doi: 10.1111/hae.14626. Epub 2022 Jul 25. PMID: 35879819.

[124] Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, Carcao M, Mahlangu J, Ragni MV, Windyga J, Llinás A, Goddard NJ, Mohan R, Poonnoose PM, Feldman BM, Lewis SZ, van den Berg HM, Pierce GF; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1–158. doi: 10.1111/hae.14046. Epub 2020 Aug 3. Erratum in: Haemophilia. 2021 Jul;27(4):699. PMID: 32744769.

[125] Peisker A, Raschke GF, Schultze-Mosgau S. Management of dental extraction in patients with Haemophilia A and B: a report of 58 extractions. Med Oral Patol Oral Cir Bucal. 2014 Jan 1;19(1):e55–60. doi: 10.4317/medoral.19191. PMID: 24121912; PMCID: PMC3909433.

finalized in the CY 2023 PFS final rule, stated that good dental and oral health benefits a patient's overall health generally. Several commenters on the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act.

We received public comments on these requests for comment. The following is a summary of the comments we received and our responses.

Comment: One commenter urged us to permit payment under Medicare Part A and Part B for preventive dental services for individuals with hemophilia. They noted that Hemophilia Treatment Centers (HTCs) are a federally supported network of care, and that the Centers for Disease Control and Prevention (CDC) lists dentists as a specialist who should be available by referral by an HTC and find it appropriate that the Medicare would provide coverage and payment for these services. They also reference World Federation of Hemophilia (WFH) Guidelines for the Management of Hemophilia. These guidelines provide that maintaining good oral health and preventing dental problems is greatly important in the prevention of oral diseases and conditions such as gingivitis, dental caries, and periodontal diseases which may cause serious gum bleeding, especially in those with severe/moderate hemophilia, and to avoid the need for major dental surgery. They noted they will submit additional comments by the February 10, deadline with information and supporting literature for why dental services are needed for bleeding disorders beyond hemophilia. Another commenter agreed that periodic dental care reduces the risks of dental complications requiring haemostatic therapy (such as tooth extractions that may require clotting factor treatment) or oral surgeries requiring clotting factor replacement therapy. Other commenters urged that we consider finalizing payment for hemophilia as one of the clinical scenarios for which medically necessary dental care could be covered.

Response: In the case of dental services for individuals living with hemophilia, we would need to identify one or more specific clinical scenarios where there is clinical evidence that certain dental services are so integral to the clinical success of the medical services to manage or treat hemophilia or complications resulting from the condition that they are inextricably linked to the other covered service(s). We thank the commenters for their perspectives, and while we agree that maintaining good oral health and preventing dental problems is greatly important in the prevention of oral diseases that can lead to serious gum bleeding, which is particularly problematic for individuals with hemophilia, we are seeking specific evidence supporting specific medical services for which dental services are inextricably linked to their clinical success. We welcome additional submissions by the February 10, deadline with information and clinical evidence, discussed above at section II.K.1.c. of this final rule, supporting the conclusion that certain dental services are integral and inextricably linked to other covered services related to hemophilia and any other bleeding disorders.

5. Request for Comment Regarding Dental Services Possibly Inextricably Linked to Other Medicare-Covered Services

Commenters, submitters, and other interested parties have urged us to consider the importance of access to oral health care for people with chronic auto-immune conditions and other chronic disease conditions, such as, but not limited to, diabetes. They have also suggested that we consider making payment for dental services associated with other conditions such as chronic kidney disease and end stage renal disease, and procedures such as joint replacement, and services such as inpatient substance use disorder treatment and long-term use of immunosuppressants for the treatment of colitis, Crohn's, lupus, multiple sclerosis, rheumatoid arthritis, and Sjögren's disease. After consideration of public comments, we are not expanding the examples under § 411.15(i)(3)(i) to include dental services associated with additional covered medical services related to the conditions and procedures suggested in comments. We understand and appreciate the interest in such requests. However, the information generally provided by commenters did not establish an inextricable link between dental services and a covered medical service such that dental services would not be in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth. Because the Medicare statute generally prohibits payment for dental services, payment may be made in limited situations such as when the dental services are inextricably linked to, and substantially related and integral to the clinical success of certain other covered services as provided by our regulations at § 411.15(i)(3), or under the exceptions provided by section 1862(a)(12) of the Act and codified at § 411.15(i)(2). We urge interested parties to consider the circumstances under which dental services are inextricably linked to other covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions and support their submissions with clinical evidence or other documentation as described in section II.K.1.c. of this final rule. Details regarding the public submission process are available in the CY 2023 PFS final rule (87 FR 69669 through 69670).

As summarized above in section II.K.1.c. of this final rule, through the public submission process we finalized in the CY 2023 PFS final rule, interested parties should submit medical evidence to support an inextricable link between certain dental services and covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

As discussed previously in section II.K.1.c. of this final rule, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered services, we need to identify specific medical services for which there is medical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to the covered service. The medical evidence should support that in the case of surgery, the provision of certain dental services leads to improved healing, improved quality of surgery, and the

reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure. Medical evidence should be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the primary medical procedure such that the dental services are inextricably linked to, and substantially related and integral to, the clinical success of the covered services. Medical evidence should support that the dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient), or, medical evidence should demonstrate that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

Comment: Some commenters recited the sequelae and the oral manifestations of diabetes mellitus. They relayed that for patients with diabetes mellitus and periodontitis, the provision of preventive dental care/conservative periodontal treatment leads to a statistically and clinically significant reduction in glycated hemoglobin (HbA1c), a key measure of metabolic control, and an established risk marker for clinical complications of diabetes mellitus. The commenters also stated that conservative periodontal treatment is associated with improved health outcomes and reduced healthcare costs. They stated preventive and restorative dental care fosters a healthy diet that is key to diabetes treatment. They shared that they are in the process of exploring specific diabetes-related covered services for which the provision of inextricably linked dental care is associated with improved outcomes and reduced cost and intend to submit their findings by February 10, 2024, in nominations through the public process we have established.

Response: We thank the commenters for the information they have submitted and welcome submissions of further information through the public process we have established. Based on the information we received from commenters who indicated that they are still in the process of exploring specific diabetes-related covered services for which the provision of inextricably linked dental care associated with improved outcomes, we are not adding an additional example in § 411.15(i) related to covered medical services for diabetes at this time. We would consider information about specific diabetes-related covered services we receive under the public process by February 10, 2024, for CY 2025 rulemaking.

Comment: One commenter stated that our interpretation of section 1862(a)(12) of the Act is too restrictive to meaningfully expand coverage to those with systemic autoimmune diseases. Nevertheless, they stated that they were encouraged by our commitment to continue exploring the inextricable link between dental and covered services associated with immunosuppressant therapy. The commenters stated that because dental caries and periodontal diseases are bacterial infections, they can seed complications such as sepsis, dissecting facial space abscesses, Ludwig's angina, and cellulitis –especially when individuals are immunocompromised. They reported that physicians across the medical specialties involved in treating colitis, Crohn's, lupus, multiple sclerosis, rheumatoid arthritis, and Sjögren's disease have acknowledged that dental treatment to resolve dental infections can be integral to improving outcomes among patients requiring long-term use of immunosuppressive medications. The commenters supported us in continuing to study the relationship between dental care and medical services that cause immunosuppression in patients and urge us to adopt a more expansive view of our authorities. Other commenters wrote that while dental services are not inextricably linked to the successful treatment of severe chronic obstructive pulmonary disease (COPD), uncontrolled diabetes, epilepsy, Sjogren's disease, lupus, rheumatoid arthritis, chronic kidney disease, Ludwig's angina (and similar space infections), and/or retroperitoneal fibrosis in every case, for many Medicare beneficiaries, oral pathologies must be addressed when they are clinically determined to be a causal or highly exacerbating factor in the progression and treatment of their medical conditions.

Response: We thank the commenters for their support, perspectives, and recommendations. We agree that additional information would be necessary to demonstrate that dental services are inextricably linked to covered services for autoimmune diseases and other chronic diseases before we could add those clinical scenarios as examples in § 411.15(i)(3)(i). We note that finalized policies do not prevent a MAC from determining on a case-by-case basis that payment can be made for certain dental services in other circumstances not specifically addressed within § 411.15(i)(3)(i), as amended by this final rule. We will continue to engage with interested parties on ways to improve care for Medicare beneficiaries with autoimmune diseases.

Comment: Other commenters stated that oral health services are inextricably linked to the success of inpatient treatment for substance use disorders. Other commenters supported the coverage of dental services for joint replacement surgeries to lessen the infection risk. Other commenters supported the coverage of annual dental examinations, and treatment as clinically indicated, for individuals with chronic kidney disease and end-stage renal disease. They stated that chronic immunosuppression increases the risk of dental infections leading to potentially deadly complications including bloodstream infections, peritoneal dialysis-associated peritonitis, and the exacerbation of chronic cardiovascular conditions. They also stated that when established by patient-specific medical and dental parameters, dental services can be unquestionably integral to the outcome of covered medical procedures.

Response: We thank the commenters for the information they submitted about joint replacement surgeries, chronic kidney disease, end-stage renal disease, and inpatient treatment for substance use disorders. However, commenters did not provide medical evidence to support an inextricable link between certain dental services and covered medical services for these conditions or medical services. After consideration of public comments, we are not expanding the examples under § 411.15(i)(3)(i) to include dental services associated with additional covered medical services for the conditions and treatment suggested by commenters and would welcome submissions of medical evidence through the public process we have established.

Comment: Another commenter requested that we consider covering dental services when linked to significant facial trauma, for example, from a vehicle accident, presuming Medicare coverage instead of vehicle liability coverage.

Response: In the CY 2023 PFS final rule (87 FR 69663 through 69664), we clarified that the statute includes an exception to allow payment to be made under Medicare Part A for inpatient hospital services in connection with the

provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at § 411.15(i)(2) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (i) the individual's underlying medical condition and clinical status; or (ii) the severity of the dental procedure. It is possible that dental services for patients with facial trauma could fall within this exception, depending on the severity of the dental procedures. It is also possible that a jaw fracture or dislocation resulting from the scenario would be within the example in the regulation at § 411.15(i)(3)(i)(C) permitting payment under Parts A and B for certain dental services. The MAC could make a determination that payment is permitted for certain dental services that are inextricably linked to the clinical success of the services to treat the facial trauma. We note that this is a clinical scenario where there is wide variability in the nature of traumatic facial injury, so evidence is not likely to demonstrate that dental services are routinely inextricably linked to services to treat facial trauma.

Comment: One commenter stated that they oppose the inclusion of dental benefits into Medicare specifying that CMS does not possess legislative authority for the expansion of dental applications relating to chronic disease conditions. They believed that ''this type of proposal is unconscionable in our current regulatory and federal budgetary environment,'' as it would have ''significant financial costs for the federal government and the American public'', citing the federal budget deficit, announced on August 8, 2023, in the Congressional Budget Office, Monthly Budget Review: July 2023.

Response: We thank the commenter for their comments. In the CY 2023 final rule (87 FR 69404, 69664) we explained that if a dental service is performed as incident to and as an integral part of a covered procedure or service performed by a dentist, the total service performed by the dentist is covered, and payment can be made under Medicare Parts A and B as appropriate. This policy is based on the idea that some dental services that would ordinarily be excluded by statute from payment are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. We believe that when that is the case those dental services are not in connection with dental services within the meaning of section 1862(a)(12) of the Act, but are instead inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. As such, we finalized our interpretation of the statute under section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services and allowed payment to be made, regardless of whether the services are furnished in an inpatient or outpatient setting. Under these circumstances, we finalized that the exclusion under section 1862(a)(12) of the Act would not apply, because the service is not in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but instead is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

6. Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

We continue to consider improvements to our payment policies for dental services as finalized in the CY 2023 PFS final rule (87 FR 69663 through 69688). As such, we indicated that we were interested in receiving comments from interested parties on our proposed rule on ways to continue to implement these payment policies. Additionally, we wanted to clarify the policies we finalized in the CY 2023 PFS final rule. Therefore, we requested comments on several policies related to the implementation of policies for dental services for which Medicare payment can be made.

In the CY 2023 PFS final rule, we clarified and codified our policy on payment for dental services and added in § 411.15(i)(3)(i) of our regulation examples of circumstances where payment can be made for certain dental services, including a dental exam and services to diagnose and eliminate an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures (87 FR 69664 through 69667).

We provided as examples of dental services that could be furnished to eradicate infection services such as, but not limited to, diagnostic services, evaluations and exams (for example, CDT codes payable with D0120, D0140 or D0150), extractions (for example, CDT codes payable with D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as filling procedures—for example, CDT codes payable with D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing—for example, CDT codes payable with D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT codes payable with D3000–3999). However, we continued to believe that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source. Therefore, we reiterated that such additional services would not be inextricably linked to the specific covered services. As such, no Medicare payment is made for the additional services that are not immediately necessary to eliminate or eradicate the infection. We further clarified that we did not propose in CY 2023, nor did we propose in CY 2024, to adjust any payment policy for services involving the preparation for or placement of dentures, and maintained that these services are not payable under Medicare Parts A and B. We also reiterated our policy, as finalized in the CY 2023 PFS final rule, that Medicare could make payment for dental services occurring over multiple visits as clinically appropriate. We refer readers to 87 FR 69678 for a comprehensive discussion of this policy.

We continue to recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan, another private insurance plan offering commercial dental coverage, or for those individuals dually eligible for Medicare and Medicaid, through a state Medicaid program. As a result, we solicited comment on the coordination of multiple dental benefits that Medicare beneficiaries may have, whether and if so, how other plans currently cover and pay for dental services, and what type of guidance CMS should provide about the dental payment policies we have established and their relationship to other separate or supplemental dental coverages.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated CMS should issue clear guidance on the type of dental payment policies we have established and how that relates to any

supplemental dental coverage in order to ensure access to oral and dental health care. Some commenters also noted it would be helpful to have more information on how Medicaid, Medicare Advantage, and other plans interact with Medicare coverage to coordinate dental services.

Response: We appreciate the commenters' thoughtful feedback and questions regarding the operational aspects of this proposal, specifically regarding supplemental dental coverage and coordination of benefits, and we agree that these are necessary topics to address. We acknowledge the need to address and clarify certain operational issues, and we are working to address these issues and provide education and guidance. We will continue to work with our MACs and encourage continued feedback from interested parties to help identify concerns or questions regarding the submission and processing of dental claims in order to assist with the coordination of benefits amongst dentists and issuers. We also plan to provide guidance and engage in further rulemaking, as necessary, as operational strategies and plans are refined and implemented. We appreciate the questions raised by commenters and plan to take them into consideration as we continue to advance operational issues relating to this policy, and make any necessary changes or refinements.

Comment: Most commenters recommended that CMS develop educational and outreach materials regarding billing and claims for any payment policies we finalize. Additionally, some commenters stated that dentists and transplant providers are interested in obtaining a roadmap on matters related to submitting claims, expecting reimbursement, and referring patients to local Medicare-participating dentists.

Response: We appreciate the questions raised by commenters and plan to take them into consideration as we continue to refine operational issues relating to this policy and make any necessary refinements. We have started to create educational materials, including information regarding enrollment, through products such as Change Request 13190, *Educational Instructions for the Implementation of the Medicare Payment Provisions for Dental Services as Finalized in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Final Rule,* available at *https://www.cms.gov/files/document/r12047bp.pdf* and have provided content as well as information regarding dental claims form (837D) via the CMS website at *https://www.cms.gov/medicare/coverage/dental*. We encourage MACs to utilize information provided in the CR to develop their own educational and billing materials. We intend to make additional modifications to our informational and guidance materials, including the Medicare Claims Processing Manual, and create educational materials to reflect refinements to payment policy for dental services, as well as describe updates to operational and implementation aspects of this policy. We appreciate the ongoing interest and engagement from interested parties on all aspects of this policy.

We also solicited comment on approaches utilized by other health plans to mitigate issues with third party payment, including when Medicare is secondary payer and when coordinating with state Medicaid programs. In addition, we noted there is an informal practice whereby dental professionals may submit a dental claim to Medicare for the purposes of producing a denial so that Medicaid or another third-party payer can make primary payment.

Given the complexity of dental professionals submitting claims for purposes of denial, we solicited comment on the impact of third-party payers, including state Medicaid programs, requiring a Medicare denial as a prerequisite for adjudication of primary payment for dental services that are not inextricably linked to another specific covered service. In these cases where the dental services are not inextricably linked to another specific covered service, dental professionals must include the appropriate HCPCS modifier on the respective dental claim form, which serves as a certification that the professionals believe that Medicare should not pay the claim.

We also solicited comment regarding an informal process on claims denials for the purposes of supporting payment by other payers is currently achieved in practice when using the dental claim form 837D. We note that the submission of a claim without one or more of the HCPCS modifier(s) meant to produce a denial shows belief by the enrolled billing practitioner that Medicare, not another payer, should be the primary payer in accordance with all applicable payment policies. As such, submission of a claim for dental services without such a modifier would mean that the billing practitioner believes the dental service is inextricably linked to another Medicare-covered service, or that payment for the service is otherwise permitted under our regulation at § 411.15(i).

We solicited comment on the practices of other payers related to submission of claims in order to generate a denial and how these practices impact claim submission and claim adjudication with third party payers, including state Medicaid programs.

Additionally, we solicited comment on types of guidance, such as best practices or criteria, that are needed for purposes of coordinating payment for dental services under the policies specified in the rule.

The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that CMS should provide clear guidance for when Medicare is a primary or secondary payer. Additionally, these commenters stated that they believe that Medicare coverage of medically necessary dental services should be in addition to any third-party dental plans.

Response: We appreciate the feedback from commenters as we work towards coordinating efforts with any third-party payers, including state Medicaid programs.

Comment: Many commenters supported CMS pursuing the adoption of the 837D dental claim form and believe implementing this form will provide efficiency when processing dental claims. However, one commenter did not support the idea of adopting the dental claim form because the commenter stated they believe both the dental claim form and medical claim form are significantly different and that the dental claim form does not allow for modifiers, which would provide a barrier when determining which services qualify as Medicare basic benefit. Instead, this commenter suggested creating two new modifiers to make a distinction for inextricable linkage, for example, one modifier that attests to a particular dental service being inextricably linked and a second modifier that attests to a particular dental service not inextricably linked.

Response: We continue to work to address issues raised by commenters, including questions related to claims processing and efforts to accommodate the dental claim form within our claims processing systems, effective 2024. As efforts advance to address the implementation and functionality of claims processing systems for the dental claim form, we intend to provide appropriate guidance and education to interested parties. Additionally, we continue to explore options for addressing the need to identify claims confirming inextricable linkage between the covered medical and dental services. These options include utilizing a HCPCS, CPT, or CDT modifier that may

allow dentists to attest to a particular dental service being inextricably linked and/or a second HCPCS, CPT, CDT modifier to attest that a particular dental service is not inextricably linked. We believe that the possible implementation and usage of distinct modifiers or codes for the purposes of confirming inextricable linkage will better enable us to quantify dental services and better understand the billing patterns of practitioners that typically furnish them. This information is helpful to CMS for program integrity purposes and may also inform us on whether we need to revise the policies for these services in future rulemaking. We intend to provide additional guidance and education around the possible usage of situationally appropriate HCPCS, CPT, and CDT modifiers that may be utilized in order to document inextricable linkage in claims processing. Additionally, we note that we intend to make conforming changes to the Internet Only Manual (IOM) Publication 100–04, Medicare Claims Processing Manual, to reflect any modifications to the guidance on the submission of claims for the purpose of denials from CMS so third-party payers can pay as primary and intend to provide education regarding these operational aspects of this policy.

Comment: Some commenters stated they oppose the informal practice of dental professionals submitting a dental claim to Medicare to produce a denial because they believe that it creates an administrative burden for health care providers. These commenters noted it also causes significant delays with reimbursement and can be confusing to patients as well. A few commenters questioned the legality and validity of the practice of submitting claims to elicit a denial. Many commenters highlighted that the current version of the American Dental Association dental claim form has no box for HCPCS modifiers and the commenters are not aware of any medical carriers that currently accept the 837D dental claim form. These commenters stated that the CMS–1500 form is typically used when a medical denial is needed for a dental service. However, a few commenters supported the possibility of using HCPCS modifiers on the 837D dental claim form for the purpose of Medicare denial and coordination benefits.

Response: We note that dentists may continue submitting claims using the 837P and 837I claims types with existing Healthcare Common Procedure Coding System (HCPCS) modifiers when third-party payers need a Medicare claim denial. We continue to explore options for addressing the need to submit a dental claim to Medicare for the purpose of obtaining a denial so that another carrier or third-party payer may issue primary payment via the 837D dental claims format. In addition, we will take into consideration the potential usage of situationally appropriate modifiers or other codes that may be utilized in making clear that claims have been submitted expressly for the purpose of eliciting a denial. Additionally, we note that we will make conforming changes to the Internet Only Manual (IOM) Publication 100–04, Medicare Claims Processing Manual, to reflect any modifications to the guidance on the submission of claims for the purpose of denials from CMS so third-party payers can pay as primary, including the 837D dental claim format and provide education to the public regarding these efforts.

As described in the CY 2023 PFS final rule (87 FR 69663 through 69688), Medicare payment under Parts A and B may be made for dental services that are inextricably linked to other covered services. We believe the dental services and the other covered services would most often be furnished by different professionals and that in order for the dental services to be inextricably linked to other covered services such that Medicare payment can be made, there must be coordination between these professionals. This coordination should occur between the practitioners furnishing the dental and covered services regardless of whether both individuals are affiliated with or employed by the same entity. This coordination can occur in various forms, such as, but not limited to, a referral or exchange of information between the practitioners furnishing the dental and covered services. Additionally, any evidence of coordination between the professionals furnishing the primary medical service and dental services should be documented. If there is no evidence to support the exchange of information, or integration, between the professionals furnishing the primary medical service and the dental services, then there would not be an inextricable link between the dental and other covered services within the meaning of our regulation at § 411.15(i)(3)(i). As such, Medicare payment for the dental services would be excluded under section 1862(a)(12) of the Act (though payment for the dental services might be available through supplemental health or dental coverage). Additionally, we sought information regarding the potential impact of these payment policies in settings other than inpatient and outpatient facilities, such as Federally qualified health centers (FQHCs), rural health clinics (RHCs), etc. We understand that some Medicare beneficiaries may access dental services in these settings and seek to understand what, if any, impact may potentially occur within the context of this payment policy.

As stated in the CY 2023 PFS final rule, we note that to be eligible to bill and receive direct payment for professional services under Medicare Part B, a dentist must be enrolled in Medicare and meet all other requirements for billing under the PFS. Alternatively, a dentist not enrolled in Medicare could perform services incident to the professional services of a Medicare enrolled physician or other practitioner. In that case, the services would need to meet the requirements for incident to services under § 410.26, including the appropriate level of supervision, and payment would be made to the enrolled physician or practitioner who would bill for the services (87 FR 69673). In the CY 2023 PFS final rule (87 FR 69687), we finalized that we would continue to contractor price the dental services for which payment is made under § 411.15(i). We will maintain this policy and continue to contractor price the dental services for which payment is made under § 411.15(i) for CY 2024. Additionally, in the CY 2023 PFS final rule, we agreed with the suggestions made by commenters that there may be publicly available data sources that could aid MACs in determining these payment rates in order to account for geographic variation. We solicited comment on what specific information could help inform appropriate payment for these dental services (87 FR 69679).

The following is a summary of the comments we received and our responses.

Comment: Majority of commenters supported the idea that coordination between medical and dental professionals must be properly documented. However, one commenter mentioned that requiring MACs to document coordination is difficult since any coordination will vary between different MACs. Therefore, these MACs requested that CMS to provide guidance that ensures compliance with the coordination requirement will be clear and simple. A few commenters requested clarification on how practitioners should demonstrate the exchange of information between medical and dental professionals to support Medicare payment for dental services as inextricably linked to other covered services and suggested the potential usage of existing CDT or CPT

codes or modifiers as a mechanism to establish the inextricable link between the dental and covered medical service.

Response: We appreciate the commenters' feedback regarding documentation of the coordination and exchange of information between the medical and dental professionals. In the CY 2023 PFS final rule, we stated that we would make payment when a doctor of dental medicine or dental surgery (referred to as a dentist) furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician, or nonphysician practitioner, treating the primary medical illness. However, we explained that if there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) about the primary medical service and the dentist regarding the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3) (88 FR 69673). We continue to investigate operational mechanisms to demonstrate that the exchange of information between the Medicare enrolled medical and dental professional, such as the usage of the CPT or CDT modifiers or codes, including the KX HCPCS modifier, the CDT code D9311 (consultations with a medical health care professional), CPT code for interprofessional consultation (such as CPT 99452), or other modifiers/codes. As these operational aspects are implemented, we intend to provide educational materials regarding documentation of the exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) in regard to the primary medical service and the dentist in regard to the dental services.

Comment: One commenter opposed the requirement that only dentists enrolled in Medicare are eligible to receive direct payment from Part B because the commenter stated they believe this would limit Medicare beneficiary access to medically necessary dental benefits.

Response: As explained in the CY 2023 PFS final rule, dentists not enrolled in Medicare may provide services incident-to the professional services of a Medicare enrolled physician or other practitioner who would bill for the services as long as the requirements under § 410.26 for incident-to services are met (87 FR 69673). Additionally, dentists not enrolled in Medicare must coordinate payment with the Medicare enrolled physician or other practitioner to receive payment from Medicare.

Comment: Many commenters expressed their support for our current policy to contractor price dental services and believe using claims data will help inform appropriate payment for these services. However, a few commenters were opposed to contractor pricing of dental services and instead recommended that we should price the CDT codes in PFS RVU files to ensure consistent payment for each code while still accounting for geographic resource cost variations through the application of the PFS GPCIs. Additionally, several commenters expressed concerns regarding existing constraints on PFS funds due to the significant amount of other physician services currently included in the PE RVU Methodology. Therefore, these commenters noted that they believe that any expansion of Medicare to include dental services should be paid through a separate program independent of the physician fee schedule.

Response: We continue to believe that MACs are appropriately situated to establish contractor prices for these services, given that the MACs currently establish contractor pricing for the dental services for which payment is currently made. We believe it is appropriate to continue contractor pricing for dental services for which payment is made in the additional clinical scenario examples we are finalizing in this final rule, until we have additional pricing data that could enable national pricing. We encourage MACs to continue to engage with interested parties by providing information on how they price these services. As such, we will continue to contractor price these services based on the applicable payment system for services furnished. We intend to continue engaging with interested parties regarding establishing national payment rates for these applicable dental services. Regarding the comment that Medicare payment for dental services should be made through a separate program independent of the PFS, we appreciate the commenters' feedback and note that we have clarified our interpretation of section 1862(a)(12) of the Act, and subsequently codified certain aspects of our current Medicare PFS payment policies for dental services. Additionally, while we recognize that the impact of access to these services to individual beneficiaries may be very significant, we still do not anticipate a significant impact in the context of overall spending and utilization under the PFS. We intend to closely study the trends in utilization and payment for these services and make refinements to the payment policy as needed in future rulemaking.

Comment: Many commenters requested that we provide payment for inextricably linked dental services in the FQHC setting. Commenters stated that it is critical that CMS consider FQHCs' unique Medicare payment structure and that CMS ensure that policy changes for FQHCs are analogous to any changes made under the PFS. Commenters noted that many FQHCs provide dental services on-site, and health center patients could benefit from the payment policies for dental services inextricably linked to other covered services and suggested that the FQHC billing codes should be edited in tandem. Commenters further noted that ''physicians' services'' component of the Medicare FQHC benefit includes services furnished by dentists. Several commenters urged that the list of billable visit codes modified in the proposed rule be included in the dental bundle for FQHCs or otherwise added to the list of codes that may be billed in the FQHC setting and also requested that any expansion in codes recognized under the PFS for dental-related services also be applied to FQHCs.

Response: We appreciate the thoughtful feedback from commenters. We note that we intend to continue to refine the policy's operational aspects to ensure that the updates to this PFS payment policy are implemented in various applicable settings, including FQHCs. We acknowledge that the updates to the PFS payment policies for the purposes of this policy may be appropriate in other settings that provide PFS physician services, and we intend to make necessary modifications to operational procedures to reflect the expansion of this PFS payment policy, including potential updates to billable code lists and other relevant policies in the FQHC setting. We also note that we intend to provide additional guidance and education around the possible usage of situationally appropriate HCPCS or other modifiers or other CPT and/or CDT codes that may be utilized on FQHC claims in order to document inextricable linkage in claims processing or to elicit a denial for the purposes of payment by another payor, including Medicaid. We continue to seek engagement with interested parties on the appropriate application of this payment policy in other settings and encourage the public to continue to provide additional information regarding settings that may require special consideration in the context of this payment policy.

In the CY 2023 PFS final rule (87 FR 69682), we stated that we would update our payment files so that these dental services could be billed appropriately under the applicable payment system for services furnished in the inpatient or outpatient setting. We have revised the HCPCS and PFS payment and coding files to include payment indicators for Current Dental Terminology (CDT) codes, such as bilateralism, multiple procedures, and other indicators that are included in the files (posted at our website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files*) for CDT codes. We solicited comment on whether payment indicators, as outlined in the PFS RVU files, appropriately align with existing dental billing and coding conventions or whether edits are necessary.

Although we proposed to continue contractor pricing services billed using CDT codes, we solicited comment on whether the current payment indicators included for these CDT codes follow existing dental billing conventions, for example, for payment adjustment for multiple procedures, and whether there is a need for additional guidance regarding the submission of claims for services for which payment is permitted under the regulation at § 411.15(i)(3). In the CY 2023 PFS final rule (87 FR 69679), we acknowledged the need to address and clarify certain operational issues, and we are continuing to work to address these operational issues, including efforts to adopt the dental claim form. These efforts include continuing to work with our MACs and encouraging continued feedback from interested parties to help identify concerns or questions regarding submitting and processing dental claims.

Finally, to promote the correct coding and processing of Medicare claims, we solicited comment on whether additional specialty codes besides specialty codes, specialty 19 (oral surgery—dentists only) or specialty 85 (maxillofacial surgery), should be considered for use in Medicare.

We also solicited comment on whether these specialty codes may impact the coordination of benefits with a third-party payer.

Finally, we acknowledged that issues could occur related to the coordination of benefits for dual eligible beneficiaries, for example, beneficiaries with hemophilia, and we solicited comment on how to best coordinate a potential payment policy in this area with respect to state Medicaid plans or private insurance.

We also solicited comment on other coordination of benefits issues, or implementation topics that would be helpful for CMS to address in relation to continuing to implement these PFS payment policies, and we received public comments. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that multiple procedure reductions and payment indicators should be removed from the PFS payment files because they do not align with existing dental billing and coding conventions.

Response: We note that the multi-procedure payment reductions are a standard payment indicator used for any service priced on the PFS payment file. However, given feedback from interested parties, CMS has recently removed multi-procedure payment reductions payment indicators for dental services (described by current dental terminology(T) codes in the July 2023 release of the PFS RVU files. Additionally, we will continue to study and refine the payment files for dental services, including the applicability of other payment indicators. We also intend to identify appropriate modifications to the dental services code set on the PFS payment files to better align with clinical practice and implement edits in the practitioner claims processing systems to reflect that codes for some procedures would not likely be appropriate for usage in situations where medical services are inextricably linked dental services, such as procedures that are solely cosmetic in nature. We will also update appropriate Medicare payment data files to ensure that covered dental services can be billed and paid based on the applicable payment system for services furnished. For more information regarding dental codes that are available for payment under Medicare, we refer readers to the PFS RVU Files posted on our website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

As we consider refinements to the payment file in the context of how dentists furnish these services, we would be interested in obtaining information regarding certain dental codes that would not be covered in the context of the policies we describe. This information, as well as additional comments or considerations, can be submitted through the public submissions process described in section II.K.1.c. of this rule.

Comment: A few commenters supported CMS creating new dental specialty codes for use by dentists enrolling in the Medicare program to promote the correct coding and processing of Medicare claims for dental services.

Response: We appreciate the commenters' suggestion that CMS create new dental specialty codes to advance accurate coding and claims processing. We note that CMS issued guidance on August 31, 2023 via Change Request 13323, *New Dental Specialty Codes for Medicare,* announcing new dental specialty codes that dentists may use beginning on January 2, 2024. These new specialty codes include: E3—Dental Anesthesiology, E4—Dental Public Health, E5—Endodontics, E6—Oral and Maxillofacial Pathology, E7—Oral and Maxillofacial Radiology, E9—Oral Medicine, F1—Orofacial Pain, F2—Orthodontics and Dentofacial Orthopedics, F3—Pediatric Dentistry, F4—Periodontics, F5—Prosthodontics. More details regarding this change request are available at *https://www.cms.gov/files/document/r12231cp.pdf.*

We thank the public for their comments regarding the implementation considerations for these dental policies, and we will continue to work with MACs and other interested parties to address issues raised by the commenters. We continue to encourage feedback from interested parties to help identify concerns or questions regarding submission and processing of dental claims and other operational and implementation concerns. We plan to provide guidance and engage in further rulemaking, as necessary, as operational strategies and plans are refined and implemented. We will also monitor service utilization to identify any concerns about consistency of claims processing and adequacy of access across the country. We appreciate the questions raised by commenters and plan to take them into consideration as we continue to refine operational issues relating to this policy and make any necessary refinements.

In conclusion, after consideration of the public comments, clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research, we are finalizing additions to our regulation at § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment

of cancer to the list of examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B. We are also finalizing, with modifications, the addition of § 411.15(i)(3)(i)(E) to add dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these, to the list of examples of clinical scenarios that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B.

Additionally, we reiterate that MACs have the flexibility to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). We further note that the finalized policies outlined in this section of this final rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed within this final rule and the finalized amendments to § 411.15(i). We remind readers once again that, to be considered for purposes of CY 2025 PFS rulemaking, submissions through our public process for recommendations on payment for dental services should be received by February 10, 2024, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Interested parties should include the words ''dental recommendations for CY 2025 review'' in the subject line of their email submission to facilitate processing. We continue to stress to submitters that recommendations must include at least one of the types of evidence listed earlier when submitting documentation to support the inextricable link between specified dental services and other covered services. We further note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Provisions From the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B (§§ 410.152, 414.902, 414.904, 489.30)

Drugs and biologicals (for the purposes of the discussion in this section III.A., ''drugs'') payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(n) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

The Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (hereinafter referred to as ''IRA'') contains several provisions that affect payment limits or beneficiary out-of-pocket costs for certain drugs payable under Part B. Among those provisions, two affect payment limits for biosimilar biological products (hereinafter referred to as ''biosimilars''):

- Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. We proposed to codify this provision in regulation.
- Section 11403 of the IRA increased the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years. We implemented section 11403 of the IRA under program instruction,[126] [127] as permitted under section 1847A(c)(5)(C) of the Act. We proposed conforming changes to regulatory text to reflect these provisions.

In addition, two provisions (among others in the IRA) make statutory changes that affect beneficiary out-of-pocket costs for certain drugs payable under Medicare Part B:

- Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. We issued initial guidance implementing this provision, as permitted under section 1847A(c)(5)(C) of the Act, on February 9, 2023.[128] We proposed conforming changes to regulatory text.
- Section 11407 of the IRA provides that for insulin furnished through an item of DME on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME. We have implemented this provision under program instruction for 2023, as permitted under section 11407(c) of the IRA.[129] We proposed to codify this provision in a manner that is consistent with the program instruction for 2023.

a. Payment for Drugs Under Medicare Part B During an Initial Period

In the CY 2024 PFS proposed rule (88 FR 52385), we explained that section 1847A of the Act provides for certain circumstances in which the payment limit of a drug is based on its wholesale acquisition cost (WAC). For a single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act), the Medicare payment could be determined based on WAC under the methodology specified in section 1847A(b)(4) of the Act and described at § 414.904(d)(1), which requires that payment limits for such drugs are determined using the lesser of ASP plus 6 percent or WAC plus 6 percent. Typically, the ASP-based payment limit is the lesser of the two. Under section 1847A(c) of the Act, payments for new drugs during an initial period for which ASP data is not sufficiently available are based on WAC or the Medicare Part B drug payment methodology in effect on November 1, 2003. Historically, WAC-based payment under section 1847A(c)(4) of the Act was up to 106 percent of WAC, but in the CY 2019 PFS final rule (83 FR 59661 through 59666), we adopted a policy of paying up to 103 percent of WAC in this instance. Subsequently, section 6 of the Sustaining Excellence in Medicaid Act of 2019 (Pub. L. 116–39, enacted August 6, 2019), amended section 1847A(c)(4) of the Act to specify, effective January 1, 2019, a payment limit not to exceed

[126] *https://www.cms.gov/files/document/r11496cp.pdf.*

[127] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[128] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[129] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text.*

103 percent of the WAC or based on the Part B drug payment methodology in effect on November 1, 2003 during an initial period when ASP data is not sufficiently available. There were no regulatory changes at that time. Therefore, we proposed to amend § 414.904(e)(4) to reflect this statutory change.

In the CY 2024 PFS proposed rule (88 FR 52385), we explained that more recently, section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A) of the Act. The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not sufficiently available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.

We proposed to codify these changes to section 1847A(c)(4) of the Act at § 414.904. Specifically, we proposed to revise paragraph (e)(4) at § 414.904 by adding paragraphs (e)(4)(i)(A) and (B) to conform the regulatory text for WAC-based payment limits before January 1, 2019 and for such payment limits on or after January 1, 2019 with the requirements established in section 6 of the Sustaining Excellence in Medicaid Act of 2019. We also proposed to add paragraphs (A) and (B) to § 414.904(e)(4)(ii) to codify the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period as required by section 1847A(c)(4)(B) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received regarding implementation of the IRA provisions in general and our responses.

Comment: Several commenters expressed general support for proposed regulatory changes that will reduce out-of-pocket costs for prescription drugs.

Response: We thank the commenters for their support.

Comment: Two commenters expressed support for CMS's ongoing efforts to implement the IRA by codifying provisions relating to Medicare Part B payments for certain biosimilar products, and one commenter stated that they support the proposal as a straightforward implementation of the statute. One commenter stated that these changes will help support the availability and use of biosimilar products and ensure that Medicare beneficiaries benefit from the savings that were intended by the passage of the new law.

Response: We thank these commenters for their support.

Comment: One commenter expressed concern about the financial impact the implementation of the IRA's provisions related to the payment of drugs will have on physician practices and requested we consider taking steps to offset revenue losses.

Response: We appreciate the commenter's concern. In limited circumstances, the implementation of the new lesser-than methodology for the add-on payment for biosimilar products established under section 11402 of the IRA may reduce provider payments, but this reduction lasts only during the period of marketing before ASP data is available. The temporary add-on payment for certain biosimilars with an ASP that is not more than the ASP of the reference biological established under section 11403 of the IRA, on the other hand, increases payments to providers.

The following is a summary of the comments we received regarding implementation of section 11402 of the IRA and our responses.

Comment: Regarding payment for drugs under Part B during an initial period, one commenter stated that based on the statutory language in section 11402 of the IRA that CMS proposes to implement, it appears that CMS has the authority to eliminate the 3 percent add-on payment for new drugs paid based on WAC. Therefore, the commenter urged the Secretary to reduce the payment rate for new drugs lacking ASP data from 103 percent to 100 percent of WAC. Because WAC is generally a higher price than ASP and does not reflect discounts, eliminating the WAC add-on would reduce excess payments, increase affordability for beneficiaries and taxpayers, and improve financial incentives. The commenter noted that in its June 2023 report to Congress,[130] the Medicare Payment Advisory Commission (MedPAC) recommended eliminating add-on payments for drugs lacking ASP data that are paid based on WAC to improve Medicare's Part B drug payment system.

Response: We thank commenters for these policy suggestions, and we may consider these policies in future rulemaking. We note that under the proposed policy, Medicare Administrative Contractors (MACs) are not required to pay an amount equal to 103 percent of the WAC. In the common circumstance that a WAC-based payment limit is not published on the ASP Drug Pricing File during the initial period, MACs will be given instruction to price drugs during the initial period in a manner consistent with these provisions, including language stating that the WAC-based payment limit under these policies is not to exceed 103 percent of the WAC. These instructions would not preclude MACs from making payments that are less than 103 percent of the WAC, but rather set a ceiling payment limit amount.

Comment: One commenter requested that we clarify whether and how CMS determines Medicare payment and patient cost-sharing responsibility for covered drugs assigned a temporary, unspecified billing and payment code. The commenter suggested having temporary HCPCS codes to facilitate drug payment during the initial period.

Response: Generally, new drugs in the initial period for which ASP data is not sufficiently available are not included on the ASP Drug Pricing File or the Not Otherwise Classified (NOC) Pricing File. Policies regarding WAC-based pricing during the initial period were finalized in the 2019 PFS final rule (83 FR 59661 through 59666) as discussed above in this section. These policies are currently reflected in section 20.1.3, Chapter 17 of the Medicare Claims Processing Manual,[131] which provides instruction for MACs to price new drugs and biologicals that are not included on the ASP Drug Pricing File or NOC Pricing File. The manual currently states that, for claims with dates of service on or after January 1, 2019, the add-on percentage is up to 3 percent for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available. Similarly, Chapter 17 of the Medicare Claims Processing Manual will be updated following the publication of this final rule to reflect policies finalized in this final rule regarding payment in the initial period for new drugs. In these circumstances, when the drug is billed using a NOC code, the MAC will instruct the provider on how to submit a claim using a NOC code and will determine the payment amount consistent with CMS policies. Therefore, we disagree that a temporary

[130] Medicare Payment Advisory Commission. 2023. Report to the Congress: Medicare and the health care delivery system. Washington, DC: MedPAC.

[131] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf,* accessed September 20, 2023.

billing and payment code is necessary to facilitate these payments.

Comment: One commenter encouraged CMS to conduct additional outreach to providers so that they can better understand the reimbursement policy for biosimilars.

Response: The Medicare Claims Processing Manual is typically updated with finalized policies following the publication of a final rule. Near the time this CY 2024 PFS final rule is issued, these updates will be accompanied by other CMS communications, such as an MLN Matters® article, to the provider community.

Comment: One commenter requested CMS clarify how the payment limits for new biosimilars as amended by section 11402 of the IRA will be implemented should legal challenges prevent or delay implementation of the drug price negotiation program, specifically regarding the maximum fair price (MFP) and encouraged CMS to provide education to providers regarding the potential impacts of this policy for reimbursement purposes, given changes related to the MFP.

Response: This comment is outside of the scope of the proposals for payment of drugs and biologicals during the initial period. While we appreciate the commenter's request, we cannot speak to future legal matters, nor can we give future policy guidance with respect to these matters.

After consideration of public comments, we are finalizing as proposed that we will codify requirements established in section 6 of the Sustaining Excellence in Medicaid Act of 2019 and section 11402 of the IRA. Specifically, we are revising paragraph (e)(4) at § 414.904 by adding paragraphs (e)(4)(i)(A) and (B) to conform the regulatory text for WAC-based payment limits before January 1, 2019 and for such payment limits on or after January 1, 2019 to the requirement that the payment amount for a drug (except as provided in paragraph (e)(4)(ii)) is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003. We are also finalizing as proposed the addition of paragraphs (A) and (B) to § 414.904(e)(4)(ii) to codify the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period as required by section 1847A(c)(4)(B) of the Act.

b. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products

In the CY 2024 PFS proposed rule (88 FR 52385 through 52386), we stated that, consistent with section 1847A(b)(8) of the Act, the Medicare Part B payment limit for a biosimilar is its ASP plus 6 percent of the reference biological product's ASP. We noted that in the CY 2016 PFS final rule (80 FR 71096 through 71101), we clarified that the payment limit for a biosimilar biological product is based on the ASP of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code and amended § 414.904(j) to reflect this policy. We also noted that in the CY 2018 PFS final rule (82 FR 53182 through 53186), we finalized a policy to separately assign individual biosimilar biological products to separate billing and payment codes and pay for biosimilar biological products accordingly. However, we did not change the regulation text at § 414.904(j) at that time.

In the CY 2024 PFS proposed rule, we explained that section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment limit increase for qualifying biosimilar biological products furnished during the applicable 5-year period. Section 1847A(b)(8)(B)(iii) of the Act defines a ''qualifying biosimilar biological product'' (hereinafter referred to as a ''qualifying biosimilar'') as a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii)(I) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made under section 1847A(b)(8) of the Act (that is, payment of ASP plus 6 percent of the reference product's ASP) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made under section 1847A(b)(8) of the Act during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment.[132]

In the CY 2024 PFS proposed rule, we proposed to add definitions of ''applicable 5-year period'' and ''qualifying biosimilar biological product'' at § 414.902 to reflect the definitions in statute. In addition, we proposed to make conforming changes to regulatory text to reflect the requirements mandated under section 1847A(b)(8)(B) of the Act for the temporary payment limit increase for qualifying biosimilar biological products at § 414.904 (j) by adding paragraphs (j)(1) and (2).

We received public comments on our proposals related to the temporary increase in Medicare Part B payment for certain biosimilar biological products. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported CMS's ongoing efforts to implement the IRA by codifying provisions relating to Medicare Part B payments for certain biosimilar drugs. One commenter stated that these changes will help support the availability and use of biosimilar products and ensure that Medicare beneficiaries benefit from the savings that were intended by the passage of the new law.

Response: We thank these commenters for their support.

Comment: One commenter encouraged CMS to conduct additional outreach to providers so that they can better understand the reimbursement policy for biosimilars.

Response: We appreciate the commenter's recommendations related to outreach and education. CMS has included information on our website related to section 11403 [133] and following the publication of this final rule, the Medicare Claims Processing Manual will be updated with the finalized policies regarding payment of biosimilars. These updates will be accompanied by other CMS communications, such as an MLN Matters® article, to the provider community. Overall, CMS shares the commenter's interest in ensuring providers have the educational

[132] In accordance with these provisions, the ASP Drug Pricing File reflects the temporary increased payment limit for qualifying biosimilars beginning with the October 2022 file available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[133] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/asp-reporting#WhatstheTemporaryIncreaseinPaymentforBiosimilarBiologicals.*

resources needed to understand payment policies.

After consideration of public comments, we are finalizing as proposed the definitions of ''applicable 5-year period'' and ''qualifying biosimilar biological product'' at § 414.902 to reflect the definitions in statute. In addition, we are finalizing as proposed making conforming changes to regulatory text to reflect the requirements mandated under section 1847A(b)(8)(B) of the Act for the temporary payment limit increase for qualifying biosimilar biological products at § 414.904(j) by adding paragraphs (j)(1) and (2).

c. Inflation-Adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

As discussed in the CY 2024 PFS proposed rule (88 FR 52386), section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as directed under section 1847A(c)(5)(C) of the Act. As such, we issued guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1874A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[134] [135] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare.*

Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug. We proposed to codify the coinsurance amount for Part B rebatable drugs as required by section 1847A(i)(5) of the Act in § 489.30, specifically by adding a new paragraph (b)(6).

Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act) exceeds the inflation-adjusted payment amount of a Part B rebatable drug, the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. In the proposed rule, we proposed to codify the Medicare payment for Part B rebatable drugs in § 410.152, specifically by adding new paragraph (m).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposed codification of section 11101 of the IRA, including one that cited that it would reduce Medicare beneficiaries' out-of-pocket costs.

Response: We thank the commenters for their support.

Comment: One commenter pointed out that we inverted text in the preamble of the proposed rule at 88 FR 52386 describing the amendment section 11101(b) of the IRA made to section 1833(a)(1) of the Act and identified a typographical error in the text of proposed new paragraph (b)(6) at 42 CFR 489.30.

Response: We thank the commenter for identifying our errors in the preamble and proposed regulatory text. We are correcting both errors in this final rule.

Comment: One commenter requested that we clarify whether a reduction or waiver of an inflation rebate due to shortage would affect the reduced beneficiary coinsurance for that drug. The commenter stated that the section relating to the reduction or waiver of the rebate for shortages and severe supply chain disruptions, section 1847A(i)(3)(G) of the Act, makes no cross-references to the application of the inflation-adjusted beneficiary coinsurance, which is implemented in section 1847A(i)(5) of the Act.

Another commenter advocated against of the inclusion of Medicare Advantage units in the calculation of Part B drug inflation rebates. The commenter stated the statutory definition of a Part B rebatable drug in section 1847A(i)(2)(A) of the Act precludes counting payments for drugs under Part C.

Response: We note that since we did not make any proposals in this rulemaking related to the calculation of the inflation-adjusted payment amount described in section 1847A(i)(3)(C) of the Act, the calculation of the rebate amount in section 1847(i)(3)(A) of the Act, or the reduction or waiver for shortages and severe supply chain disruptions described in section 1847A(i)(3)(G) of the Act, these comments are out of scope. We note that these issues were addressed in the Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments dated February 9, 2023 (the ''initial Part B inflation rebate guidance''), and we gave interested parties the opportunity to comment on the initial Part B inflation rebate guidance. We will consider the comments we received in response to the initial Part B inflation rebate guidance when developing future guidance on the Medicare Prescription Drug Inflation Rebate Program.

After consideration of public comments, we are finalizing the codification of the coinsurance amount and the Medicare payment for Part B rebatable drugs at § 489.30 and § 410.152, respectively, as proposed, except insofar as correcting the typographical error in new paragraph (b)(6) at § 489.30.

d. Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

In the CY 2024 PFS proposed rule (88 FR 52386), we stated that drugs furnished through a covered item of DME are covered under Medicare Part B as provided in sections 1861(n) and (s)(6) of the Act. Insulin administered through covered DME, such as a durable

[134] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[135] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

insulin pump, is covered under this benefit. As required by section 1842(o)(1)(C) and (D) of the Act, effective January 1, 2017, infusion drugs furnished through DME, including insulin, are paid under section 1847A of the Act (see 82 FR 53180 through 53181), which is typically ASP plus 6 percent. Prior to July 1, 2023, beneficiaries are responsible for coinsurance of 20 percent of the payment amount of such insulin, subject to the Part B deductible.

In the CY 2024 PFS proposed rule we explained that section 11407 of the IRA made three changes to the way beneficiaries pay for insulin furnished through covered DME. First, section 11407(a) of the IRA amended section 1833(b) of the Act to waive the Part B deductible for insulin furnished through covered DME on or after July 1, 2023. Second, section 11407(b)(2) of the IRA amended section 1833(a) of the Act to establish a limit of $35 on the beneficiary coinsurance amount for a month's supply of such insulin furnished on or after July 1, 2023. This statutory change means that the beneficiary coinsurance responsibility, which is limited to $35 for a month's supply of insulin, could equal less than 20 percent if the Part B payment amount of a month's supply of insulin is greater than $175. Third, section 11407(b)(2) of the IRA also added a new sentence to section 1833(a) of the Act to require the Secretary to increase to the Medicare Part B payment to above 80 percent in the case the coinsurance amount for insulin furnished through covered DME equals less than 20 percent of the payment amount to pay for the full difference between the payment amount and coinsurance. The adjustment specified in paragraph (b)(2) ensures the supplier is not responsible for the reduction in the beneficiary coinsurance amount.

The above provisions were implemented through program instruction,[136] as required by section 11407(c) of the IRA, for CY 2023. Section 80 in Chapter 17 [137] and section 140 in Chapter 20 [138] of the Medicare Claims Processing Manual will be updated to reflect these changes, effective July 1, 2023. To operationalize this provision, we stated that the $35 coinsurance limit applies to the duration of the calendar month in which the date of service occurs. As stated in the section 110.5, Chapter 15 of the Medicare Benefit Policy Manual,[139] the date of service on the claim must be the date that the beneficiary or authorized representative receives the insulin or, for mail order, the date the insulin is shipped. A new $35 coinsurance limit for a month's supply applies to each calendar month. It follows that, as stated in the program instruction, when a 3-month supply (that is, the amount of such insulin that is required for treatment for up to 3 calendar months) is billed for insulin furnished through covered DME, a coinsurance limit of $105 would apply for that 3-calendar month period ($35 coinsurance limit for each month's supply of insulin). The program instruction also states that the MACs will ensure that coinsurance does not exceed $35 for a 1-month supply or $105 for a 3-month supply for claims billing insulin administered through covered DME.

In the CY 2024 PFS proposed rule, we proposed to codify these elements (that are currently in program instruction) for CY 2024 and future years in regulation text, because section 11407(c) of the IRA states that only implementation for CY 2023 may be through program instruction or other forms of guidance. Specifically, we proposed to codify the new statutory monthly coinsurance limits of $35 for a 1-month supply and $105 for a 3-month supply at § 489.30 by adding paragraph (b)(7) and the adjustment to the supplier payment at § 410.152 by adding paragraph (n). In addition, we proposed to codify at § 489.30 that the $35 coinsurance limit for a month's supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs. In other words, the $35 coinsurance limit will apply for a month's supply of insulin each calendar month. Similarly, we proposed to codify that the $105 coinsurance limit for 3 months' supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs and the 2 following calendar months.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for our proposed regulatory codification of section 11407 of the IRA.

Response: We thank the commenter for their support.

Comment: One commenter requested clarification that compounded insulin is exempt from the Part B insulin coinsurance limitation consistent with how compounded insulin is treated for purposes of the Medicare Part D Coverage Gap Discount Program (CGDC) and the Manufacturer Discount Program. The commenter requested that we clarify that several forms of compounded insulin are exempt from the coinsurance limitation, including insulin transferred from vials to a cartridge for insertion into a pump, pre-drawn syringes for patients who cannot prepare their own medication, insulin drips, and insulin added to total parenteral nutrition (TPN) or intradialytic parenteral nutrition (IDPN).

Response: We thank the commenter for their question. Products that the commenter refers to as ''compounded insulin'' that are furnished through a covered item of DME are subject to the monthly coinsurance limitation. The coinsurance limitation of $35 for a month's supply would apply to insulin that is transferred from vials into a cartridge for insertion into an insulin pump given that the pump is a covered item of DME. However, insulin that is not administered through a covered item of DME and is instead administered through, for example, pre-drawn syringes, would not be subject to the monthly coinsurance limitation. For information on the applicability of the coinsurance limitation to insulin administered through syringes, see the Part D Inflation Reduction Act (IRA) Cost Sharing Maximum Reports for Part D Sponsors memorandum [140] and Frequently Asked Questions about Medicare Insulin Cost-Sharing Changes in the Prescription Drug Law.[141]

We note that intravenous (IV) insulin drips are not commonly administered in physician offices and coverage for outpatient IV insulin therapy (OIVIT) was rescinded in 2010 for claims with dates of service on and after December 23, 2009, pursuant to Change Request 6775,[142] after CMS determined from a review of evidence that OIVIT does not improve health outcomes in Medicare beneficiaries. Typically, IV insulin drips would not occur in a patient's home because of the inability for a patient or

[136] *https://www.cms.gov/files/document/r11917cp.pdf.*

[137] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[138] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c20_dmemay23_r2.pdf.*

[139] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/bp102c15.pdf.*

[140] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/IRA_Cost_Sharing_Maximum_Reports_508_G.pdf.*

[141] *https://www.cms.gov/files/document/frequently-asked-questions-medicare-part-d-insulin-benefit.pdf.*

[142] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1930cp.pdf.*

a patient's caregiver to safely supervise the administration. Therefore, we do not anticipate administration of IV insulin drips outside of a hospital setting under close monitoring, not covered under DME. Regarding parenteral nutrition, we note that parenteral nutrition is covered under the Medicare Part B benefit for prosthetic devices. Insulin that is not administered through a covered item of DME and is instead administered through, for example, a prosthetic device, would not be subject to the monthly coinsurance limitation.

After consideration of public comments, we are finalizing as proposed the new paragraph (b)(7) at § 489.30 for the limitations on monthly coinsurance for insulin furnished through a covered item of DME. We are also finalizing as proposed the new paragraph (n) at § 410.152 for the adjustment to the supplier payment under Medicare Part B.

e. Indexing the Part B Deductible to Inflation

Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110.00, section 629 of the MMA (amending section 1833(b) of the Act) required that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees aged 65 and over. Specifically, the 2024 Part B deductible is calculated by multiplying the 2023 deductible by the ratio of the 2024 aged actuarial rate to the 2023 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.00. Although § 410.160 was amended to reflect the statutory change, we did not make the corresponding revision in § 489.30. Earlier in this section, we finalized additional changes to the regulatory text for allowable charges under Part B for rebatable drugs and insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n) of the Act in § 489.30(b)(6) and (7), respectively. Therefore, we are finalizing the revision to § 489.30(b)(1) to conform the regulatory text for the Part B deductible with the statutory change made by section 629 of the MMA and the IRA provisions that make statutory changes that affect beneficiary out-of-pocket costs for certain drugs payable under Medicare Part B.

2. Request for Information (RFI): Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Section 1861(s)(2)(A) of the Act allows Medicare to pay for services and supplies, including drugs and biologicals (hereafter, drugs) that are not usually self-administered by the patient, which are furnished as ''incident to'' a physician's professional service. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) amended the above-referenced sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, which formerly referred to drugs ''which cannot be self-administered,'' to read, ''which are not usually self-administered.'' Drugs that are ''usually self-administered'' are thus statutorily excluded from coverage and payment under Part B under the ''incident to'' benefit.

We have provided definitions and other guidance for MACs regarding determinations on drugs that are ''not usually self-administered by the patient'' in Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual.[143] Chapter 15 also describes the evidentiary criteria that MACs should use in determining whether a drug is usually self-administered. The guidance directs MACs to publish a description of the process they use to make that determination, and to publish a list of the drugs that are subject to the self-administered exclusion on their website.[144] The guidance also requires that this list include the data and rationale that led to the determinations. This list is referred to as the ''self-administered drug (SAD) list,'' and each MAC maintains their own version of the list, which is applicable to that MAC's area of jurisdiction. While the lists are often similar between MACs, they are not identical. Drugs that are put on a SAD list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage. For several years, interested parties have requested that we update and clarify this SAD list guidance. These parties believe that the current guidance may not adequately address circumstances posed by newly approved drugs.

In a similar vein, we have received concerns from interested parties that non-chemotherapeutic complex drug administration payment has become increasingly inadequate due to existing coding and Medicare billing guidelines that do not accurately reflect the resources used to furnish these infusion services. Interested parties have asserted that these infusion services are similar to complex and clinically intensive Chemotherapy and Other Highly Complex Biological Agent Administration (''Chemotherapy Administration'') services that are billed using CPT code series 96401–96549, as opposed to Therapeutic, Prophylactic, and Diagnostic Injections and Infusion services billed using CPT code series 96360–96379. We note that we discuss our policies for these services in Pub. 100–04 Medicare Claims Processing Manual, Chapter 12, Section 30.5D.[145]

In the CY 2024 PFS proposed rule (88 FR 52387), we solicited comments on the above two policy areas, since they both involve Part B drug payment policies that have been impacted by new developments in the field. In an effort to promote coding and payment consistency and patient access to infusion services, we solicited comments and information from interested parties regarding the relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration. We solicited comments on whether or not we should revise our policy guidelines as discussed to better reflect how these specific infusion services are furnished and should be billed.

We also solicited comments regarding our policies on the exclusion of coverage for certain drugs under Part B which are usually self-administered by the patient. Specifically, we solicited comments regarding our policies for the following items:

- Definitions of the following terms, as referenced in this section:
  - ++ ''Administered.''
  - ++ ''Self-Administered.''
  - ++ ''Usually.''
  - ++ ''By the patient.''
- The process for determining which drugs are classified as those ''not usually self-administered by the patient.''
- The process for issuing decisions on which drugs are classified as those ''not usually self-administered by the patient,'' and the process for issuing any changes to those classifications.
- The relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be

[143] Ibid.

[144] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.*

[145] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.*

used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration.

- Whether or not CMS should revise policy guidelines to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments regarding our policies on self-administered drugs. The comments addressed several critical issues in this space, including appeals, FDA labeling, and accommodating patients who are under caregivers' care and/or patients who do not have the ability self-administer drugs. Commenters provided robust feedback on the self-administered drug issues listed above, and on related issues as well.

Response: We thank commenters for their attention to these policies and for sharing our desire to improve health equity and healthcare access for Medicare enrollees. We plan to consider all comments, and we look forward to continued discussions with interested parties as we work towards potentially developing changes to these policies in future rulemaking.

Comment: We received a number of comments in response to our Request for Information (RFI) regarding appropriate reimbursement for non-chemotherapeutic complex drug administration coding. Commenters urged CMS to provide additional guidance clarifying the conditions under which infusion drugs can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401–96549. Commenters expressed concern with the MAC guidance currently in effect for complex drug administration services. Commenters asserted that the current reimbursement rates and billing considerations for non-chemotherapeutic complex infusion services provided by the MACs are inconsistent, inadequate, and in conflict with CMS billing policies.

Response: We appreciate commenters' concerns regarding the complex drug administration payment policy. Our current guidance regarding coding rules for chemotherapy administration and nonchemotherapy injections and infusion services, as documented in 100–4 Chapter 12, section 30.5 of our internet Only Manual (IOM), outlines the categories under which payment is made for both types of injections and infusions and the considerations for determining what drugs may be considered chemotherapy under Medicare.[146] There, we state that ''Chemotherapy administration codes (CPT codes 96401–96549) apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also, to anti-neoplastic agents provided for treatment of noncancer diagnoses (for example, cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers.'' We also provide examples of specific drugs, including monoclonal antibody drugs, but we also clarify that the examples discussed do not represent an exhaustive list of drugs that may be administered using complex administration services. We further state that ''A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.''

We acknowledge the commenters' position that the clinical work and expense for some complex drug infusion services are not adequately accounted for as currently reimbursed by Medicare. However, we note that Medicare payment for the chemotherapy administration CPT code series (96401–96549) accounts for clinical staff and supply costs as part of physician practice expenses for the administration service. The practice expense costs include preservice preparation activities, intra-service constant monitoring, and post-service period activities performed by registered nurses or oncology-certified nurses. The supply items also include equipment such as a biohazard hood. Medicare payment for the therapeutic, prophylactic, and diagnostic injections and infusion CPT code series (96360–96379) also accounts for clinical staff activities and supply equipment as part of the practice expense for the administration service with less clinical staff service time and fewer equipment items. However, we understand and acknowledge the constantly evolving practice of medicine and advancements in complex drug administration that may need to be considered relative to our existing payment policies. We are interested in future discussions with interested parties to work towards developing policies that accurately account for the costs involved in complex drug administration services.

[146] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.*

3. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter is referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereafter referred to as ''refundable drug''). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

In the CY 2023 PFS final rule (87 FR 69710 through 69734), we adopted many policies to implement section 90004 of the Infrastructure Act. We finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. We also finalized the requirement that billing providers and suppliers report the JZ modifier for all such drugs with no discarded amounts beginning no later than July 1, 2023, and we stated that we would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023 (87 FR 69718 through 69719). Subsequent to the issuance of the CY 2023 PFS final rule, CMS published the JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document [147] addressing the correct use of these modifiers. We adopted a definition of ''refundable single-dose container or single-use package drug'' at § 414.902, which also specifies exclusions from this definition (87 FR 69724). These three exclusions are: radiopharmaceutical or imaging agents, certain drugs requiring filtration, and drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months. Regarding reports to manufacturers, we specified that we would send reports (including information described in section 1847A(h)(1) of the Act) for each

[147] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

calendar quarter on an annual basis to all manufacturers of refundable drugs (87 FR 69726). We finalized how the refund amount will be calculated at § 414.940 (87 FR 69731). Regarding drugs with unique circumstances for which we can increase the applicable percentage otherwise applicable for determining the refund, we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69731). Lastly, we adopted a dispute resolution process through which manufacturers can challenge refund calculations, and we established enforcement provisions (including manufacturer audits, provider audits, and civil money penalties required by statute) (87 FR 69732 through 69734).

As noted in the CY 2023 PFS final rule (87 FR 69711), sections 11101 and 11102 of the Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (IRA) established new requirements under which manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. Drug manufacturers are required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation for quarters beginning with the first quarter of 2023; drug manufacturers are required to pay rebates to Medicare if prices for certain Part D drugs increase faster than the rate of inflation over 12-month periods, starting with the 12-month period that began October 1, 2022.

We explained that we believe implementation of the Part B and Part D inflation rebate programs established under the IRA should be considered together with the operational implications of the discarded drug refunds, because the refunds and rebates both require CMS to accept from drug manufacturers payments that must be deposited into the Federal Supplementary Medical Insurance (SMI) Trust Fund.

Therefore, to align the operation of these programs and minimize burden, we declined to finalize some aspects of the invoicing and collection of discarded drug refunds. Specifically, we declined to finalize the timing of the initial reports and which quarters' information will be included in each report. We also declined to finalize specific dates by which manufacturer refund obligations are due and those associated with the dispute resolution process, as those are scheduled in tandem with the reporting dates. Lastly, we stated our intent to address these aspects in future rulemaking.

In the CY 2024 PFS proposed rule (88 FR 52388 through 52395), we proposed the date of the initial report to manufacturers, the date for subsequent reports, method of calculating refunds for discarded amounts in lagged claims data, method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking. We also proposed modification to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug.

b. Provision of Information to Manufacturers

In the CY 2023 PFS final rule (87 FR 69724 through 69726), we discussed our proposals related to meeting the requirements under section 1847A(h)(1) of the Act related to the timing and contents of the report to manufacturers, including what types of information to include, which quarters' data we would include in the initial report, the amount of lagged claims data we would include, whether to send reports quarterly or annually, and the definition of a manufacturer. However, we explained that due to the enactment of the IRA and our efforts to align the operations of the refunds with the inflation rebate programs and minimize burden, we did not finalize certain aspects of the discarded drug refund provision. Specifically, we did not finalize the date that we would send the first report to manufacturers or which quarters' information would be included in each report.

Although we did not finalize the noted aspects related to timing, we adopted regulations at § 414.940(a)(3) providing that we will send reports to manufacturers on an annual basis and indicated in the preamble text that reports will contain discard information (described in section 1847A(h)(1)(A) of the Act) for each calendar quarter (87 FR 69724 through 69726). We also finalized that we would send reports to all manufacturers of refundable drugs. In addition, in response to commenters suggesting that we provide manufacturers an opportunity to engage with us on discard amount data in the first year of this provision's implementation, we stated that we would issue, no later than December 31, 2023, a preliminary report on estimated discarded amounts based on available claims data from the first two quarters of CY 2023.

In the CY 2024 PFS proposed rule (88 FR 52388 through 52389), we discussed implementing the discarded drug refund in a timely manner. We proposed to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. (Note that this report, which we refer to as the ''initial refund report'' in this final rule, will be separate and distinct from the preliminary report that we will issue by December 31, 2023, which will include estimated discarded amounts based on available claims data for the first 2 quarters of CY 2023.)

With respect to subsequent annual reports, that is, reports for quarters in CY 2024 and thereafter, we stated our intent to align delivery of the refund reports with the delivery of Part B and Part D inflation rebate reports to the extent practicable. We noted that in the initial guidance for Part B inflation rebates,[148] it states that inflation rebate reports will be sent on a quarterly basis, each no later than 6 months after the end of the calendar quarter as required in section 1847A(i)(1)(A) of the Act. We also noted that the guidance states, consistent with section 1847A(i)(1)(C) of the Act, that we may delay reporting Part B inflation rebate information for calendar quarters in CY 2023 and CY 2024 until not later than September 30, 2025.[149]

To align these reports, we proposed that, other than for the initial refund report, (which we are finalizing that we will issue no later than December 31, 2024, as described in section III.A.3.b of this final rule), we would send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time we plan to send Part B inflation rebate reports for the first quarter of the following year. Thus, for example, we would send the second refund report for the calendar quarters in 2024 when we plan to send the inflation rebate report for Q1 2025, which is required to be sent no later than September 30, 2025, as required in section 1847A(i)(1)(C) of the Act. We note that the timeframe for Part B inflation rebate reports has not yet been finalized; the final timing will be addressed in the revised Part B inflation rebate guidance.

[148] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[149] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

We noted in the CY 2023 PFS final rule (87 FR 69725), because providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, there can be a lag between the date of service when a drug is administered and when the claim is submitted and adjudicated. Therefore, there is a lag in available JW modifier data for any given date of service quarter. We provided our evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting that showed 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months after the date of service, 99.83 and 100 percent of the claims, respectively, were final.

In the CY 2024 PFS proposed rule, we explained that based on our evaluation of the 2010 claims data, a small percentage of lagged claims data from a calendar quarter likely would not be available when the quarter is first included on a report, and therefore we proposed that annual reports (subsequent to the initial report) include lagged claims data (that is, true-up information) for quarters from 2 calendar years prior. In other words, we proposed that each report would include information for 8 calendar quarters: 4 quarters from the previous calendar year (hereafter, referred to as new refund quarters) and 4 quarters from 2 calendar years prior (hereafter, referred to as updated refund quarters). See Table 20, which shows which refund quarters will be in each refund report. We proposed all reports (except the initial refund report) would include the following information for updated refund quarters to address lagged claims data:

- The updated total number of units of the billing and payment code of such drug, if any, that were discarded during such updated refund quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The updated refund amount that the manufacturer is liable for with respect to such updated quarter that was not previously accounted for in the prior year's report.

For example, as discussed above, the second annual report (sent no later than September 30, 2025) would include: (1) the total number of units of the billing and payment code of such drug, if any, that were discarded during new refund quarters (all calendar quarters in 2024), (2) the refund amount for which the manufacturer is liable under section 1847A(h)(3) of the Act for all calendar quarters in 2024, (3) the updated total number of units of the billing and payment code of such drug, if any, that were discarded during the updated refund quarters (all calendar quarters in 2023), and (4) the refund amount that the manufacturer is liable for or the amount CMS owes the manufacturer under section 1847A(h)(3) of the Act for all calendar quarters in 2023 that were not accounted for in the previous year's report.

TABLE 20: Timing of Refund Reports and Which Calendar Quarters are Included in Each Report

Timing of Report	New Refund Quarters Included	Updated Refund Quarters Included
Not later than December 31, 2024 (Initial Refund Report)	Calendar quarters in 2023	None
Not later than September 30, 2025	Calendar quarters in 2024	Calendar quarters in 2023
Not later than September 30, 2026	Calendar quarters in 2025	Calendar quarters in 2024
Not later than September 30, 2027	Calendar quarters in 2026	Calendar quarters in 2025
Not later than September 30, XXXX	Calendar quarters in the year prior to XXXX	Calendar quarters in the year 2 years prior to XXXX

We proposed to define ''new refund quarter'' and ''updated refund quarter'' at § 414.902 and to revise § 414.940(a)(1)(iii) to reflect the inclusion of lagged data in reports subsequent to the initial refund report. We solicited comments on these proposals (88 FR 52389). See section III.A.3.d. of this final rule for the discussion regarding calculation of refund amounts and for updated refund quarters.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposal to align timing of discarded drug refund reports, beginning with the second refund report, with inflation rebate reports.

Response: We thank the commenters for their support.

Comment: Two commenters opposed inclusion of more than one quarter of lagged claims data for which manufacturers would be liable. One commenter stated that since manufacturers are not responsible for delays in claims submission, they should not bear the burden of refunds on lagged claims. The other commenter stated that limiting lagged data to one quarter would provide a better balance of administrative burden and the accuracy of discarded amount assessments.

Response: We thank the commenters for their feedback. We disagree that discarded amounts of refundable drugs for claims properly submitted to Medicare contractors should not be considered for the calculation of discarded drug refund obligations. Under 42 CFR 424.44, providers and suppliers generally have one calendar year after the date of service to submit claims, and the process by which contractors review and finalize claims can sometimes take several additional months.[150] To accurately determine the number of discarded units in a given quarter, the reconciliation of discard amounts for each quarter one year after discard amount information is initially reported provides an operational process that more accurately determines discarded amounts and refunds for each quarter as compared to the accuracy of such information if updated refund quarters were not included in the reports.

[150] *https://www.ecfr.gov/current/title-42/section-424.44.*

After considering the comments, we are finalizing the definitions of ''new refund quarter'' and ''updated refund quarter'' at § 414.902, as proposed. We are also finalizing the inclusion of four updated refund quarters (one calendar year) in reports subsequent to the initial refund report at § 414.940(a)(1)(iii) as proposed. With respect to timing of refund reports, we reiterate our intent to provide refund reports as follows:

- As discussed in the 2023 PFS final rule at 87 FR 69726, we intend to send a preliminary refund report to manufacturers no later than December 31, 2023 to provide estimated discarded amounts based on available claims data from the first 2 quarters of CY 2023;
- We intend to send the initial refund report to manufacturers not later than December 31, 2024, which will contain information for all calendar quarters of 2023; and
- For subsequent years, we intend to send annual refund reports for discarded drug refunds for the 4 quarters from the previous calendar year (new refund quarters) and 4 quarters from 2 calendar years prior (updated refund quarters) prior to or around the time we plan to send Part B inflation rebate reports for the first quarter of the following year (not later than September 30).

c. Manufacturer Provision of Refund

In the CY 2023 PFS final rule (87 FR 69726 through 69727) we adopted § 414.940(b), which requires manufacturers to pay refunds in 12-month intervals in a form and manner specified by CMS. In the CY 2023 PFS final rule (87 FR 69727), we also discussed our proposal for the timing of both the initial refund report and manufacturers' corresponding refund obligations. That is, we proposed to issue reports to manufacturers by October 1 and require refund obligations to be paid by December 31, except in circumstances where a dispute is pending. Regulations at § 414.940(b)(2) specify that in the case that a disputed report results in a refund amount due, that amount must be paid no later than 30 days after resolution of the dispute.

However, we did not finalize the deadlines by which manufacturer refund obligations are due and those associated with the dispute resolution process in the CY 2023 PFS final rule, because those deadlines correspond with the dates of the annual refund reports, which we declined to finalize in order to align the operation of the discarded drug refunds with the inflation rebate programs. In the CY 2023 PFS final rule (87 FR 69727), we stated our intent to revisit the process and timeline for manufacturers' provisions of refunds in future rulemaking.

In the CY 2024 PFS proposed rule (88 FR 52389), we proposed to issue the initial refund report to manufacturers no later than December 31, 2024. As discussed above, we are finalizing this policy. We explained that a payment deadline that is 2 calendar months after the issuance of the report may provide adequate time for manufacturers to review the reports and submit a dispute if needed prior to the refund payment deadline. Accordingly, we proposed to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute.

We also noted the proposal regarding issuance of the second annual refund report to manufacturers be no later than September 30, 2025, and once annually thereafter no later than September 30 for every year thereafter. We contemplated this deadline along with our belief that a payment deadline that is 2 calendar months after the issuance of the report provides adequate time for manufacturers to review the reports and submit a dispute if needed prior to the refund payment deadline. Accordingly, we proposed to require manufacturers to pay refunds specified in each report (beginning with the second report) no later than December 31 of the year in which the report is sent, except in circumstances where a report is under dispute. In cases in which a manufacturer disputes a report, we proposed that beginning with the initial refund report, any manufacturer liability determined upon the resolution of the dispute would be due by the above stated due date or 30 days following the resolution, whichever is later. We proposed to revise § 414.940(b)(1) and (2) to reflect these dates.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters expressed support for the payment timeline of liabilities for circumstances in which there is no dispute, as well as circumstances where there is a dispute with the extended deadline.

Response: We thank the commenters for their support.

Comment: One commenter stated that CMS's implementation of section 1847A(h) of the Act violates the due process principle of fair notice because it attaches new legal consequences to decisions made in compliance with applicable laws and regulations, such as the determination of vial sizes, prior to enactment of the Infrastructure Act. The commenter asserted their belief that neither Congress nor agencies may impose retroactive penalties unless there is express legislative authorization, which they stated does not appear in the statutory provision for the discarded drug refund policy.

Response: Legislative recommendations for Congress are outside of the scope of this rulemaking. As these policies affect refunds that will be paid in the future after the promulgation of the rule, we disagree that our proposed implementation of section 1847A(h) of the Act violates the due process principle of fair notice. There are no retroactive effects on payments that have already been made.

After consideration of public comments, we are finalizing revisions to § 414.940(b)(1) as proposed. That is, refund amounts specified in the initial refund report for calendar quarters in CY 2023 must be paid no later than February 28, 2025, and for calendar quarters in each subsequent calendar year, no later than December 31 of the year in which the report is sent, except in circumstances where a report is under dispute. Regarding cases in which a manufacturer disputes a refund report, we are finalizing revisions to § 414.940(b)(2) as proposed to reflect that any refund amounts determined upon the resolution of the dispute will be due by the due date specified in § 414.940(b)(1) or 30 days following the resolution, whichever is later.

d. Refund Amount

(1) Calculation of Refund Amounts for Updated Quarters

In the CY 2024 PFS proposed rule (88 FR 52389 through 52390) we explained how we would calculate the refund amount for updated quarters since we need to contemplate lagged claims data in all reports other than the initial refund report. That is, we proposed that such additional lagged JW modifier data, if any, will be used to calculate revisions to the manufacturer refund amount. Specifically, we proposed to calculate the refund with updated data in the same manner as was finalized in the 2023 PFS final rule (87 FR 69727) and subtract the refund amount that already paid for such refundable drug for such quarter to determine the updated quarter refund amount. We proposed that the refund amount owed by a manufacturer, with respect to a refundable drug assigned to a billing and payment code for an updated refund quarter is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

• Exceeds the difference of:

++ An amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The refund amount previously paid for such refundable drug for the given quarter.

We proposed that if the resulting refund calculation for an updated quarter is a negative number, then it will be netted out of the any refund owed for other updated quarters or new quarters.

We proposed to revise § 414.940 by adding new paragraphs (c)(2) and (3) to reflect the proposed method of calculation of revisions to the refund amount owed for quarters in the year that is 2 calendar years prior.

We received one public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: One commenter expressed support for our proposal to use the same refund calculation methodology for new and updated quarters' claims data. The commenter stated the use of a consistent methodology will provide manufacturers predictability.

Response: We appreciate the commenter's feedback.

After consideration of public comments, we are finalizing revision of § 414.940 by adding paragraphs (c)(2) and (3), as proposed, to reflect the method of calculation of revisions to the refund amount owed for quarters in the year that is 2 calendar years prior. That is, we will calculate the refund with updated data in the same manner as described above and subtract the refund amount already paid for such refundable drug, for such quarter, to determine the updated quarter refund amount owed by the manufacturer.

(2) Calculation of Refund for a Drug When There are Multiple Manufacturers

In the CY 2023 PFS final rule (87 FR 69727 through 69731), consistent with section 1847A(h)(3) of the Act, we adopted regulations at § 414.940(c) specifying the manner in which the refund amount will be calculated with respect to a refundable drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023. The refund for which the manufacturer is liable is the amount equal to the estimated amount (if any) by which:

• The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

• Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

In the CY 2023 PFS final rule, we proposed a policy to estimate the total allowed charges during the quarter by multiplying the drug's payment amount for the quarter by the total number of units of the billing and payment code of such drug that were subject to JW modifier reporting including those for which the JZ modifier would be required if no units were discarded. As specified in section 1847A(h)(1)(C) of the Act, the total number of units of the billing and payment code of a refundable drug furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), exclude such units that are packaged into the payment amount for an item or service and are not separately payable.

In the CY 2024 PFS proposed rule (88 FR 52390 through 52391) we discussed situations where single source drugs or biologicals have multiple manufacturers. We explained that because refundable drugs are single source drugs or biologicals, they typically will have one manufacturer. However, a refundable drug could have more than one manufacturer, for example, in the circumstance where a refundable drug is produced by one manufacturer, and also by one or more manufacturer(s) that is a repackager or relabeler. Multiple manufacturers of a refundable drug could also occur in the case of one or more authorized generic products that are marketed under the same FDA-approval as the original FDA applicant. In such cases, the National Drug Codes (NDCs) for the drug typically are assigned to the same billing and payment code, and each manufacturer is responsible for reporting ASP data to CMS, which includes sales volume.

In the CY 2023 PFS final rule (87 FR 69724 through 69726), we stated that we would identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable drug. Therefore, in the CY 2024 PFS proposed rule, we discussed our proposal to establish a method for apportioning billing units of a refundable drug sold during a calendar quarter in situations where there are multiple manufacturers of a refundable drug. When calculating the refund amount owed by manufacturers for a refundable drug that has more than one manufacturer, we proposed to identify such refundable drugs using the ASP sales data reported for the calendar quarter for which a refund amount is calculated. Furthermore, we proposed to apportion financial responsibility for the refund amount among each manufacturer in the following manner: by dividing the sum of the individual manufacturer's billing units sold during the refund quarter for all the manufacturer's NDCs assigned to the billing and payment code (as reported in the ASP data submissions), by the sum of all manufacturers' billing units sold during the refund quarter for all NDCs of the refundable drug assigned to the billing and payment code (as reported in the ASP data submissions).

We explained that this calculation approach is consistent with the approach for apportioning inflation rebate obligations discussed in section 50.13 of the Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments,[151] released on February 9, 2023.

In addition, we proposed to apportion the discarded drug refund when there is more than one manufacturer for a refundable drug, using the proportion of billing unit sales, expressed as a percentage, attributed to each NDC (at the NDC–11 level) assigned to the billing and payment code for such refund quarter. The number of billing unit sales for each NDC would be the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC. We proposed that the refund amount attributed to such NDCs for which the manufacturer is liable would be the amount equal to the estimated amount (if any) by which:

• The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter;

[151] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

++ The percentage of billing unit sales of the applicable code attributed to the NDC; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

• Exceeds an amount equal to the product of:

++ The applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The percentage of billing unit sales of the applicable code attributed to the NDC.

For example, if a billing and payment code for a refundable drug includes three NDCs, each from a different manufacturer as shown in Table 21, there were 3,000 units discarded during the refund quarter out of 21,000 total billing units of a billing and payment code administered, the payment limit amount for the refundable drug was $50.00 per billing unit, the applicable percentage was 10 percent, and the estimated total allowed charges for the refundable drug during the refund quarter was $1.05 million, the proposed calculation for the refund amount owed by Manufacturer 1, which reported 23.81% of billing unit sales for the billing and payment code for the refund quarter, would be as follows: (3,000)(23.81%)($50) − (21,000)(10%)(23.81%)($50) = refund amount of $10,714.50.

TABLE 21: Example of Proportion of Sales Calculation when there are Multiple Manufacturers for a Refundable Drug

NDC	Manufacturer	Refund Quarter Sales (billing units)	Proportion of Sales (percent)
12345-6789-01	Manufacturer 1	5,000	23.81%
23456-7890-01	Manufacturer 2	6,000	28.57%
34567-8901-01	Manufacturer 3	10,000	47.62%
	TOTAL:	21,000	100%

Using this example and following the proposed calculation, the report to manufacturers, discussed above in section III.A.3.b of this final rule, would include: (1) the total number units of the billing and payment code of such drug attributed to the manufacturer's NDC assigned to the billing and payment code of the refundable drug that were discarded during such quarter, if any; and (2) the refund amount for which the manufacturer of that NDC is liable under section 1847A(h)(3) of the Act. We proposed that this method of calculation apply beginning with calendar quarters in CY 2023 included in the initial refund report, which, as described in section III.A.3.b in this final rule, we are finalizing be sent no later than December 31, 2024. We proposed that this method of calculation will be done for new refund quarters and updated refund quarters.

We proposed to revise § 414.940 by adding a new paragraph (c)(4) to reflect the above proposed method of calculation of the refund amount attributed to a NDC when there are multiple manufacturers.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters expressed support of the proposed methodology for calculating the refund for drugs with multiple manufacturers.

Response: We thank the commenters for their support.

Comment: Two commenters opposed the proposed methodology because they claim that the calculation could result in a manufacturer owing a discarded drug refund even if the amounts discarded from the manufacturer's refundable drugs did not exceed the applicable percentage. One commenter urged CMS to ensure that Part B claims data correctly indicate the specific products prescribed and administered to patients. Commenters stated that each manufacturer's refund liability should only be determined based on that manufacturer's product. The commenters also stated that the statute precludes our methodology, as it states that ''a refund . . . [shall be] equal to the amount specified in paragraph (3) for such drug for such quarter.'' The commenters state that the discarded drug refund should be calculated at the NDC–11 level if a refund is due for a refundable drug when there are multiple manufacturers of such drug. One commenter states that the plain language of section 1847A(h) of the Act requires CMS to implement a process that precisely identifies refund liability based on each manufacturer's refundable drug. In such a case, CMS should develop a process to require reporting of NDC–11s on the CMS–1500 and 837P claim forms and reject as incomplete any forms without required NDC–11s. Another commenter urged CMS to assure that refund reports are accurate with respect to manufacturers that owe them.

Response: We thank commenters for their input. In considering the issues raised by commenters about manufacturers owing refunds that they assert should be the responsibility of other manufacturers, we considered the proposed methodology for calculating the refund using actual data. To that end, we identified 12 refundable drugs with multiple manufacturers and found that in a vast majority of these cases, each manufacturer is packaging the product in the same sized container(s). We found one instance where a repackager manufactures two of the four package sizes available from the other manufacturer of the refundable drug, but the repackager did not produce any product sizes that were not also produced by the other manufacturer.

Based on this analysis showing that the available product size(s) are typically the same or very similar between manufacturers (when there is more than one manufacturer for a refundable drug), it is unlikely that the discarded amounts from such package sizes would be significantly different. In addition, we do not have data that certain NDCs of a refundable drug from one manufacturer would be furnished to Medicare beneficiaries more often than another manufacturer when such a drug has more than one manufacturer. Therefore, we are not convinced that the proposed methodology for calculating the refund would result in one manufacturer owing any significant amount of refund that would have been owed by the other manufacturer because we expect discarded amounts to be the same in nearly all instances in which a product is used from the same size containers (with same labeled amount of drug) regardless of who is

manufacturing the product. For example, we would expect a vial containing 1 mg of a drug to have, on average, the same discarded amount as another vial containing 1 mg of the same drug (under the same approval, such as an NDA or BLA), even if it is from a different manufacturer. As this policy is operationalized, CMS will monitor report information for refundable drugs with multiple manufacturers. We welcome input and data from manufacturers and may address this issue further in future rulemaking, if appropriate.

We thank the commenter for suggesting the requirement that NDC–11 should be required on claims forms to facilitate accurate calculation of the refund, however, this is out of the scope of this proposal.

After reviewing public comments, we are finalizing the revision to § 414.940 by adding (c)(4), as proposed, to reflect the method of calculation of the refund amount attributed to a NDC when there are multiple manufacturers of a refundable drug. We clarify that the sales quarter of the ASP data used for this method of calculation will align with the dates of service for a new refund quarter or updated refund quarter. For example, calculation of refunds for the first calendar quarter of 2023 will use ASP data that reflect sales from that quarter. This data is reflected in the July ASP Drug Pricing File because of the two-quarter lag between the sales quarter and when that data is reflected in the ASP Drug Pricing File.

(3) Increased Applicable Percentage for Drugs With Unique Circumstances

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69727 through 69731), we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (§ 414.490(d)(1)). We have identified only one drug, Jelmyto® (mitomycin for pyelocalyceal solution), with such unique circumstances. We stated in that final rule that we recognize that there are drug products that may indeed have other unique circumstances, and that an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking, as required by the statutory provision. We stated that we planned to collect additional information about drugs that may have unique circumstances along with potential increased applicable percentages that might be appropriate for such drugs, and to collect additional information about a process to identify unique circumstances based on manufacturer input. We explained that we would revisit additional increased applicable percentages for drugs that have unique circumstances, and a process to identify such circumstances, through future notice and comment rulemaking. To that end, we hosted a town hall meeting on February 1, 2023 to discuss what criteria would be appropriate to determine whether a refundable drug has unique circumstances, and whether a categorical approach (that is, unique circumstances that apply to more than one drug), drug-by-drug approach, or a hybrid of these two approaches should be used for determining drugs for which an increased applicable percentage is appropriate.

In the CY 2024 PFS proposed rule (88 FR 52391 through 52395) we explained that after considering input from interested parties provided at the town hall and in subsequent meetings, we proposed a hybrid approach to determining when it is appropriate to increase the applicable percentage for a drug with unique circumstances. First, we proposed two unique circumstances along with proposed increased applicable percentages and, secondly, we proposed an application process so manufacturers may request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances (and if an increased applicable percentage is considered appropriate it would then be proposed in future notice-and-comment rulemaking).

We noted that we discussed in the CY 2023 PFS final rule and further at the town hall, the many requests from interested parties for CMS to increase applicable percentages (defined at § 414.940(c)(3) as 10 percent, except where an increased applicable percentage is applied in paragraph (d) of that section) for drugs packaged with small vial fill amounts or low-volume products (generally, those with a fill amount less than 1 mL). These parties stated that, for certain drugs, the small volume of drug contained in the vial (as identified on the package or FDA labeling) often represents the minimum volume necessary to safely and effectively prepare and administer the prescribed dose. Certain labeled amounts that are unused and discarded include amounts remaining in the syringe hub, amounts remaining in the syringe that are not part of the prescribed dose, amounts left in the vial that cannot be removed (such as drug adhering to the side of the vial or pooling around the vial stopper), and amounts left in the vial when it contains enough drug for two administration attempts.

We agreed that such drugs have unique circumstances, because certain FDA-labeled amounts on the vial or package are unused and discarded after administration of the labeled dose and these amounts are not available to be administered. The unique circumstances described for such drugs are similar to loss of product from filtration described in section 1847A(h)(8)(B)(ii) of the Act because in both circumstances, such amounts lost are amounts that are not part of the recommended dose and are not available to be administered to the patient (one being loss due to labeled amounts remaining in the filter and the other due to labeled amounts remaining in other areas such as the vial or syringe).

Since not all drugs with small fill volumes have certain labeled amounts that are unused and discarded, we believed more specific criteria are required to identify certain drugs with unique circumstances in this case. For example, if a drug is available as 0.8 mL in a prefilled syringe, the total volume in the presentation is small, however, the entire labeled amount in the syringe may be administered to the patient as part of a labeled dose; the unique circumstances described above only occur when the volume of the labeled dose that is withdrawn from a vial or container is very small and there is a labeled amount that is unused and discarded and not available for administration (based on drugs currently available in the market, we have observed this to occur with doses contained within less than 0.4 mL). Therefore, we proposed an increased applicable percentage for drugs with a ''low volume dose.'' We considered a low volume dose to be a dose of a drug for which the volume removed from the vial containing the labeled dose does not exceed 0.4 mL (which is about 8 drops of liquid). We proposed to revise § 414.902 and define a low volume dose to be a labeled dose (based on FDA-approved labeling) that is contained within no more than 0.4 mL when removed from the vial or container. For example, if a labeled dose is 4 mg and a vial contains a suspension with a concentration of 40 mg/mL, the labeled

dose will be contained in 0.1 mL, which will not exceed 0.4 mL and will, therefore, be considered a low volume dose. We proposed that this definition of low volume dose apply even if the drug is further diluted after removal from the vial and prior to administration because, even if the dose is further diluted, a dose withdrawn from the vial and diluted would still have the same physical constraints as a dose that was not diluted, and those constraints would necessitate the loss of product as described in the previous paragraph. In addition, we proposed that for a drug to meet these unique circumstances, all labeled doses of the drug would be low volume doses. We explained, as proposed, this definition would not affect the determination of units as defined at section 1847A(b)(2)(B) of the Act and codified at § 414.802, and we note that the statutory definition of unit is exclusive of any diluent without reference to volume measures pertaining to liquids. We also explained that the proposed definition of low volume dose would only be applied for the determination of whether a higher applicable percentage is warranted for a drug.

We proposed a two-tiered increased applicable percentage for drugs with low volume doses, because the percentage that is unused and discarded for these drugs decreases as the volume of the dose increases. We proposed that, for drugs with labeled doses contained within 0.1 mL or less when removed from the vial or container, the applicable percentage be increased to 90 percent. We proposed 90 percent applicable percentage for this tier because certain drugs with low volume doses of 0.1 mL or less have up to 90 percent of the labeled amount that is unused and discarded and not part of the labeled dose available to be administered.[152] [153] We explained that we did not propose to add an additional 10 percent to this number as we did in the case of hydrogel, as discussed in the CY 2023 final rule (see 87 FR 69729), because, generally, we do not believe it would be appropriate for any product to have an applicable percentage of 100 percent. Such an applicable percentage would, in effect, exclude drugs from the refund liability altogether. We believe it would be inappropriate to effectively expand the list of exclusions described in section 1847A(h)(8)(B) of the Act by proposing an increased applicable percentage of 100 percent to drugs not expressly excluded in statute. However, we considered whether some additional percentage might be appropriate in this case. We solicited comment on whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less.

As we discussed in the CY 2024 PFS proposed rule (88 FR 52392), in the second tier of the low volume dose unique circumstances, we proposed that for drugs with labeled doses contained within 0.11–0.4 mL, the applicable percentage be increased to 45 percent. Certain drugs currently marketed that fall into this category have up to 35.6 percent of the labeled amount that is unused and discarded and not part of the labeled dose to be administered. In the same manner as the applicable percentage for the hydrogel finalized in the CY 2023 PFS final rule, we proposed to add the discarded amount percentage to the applicable percentage of 10 percent that is used for drugs without unique circumstances (that is, 35.6 percent plus 10 percent), and we proposed to round that number to an applicable percentage of 45 percent for this tier.

In summary, we proposed to increase the applicable percentages for drugs with a low volume dose (a dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL). Specifically, we proposed that:

- Refundable drugs with labeled doses that are contained within 0.1 mL or less when removed from the vial or container have an increased applicable percentage of 90 percent and;
- Refundable drugs with labeled doses that are contained within 0.11–0.4 mL when removed from the vial or container have an increased applicable percentage of 45 percent.

To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 90 percent, including Triesence® (triamcinolone acetonide injection, suspension) and Xipere® (triamcinolone acetonide injection, suspension), along with some other ophthalmic drugs with such low volume doses that do not include all of the target fill volume in the labeled amount (that is, those that are labeled such that the low volume dose is equal to the labeled amount). We also noted that, although Susvimo™ (ranibizumab injection, solution) would qualify for the proposed 90 percent applicable percentage, it is excluded from the definition of refundable drug due to filtration requirements as discussed in the CY 2023 PFS final rule (87 FR 69723 through 69724). To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 45 percent, including Xiaflex® (collagenase clostridium histolyticum) and Kimmtrak® (tebentafusp injection, solution, concentrate).

In the CY 2023 PFS proposed rule (88 FR 52392 through 52393), we discussed that the second proposed unique circumstances is for orphan drugs administered to a low volume of unique beneficiaries, which we proposed to be fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year (hereafter referred to as rarely utilized orphan drugs); we proposed an increased applicable percentage of 26 percent for drugs with these unique circumstances. We explained that there is a higher probability that the percentage of discarded amounts for rarely utilized orphan drugs may not have a normal statistical distribution from quarter to quarter, which could disproportionately affect manufacturers of such drugs by resulting in highly variable refund amounts as compared with the variability of drugs administered to a higher number of beneficiaries. This is evidenced by our analysis of quarterly discarded drug data reported using the JW modifier of 30 refundable drugs identified in the 2021 Medicare Part B Discarded Drug Units data with greater than 10 percent units discarded,[154] three of which were orphan drugs furnished to a patient population of less than 100 unique fee-for-service Medicare beneficiaries in CY 2021: J9262 (*omacetaxine mepesuccinate*); J9269 (*tagraxofusperzs*); and J0223 (*givosiran*). For these drugs identified in the 2021 Medicare Part B Discarded Drug Units data, we analyzed JW modifier data for quarters in 2021 and 2022, which showed that the average standard deviation of the percentage of units discarded across quarters for the rarely utilized orphan drugs is 6.21 percent, compared with an average standard deviation for all other refundable drugs (with a percentage of discarded units over 10 percent in 2021) of 2.35 percent. In other words, the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the group of refundable drugs with larger patient populations and claims volume. In

[152] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211950Orig1s000correctedlbl.pdf.*

[153] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/022223,022048lbl.pdf.*

[154] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

addition, of the three aforementioned drugs, the most public data is associated with J9262, which shows that the percent discarded units for J9262 was 23.65 percent, 19.96 percent, and 30.98 percent in 2019, 2020, and 2021, respectively. Because of this substantial statistical variation from quarter to quarter for such drugs, we believe it would be difficult to optimize the presentation of the drug to consistently minimize the discarded amounts to less than 10 percent given the small number of patients receiving the drug. We considered the higher percentage of unused and discarded amounts from such drugs as unavoidable loss due to both the low volume of unique beneficiaries receiving the drug contributing statistically higher variability in discarded amounts. Also, due to the low numbers of patients available to study for rare disease, it may be more difficult to determine the most efficient vial size for the patient population who receive the drug post-marketing. We stated this is similar to the loss of product due to filtration described in section 1847A(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. In the case of filtration described in statute, the loss is unavoidable because certain amounts of product will be left within the filter and unavailable for administration; in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug) leading to an inability to develop a package size that will result in a consistent average percentage of discarded units (as evidenced in the analysis above in this section). In contrast, drugs administered to a larger number of beneficiaries per year have a more consistent average percentage discarded from quarter to quarter, as evidenced by the lower standard deviation in our analysis, and we believe manufacturers are able to develop availability of the drug accordingly to minimize discarded amounts.

We proposed that unique circumstances of rarely utilized orphan drugs have the following characteristics: (1) a drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a drug for a rare disease or condition; and (2) that is furnished to fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year. We proposed that the number of beneficiaries receiving such drug in the calendar year would correspond with the refund quarter. For example, for refund quarters in 2023, we would use the number of beneficiaries receiving the drug in the 2023 calendar year to determine if the unique circumstances and increased applicable percentage would apply. Data of number of beneficiaries would be analyzed at the same time as the JW modifier data for the given calendar quarters. To meet these unique circumstances, we proposed that the drug be designated an orphan-drug under section 526 of the FD&C Act for a rare disease or condition (or diseases or conditions) and be approved by the FDA only for a designated rare disease or condition (or diseases or conditions). That is, all FDA-labeled indications for the drug must be orphan indications, and if the drug has one or more indications that are for conditions that are not designated by the FDA to be a rare disease or condition, the drug would not be considered to have unique circumstances of rarely utilized orphan drugs. In addition, we proposed that the drug would meet these unique circumstances and that the increased applicable percentage would apply for as long as the drug meets these conditions, even after any orphan drug exclusivity end date.

The increased applicable percentage of 26 percent that we proposed is appropriate because the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the larger group of refundable drugs, and multiplying the applicable percentage referenced in paragraph (h)(3)(B)(i)(II) by how many times greater the variance is (in other words, 10 percent times 2.64) equals 26.4 percent, which we proposed to round to the nearest percentage.

We proposed that we will identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in the report sent to manufacturers and apply the proposed increased applicable percentages based on these unique circumstances proposals. If a manufacturer believes that the incorrect applicable percentage was applied to the refund calculation, the manufacturer may submit a dispute regarding the calculation by submitting an error report (see § 414.940(e)).

We proposed to codify these applicable percentages at § 414.940(d). Specifically, we proposed to add applicable percentages for low volume doses by creating new paragraphs (d)(3) and (4); and we proposed to add applicable percentage for orphan drugs administered to fewer than 100 unique beneficiaries per calendar year in new paragraph (d)(5). We proposed that these applicable percentages apply beginning with the initial refund report that we proposed to be sent no later than December 31, 2024.

We solicited comments on the proposed unique circumstances. Specifically, we solicited comment on the proposed volume (mL) tiers for drugs with low volume doses along with the proposed increased applicable percentages and whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less. We also solicited comment on the increased applicable percentage of 26 percent for rarely utilized orphan drugs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed unique circumstances and increased applicable percentages. One commenter expressed general support for the expansion of the scope of drugs that may be considered to have unique circumstances and be considered for an increased applicable percentage.

Several commenters expressed support for the proposed unique circumstances and increased applicable percentage for small volume drugs, some specifically supporting the increase applicable percentage of 90 percent for drugs with low volume doses of 0.1 mL or less and others specifically supporting the increased applicable percentage of 45 percent for drugs with low volume doses of 0.11—0.4 mL. One commenter stated that low volume dose drugs are particularly susceptible to having unusable product that remains after the product is administered. This commenter also expressed support of the tiered increased applicable percentage and agreed that the percentage of unusable amounts decreases as product volume increases. Another commenter added that without an increased applicable percentage for small volume drugs, as proposed, the discarded drug refund policy would lead to underdosing of anti-vascular endothelial growth factor (anti-VEGF) therapies used to treat age-related macular degeneration (AMD), diabetic retinopathy, and other vision-threatening retinal diseases. One commenter expressed support for the clarification that Susvimo™ (ranibizumab injection for intravitreal use via ocular implant) would have a proposed applicable percentage of 90 percent if it were not already excluded due to filtration requirements.

Several commenters support the proposed increased applicable percentage for rarely utilized orphan

drugs. Other commenters stated they generally support the proposal regarding orphan drugs and the increased flexibility of the proposal. Two commenters expressed support for the proposed increased applicable percentage of 26 percent and agree that rarely utilized orphan drugs possibly have high discarded amounts due to limited manufacturing capability.

Response: We thank these commenters for their support of these proposals.

Comment: One commenter stated that drug low volume doses with 0.1 mL or less should have an increased applicable percentage of 100 percent, which would effectively exempt such drugs from liability for any discarded drug refund. The commenter stated, to the extent that the purpose of this provision is to encourage manufacturers to adopt packaging that is appropriately sized to the dose, drugs with low volume doses of 0.1 mL or less have already met the objective to minimize discarded amounts. Another commenter requested an increased applicable percentage of 100 percent for drugs with a volume of 1 mL or less. This commenter stated that discarded drug modifiers add administrative burden for intravitreal, single-use drugs.

Response: As discussed above in this section, we do not believe it would be appropriate for any product to have an applicable percentage of 100 percent. Such an applicable percentage would, in effect, exclude drugs from the refund liability altogether. We believe it would be inappropriate to effectively expand the list of exclusions described in section 1847A(h)(8)(B) of the Act by proposing an increased applicable percentage of 100 percent to drugs not excluded in statute. With regard to the burden of the JW and JZ modifiers, we stated in the CY 2023 PFS final rule (87 FR 69724) that even if a drug is excluded from the definition of refundable drug (and not subject to refunds), for example, multiple source drugs, claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers in accordance with the policy. Therefore, even if CMS were to increase the applicable percentage of a drug to 100 percent, the drug would still be subject to the JW and JZ modifier policy and the increased applicable percentage would not relieve administrative burden.

Comment: Several commenters requested CMS clarify how we determined the 100-beneficiary cutoff for rarely utilized orphan drugs and an increased applicable percentage of 26 percent for drugs with these unique circumstances. One commenter stated that the qualifying criteria for rarely utilized orphan drugs is flawed and lacking details. Another commenter stated that the rationale used for establishing unique circumstances for rarely utilized orphan drugs could be applied to orphan drugs that treat more than 100 Medicare fee-for-service beneficiaries. One commenter noted that our initial proposal was limited to the 30 drugs that had discarded drug amounts exceeding 10 percent in each of 2019, 2020 and 2021. One commenter explained that the ten billing and payment codes for drugs with less than 100 beneficiaries are primarily prescribed to treat diseases for patients under the age of 65. Further, the commenter pointed out two of the three rarely utilized orphan drugs referenced in the proposed rule had a majority of patients who were non-elderly in their studies.

Three commenters asked that CMS consider increasing the less than 100-beneficiary cutoff for a drug to qualify for the unique circumstance. One commenter requested that we increase the beneficiary threshold to 500 beneficiaries a year while another commenter suggested increasing the threshold to 1,000 beneficiaries. One commenter supports a more holistic orphan disease unique circumstances and thresholds in line with current definitions of rare and ultra-rare diseases.

Some commenters ask that we consider if an increase that is higher than the proposed 26 percent in the applicable percentage for rarely utilized orphan drugs may be necessary. One commenter suggested CMS exempt orphan drugs with a single indication from discarded drug refund liability. The commenter explained that in 2022, these drugs accounted for 1 percent of total Medicare FFS, an amount that doesn't justify the high proportion of the total discarded refund liabilities that will be imposed on orphan drugmakers. This commenter also proposed that, alternatively, CMS could increase the applicable percentage to 35 percent (along with a beneficiary increase to 1,000 beneficiaries as described above in this section).

Response: For unique circumstances of rarely utilized orphan drugs, the 100-beneficiary threshold was a result of an analysis of quarterly discarded drug data from 2021 and 2022. We explained in the proposed rule that this analysis showed that there is a higher probability that the percentage of discarded amounts for rarely utilized orphan drugs may not have a normal statistical distribution from quarter to quarter, which could disproportionately affect manufacturers of such drugs by resulting in highly variable refund amounts as compared with the variability of drugs administered to a higher number of beneficiaries. The increased variability of the percentage of discarded amounts from quarter to quarter was not observed for orphan drugs administered to more than 100 unique beneficiaries per year. We explained that the average standard deviation of the percentage of units discarded across quarters for rarely utilized orphan drugs is 6.21 percent, compared with an average standard deviation for all other refundable drugs (with a percentage of discarded units over 10 percent in 2021) of 2.35 percent.

The justification for the unique circumstances in rarely utilized orphan drugs hinges on the variability of percentage of discarded amounts from quarter to quarter (not the actual percentage discarded itself). The threshold of 100 beneficiaries per year for the unique circumstances of rarely utilized orphan drugs is supported by this sharp decrease in variability of discarded percentages when the drug is administered to more than 100 unique beneficiaries. Such variability from quarter to quarter is not observed when the number of beneficiaries receiving the drug exceeds 100 per year. For example, the percentage of discarded amounts for available quarters through the end of CY 2022 for Elzonris® (tagraxofusp-erzs), which was administered to 19 unique beneficiaries in 2021, ranges from a low of 6.55 percent to a high of 34.52 percent per quarter (a spread of 27.97 percent). In contrast, the percentage of discarded amounts for Folotyn® (pralatrexate), which was administered to 155 unique beneficiaries in 2021, ranges from a low of 9.04 percent to a high of 14.87 percent per quarter (spread of 5.83 percent). We evaluated several other orphan drugs furnished to more than 100 beneficiaries and all had low variability of the percentage discarded from quarter to quarter.

The statutory provision requires that unique circumstances be similar to the loss of product due to filtration described in section 1847A(8)(B)(ii) of the Act. We stated in the proposed rule that rarely utilized orphan drugs have unique circumstances similar to filtration described in section 1847A(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. We stated that in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug)

leading to an inability to develop a package size that will result in a consistent average percentage of discarded units. We are not convinced by commenters that an alternative threshold of 500 or 1,000 beneficiaries more closely ties the unique circumstances to filtration described in section 1847A(8)(B)(ii) of the Act.

For justification of increased applicable percentage of 26 percent, we explained in the proposed rule that the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the group of refundable drugs with larger patient populations and claims volume. We multiplied the mean discarded drug percentage by the applicable percentage of drugs without unique circumstances (that is, 10 percent) to arrive at an increased applicable percentage of 26 percent. Commenters did not provide additional justification for their suggestions for an alternative increased applicable percentage, and we are not convinced by these comments that an alternative increased applicable percentage different the proposed of 26 percent is appropriate for these unique circumstances.

Comment: One commenter stated that there is a risk that basing eligibility for being considered a rarely utilized orphan drug on a single year could create unwarranted volatility as to whether the unique circumstances apply in any given calendar year. The commenter requested that the 100-beneficiary cutoff for the qualification of a drug to be considered to have unique circumstances of a rarely utilized orphan drug be determined using a 3-year rolling average.

Response: We agree with the commenter that a 3-year rolling average is reasonable to determine eligibility for having the unique circumstances of rarely utilized orphan drugs along with the increased applicable percentage for these unique circumstances because this would prevent volatility for determining whether these unique circumstances apply to an orphan drug that is nearing the 100-beneficiary threshold. Therefore, in this final rule, we are finalizing a modification to our proposal such that for the purposes of determining whether a drug is a rarely utilized orphan drug for which the applicable percentage would be 26 percent, the drug will have met the condition of being furnished to fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year if it meets one of the two conditions below:

(1) the number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or

(2) the average number of unique beneficiaries per year for the calendar year in which the refund quarter occurs and the 2 previous calendar years (3-year average) is less than 100. In the case that a drug for which at least 2 but less than 3 years of data available, we will calculate the average to determine whether the 100-beneficiary threshold is met.

Comment: One commenter asked that we allow manufacturers to provide feedback for potential future amendments to the criteria for these unique circumstances for orphan drugs. The commenter stated that there are manufacturers of orphan drugs with low patient volume that have similar circumstances to those of the three rarely utilized orphan drugs identified in the proposed rule. Specifically, the commenter stated that manufacturers of other orphan drugs have difficulty financially justifying creation of new vial sizes. One commenter requested that we continue to periodically reassess whether the 100 unique beneficiary threshold is appropriate as new rare disease therapies are developed.

Response: We welcome additional engagement on future policy development regarding unique circumstances of rarely utilized orphan drugs and their associated increased applicable percentage. We plan to continue monitoring JW and JZ modifier data and variability of the percentage discarded from quarter to quarter for orphan drugs to inform potential future policy development.

Comment: One commenter recommended that CMS clarify how we determine whether a particular drug is a low volume dose. The commenter stated that clinicians administering drugs may not know the precise amount of product contained in the vial or other container, in part because the FDA label often does not indicate such amount. Therefore, the commenter urged CMS not to depend on the clinician's own interpretation to determine if a drug has a low volume dose. Instead, the commenter suggested that CMS should maintain a list of drug products with low-volume doses, and CMS should allow manufacturers to submit information to CMS—including information not contained in the FDA label, when necessary—to demonstrate that the low-volume threshold is met. Another commenter requested we establish a process for manufacturers to request and receive confirmation before a calendar year begins whether their product has unique circumstances with an increased applicable percentage. The commenter stated that such a process would give manufacturers necessary notice whether a product was considered to have unique circumstances.

Response: We agree with commenters that CMS should communicate which drugs have been identified as meeting criteria for low volume dose unique circumstances. In the proposed rule, we stated that we would consider a low volume dose to be a dose of a drug for which the volume removed from the vial containing the labeled dose does not exceed 0.4 mL. In addition, we proposed that for a drug to meet these unique circumstances, all labeled doses of the drug must be low volume doses. Although all the necessary information is available in the FDA-approved labeling to determine if a drug has a low volume dose, we agree that this information may not be explicitly stated in FDA-approved labeling, and we agree that maintaining a list of drugs identified as having low volume doses will help provide clear communication of which drugs have these unique circumstances. Therefore, we intend to publish a list of drugs CMS has identified as having low volume doses and will have an increased applicable percentage no later than December 31, 2023, and intend to update the list no later than December 31 of each subsequent year. This would allow adequate time for manufacturers to evaluate the list prior to the deadline of February 1 for the application process for increased applicable percentage.

Similarly, we considered providing similar advance notice for rarely utilized orphan drug unique circumstances. However, the number of beneficiaries receiving the drug in the calendar year in which the refund quarter occurs (or the 3-year or 2-year average as discussed above in this section) will not be known until data is analyzed for the report. To provide information in advance, CMS intends to communicate a list of drugs that would have met conditions for having unique circumstances of rarely utilized orphan drugs for CY 2022 no later than December 31, 2023. This list would be provided as informational only and may not necessarily reflect the same list of drugs that have unique circumstances of rarely utilized orphan drugs when the data is analyzed for the initial refund report. Each year, CMS will update the list of drugs that have unique circumstances of rarely utilized orphan drugs with those that met such conditions on the previous year's report. For example, CMS will provide the list

of drugs with such unique circumstances for the initial report (containing calendar quarters in 2023) no later than December 31, 2024.

Finally, in the proposed rule, we stated that we will identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in the report sent to manufacturers and apply the increased applicable percentages based on these unique circumstances. If a manufacturer believes that the incorrect applicable percentage was applied to the refund calculation, the manufacturer may submit a dispute regarding the calculation by submitting an error report (see § 414.940(e)).

After consideration of public comments, we are finalizing revisions to § 414.902 to add the definition ''low volume dose'' and § 414.940(d) to add the increased applicable percentage of 90 percent for drugs with a low volume dose contained within 0.1 mL or less and 45 percent for a drug with a low volume dose contained within 0.11 mL up to 0.4 mL, as proposed. We also are finalizing as proposed at § 414.940(d) the increased applicable percentage of 26 percent for a drug designated an orphan drug under section 526 of the FD&C Act for a rare disease or condition (or diseases or conditions), approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and furnished to fewer than 100 unique beneficiaries per calendar year. We are adding that an average of fewer than 100 beneficiaries per calendar year for the most recent 3 years (or 2 years, in certain circumstances) as discussed above in this section would be considered to have such unique circumstances.

(4) Application Process for Increased Applicable Percentages

In the CY 2024 PFS proposed rule (88 FR 52393 through 52395), we discussed our proposal to establish an application process through which manufacturers may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We explained that manufacturers could benefit from a formal process through which they can provide information, including that which may not be publicly available, and therefore, not known to us, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of its unique circumstances.

We proposed that, to request CMS consider increasing the applicable percentage of a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study. We proposed that in evaluating requests for increased applicable percentages, we would review the documentation referenced above for evidence that amounts of drug identified in the FDA-approved package or labeling has similar loss of product as that described in paragraph section 1847A(8)(B)(ii) of the Act.

We stated that section 1847(h)(3)(B)(ii) of the Act requires that any increase to applicable percentages for refundable drugs is to be made through notice-and-comment rulemaking. Therefore, we proposed that applications for individual applicable percentage increases be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply (for example, applications for increased applicable percentages effective January 1, 2025, will be due to CMS by February 1, 2024). We proposed to discuss our analyses of applications in the PFS rulemaking immediately following the application period, and to communicate in the rule whether we consider the drug to have unique circumstances that warrant an increased applicable percentage. We would include proposals, if any, for increased applicable percentages, along with a summary of any applications for which we determined not to propose an increase in the applicable percentage. We proposed to codify this application process for increased applicable percentages in new paragraph § 414.940(e).

We stated that we do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, body surface area (BSA)-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act. FDA draft guidance, titled ''Optimizing the Dosage of Human Prescriptions Drugs and Biological Products for the Treatment of Oncologic Diseases'',[155] states: ''Various dose strengths should be available to allow multiple dosages to be evaluated in clinical trials. Perceived difficulty in manufacturing multiple dose strengths is an insufficient rationale for not comparing multiple dosages in clinical trials.'' Although optimization of dosage and available product formulations most often occurs prior to marketing a drug, we also observed several instances where the drug formulation availability has been changed and subsequently resulted in a decreased percentage of discarded amounts. For example, Kyprolis® (carfilzomib), which is cross-walked to the billing and payment code J9047, was available in only one 60-mg single-dose vial size when first approved in 2012.[156] Subsequently, a second 30-mg vial size was approved in 2016,[157] and a third 10-mg vial size was approved in June of 2018.[158] We observed in discarded drug data, based on the JW modifier, that the percentage of discarded units for J9047 was 14.27, 12.68, 5.95, 4, and 3.09 percent in 2017, 2018, 2019, 2020, and 2021, respectively. There is a sharp drop in the percent of discarded units after 2018, which correlates with the introduction of the 10-mg vial. The labeled dose of Kyprolis® is based on the patient's BSA, there is a dose escalation, there are two different dosage schedules (once weekly and twice weekly) each with differing doses, there are dosage modifications for toxicity that involve dose reductions, and there is a dose reduction for patients with hepatic impairment. With these dose variations taken into consideration, the available vial sizes of the drug allow for the percentage of discarded units to remain well below 10

[155] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/optimizing-dosage-human-prescription-drugs-and-biological-products-treatment-oncologic-diseases.*

[156] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202714lbl.pdf.*

[157] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202714s012lbl.pdf.*

[158] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202714s019lbl.pdf.*

percent after the introduction of the third vial size.

In addition, we observed that, based on the 2021 discarded drug data,[159] as the number of available package sizes increases, the percent discarded decreases (see Table 22). This example is indicative of ways in which manufacturers can optimize package sizes to reduce the percentage of discarded units in the circumstances listed above.

TABLE 22: 2021 Discarded Drug Data for Refundable Drugs and Number of Available Package Sizes

Percent Units Discarded	Number of Refundable Drugs	Percentage of Refundable Drugs with Only One Package Size
> 20%	7	100%
15—19.99%	6	83.33%
10—14.99%	20	75%
5—9.99%	22	45.45%
2—4.99%	47	29.79%

We solicited comments from interested parties on the application process for increased applicable percentage. Specifically, we solicited comment on what factors we should use in a framework for considering these applications, what factors we should use to assess appropriate increases to applicable percentages, and what types of additional or alternative documentation may help us analyze justifications for increased applicable percentages.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed approval of the proposed application process for increased applicable percentage, with several adding that the process, if finalized, would provide manufacturers transparency and predictability. One commenter specifically expressed support for the proposal to use minimum vial fill studies or dose preparation studies in CMS' evaluation of whether an increased applicable percentage is appropriate for a refundable drug because such studies examine whether a product contains a greater amount than is necessary to accurately and consistently deliver the labeled therapeutic dose. One commenter expressed support for CMS' engagement with manufacturers in the development of the application process.

Response: We thank the commenters for their support.

Comment: Several commenters requested CMS maintain flexibility in our approach to reviewing applications for increased applicable percentage and work closely with the medical community as new therapeutics and packaging practices develop. One commenter added that dialogue between CMS and interested parties is important because novel treatments may be ill-suited to the policy design of the discarded drug refund program. One commenter requested that CMS conduct outreach to manufacturers to ensure they are aware of the application process. One commenter requested additional flexibility in the application process by allowing manufacturers to request unique circumstance consideration more frequently than once a year and outside the annual rulemaking process.

Response: We thank the commenters for their feedback. We agree that working with the medical community and other interested parties is important to the implementation of the discarded drug refund program. As the discarded drug refund policy develops, we will continue to rely on feedback from the provider and manufacturer communities. Public input gathered in the CY 2023 PFS rulemaking process, the Discarded Drug Refund Policy Town Hall we hosted on February 1, 2023, and meetings with interested parties provided the basis of the two proposed unique circumstances and the framework for the application process for increased applicable percentages. We plan to issue additional guidance and communications to providers and suppliers prior to the application window for increased applicable percentages taking effect in CY 2025.

Comment: One commenter expressed concern that the February 1 deadline for supporting documentation would create a significant lag for consideration and approval of an increased applicable percentage if a drug is approved on or after the deadline. The commenter requested that companies whose drugs are nearing approval prior to the deadline be allowed a fixed supplemental period to submit the FDA-approved label after the deadline. The commenter cited precedent for this with new technology add-on payments (NTAP) applications and the prior annual Healthcare Common Procedure Coding System (HCPCS) coding process before it was transitioned to a quarterly process.

Response: We appreciate the commenter's feedback. We are persuaded by the commenter's suggestion that manufacturers whose products have not yet been approved by the FDA should have additional flexibility in completing their application submissions in anticipation of approval prior to the calendar year following the application deadline. To strike a balance between providing maximum flexibility to manufacturers seeking consideration for increased applicable percentages and the necessity that manufacturers possess sufficient information about the dosing and packaging of their product to explain and provide evidence for an unavoidable loss of product that meets the criterion for an increased applicable percentage, we will allow manufacturers to submit applications for increased applicable percentage prior to FDA approval if the product's application for FDA approval has been accepted by the FDA for review and such documentation of FDA acceptance can be provided to CMS at the time of application for increased applicable percentage prior to the application deadline. Similar to the NTAP

[159] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

submission requirements for technologies that are not already FDA-market authorized during the NTAP application period, we will require manufacturers of drugs that are not FDA-approved to provide documentation to demonstrate that an application has been accepted for review by the FDA (for example, a filing letter) at the time of submission of its application for an increased applicable percentage to CMS. We believe it is important that applicants applying for an increased applicable percentage have an accepted application for FDA review of the product because it increases the likelihood they have sufficiently studied issues related to vial size optimization and minimization of unavoidable drug loss and reduces the risk of using resources to review applications for drugs that will not be sold in the calendar year for which we are considering applicable percentage increases. Additionally, we believe documentation of FDA acceptance of review, such as a filing letter, will provide the clearest and most effective means of documenting that the applicant has submitted a complete request to FDA and therefore we intend to require one such document by February 1 for drugs that are not yet approved. Under the final policy, drugs that do not yet have FDA approval at the time of application for an increased applicable percentage will have three deadlines for their application:

- February 1 for all required documentation other than the FDA-approved label, including documentation of FDA acceptance of the product's application for review;
- August 1 for FDA approval; and
- September 1 for applicants to notify CMS of the product's FDA approval and submit the approved label.

Therefore, we are modifying our proposed policy and finalizing a policy that applicants must submit the following by February 1 of the calendar year prior to the year the increased applicable percentage would apply: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug, or, if the drug is not yet approved, documentation of the FDA acceptance of the application for review; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. We are also finalizing that a manufacturer that does not have FDA approval for its product by February 1 must receive FDA approval by August 1 and submit the FDA-approved label to CMS by September 1 for its application to be complete and eligible for consideration for an increased applicable percentage based on unique circumstances. This additional 6-month window for FDA marketing authorization is similar to the extended deadline CMS currently allows applicants for NTAP that have not received FDA marketing authorization prior to the NTAP application deadline, generally in mid-October, of the year prior to the beginning of the fiscal year for which the application is being considered. Additionally, a drug that is approved on August 1 or later will not have 18 months or more of claims paid under Part B before the beginning of the calendar year 2 years following the application period, and therefore, manufacturers will have an opportunity to apply for increased applicable percentage and for that increased applicable percentage to be effective prior the end of the 18-month exclusion from the definition of refundable drug (as described in section 1847A(h)(8)(B)(iii) of the Act).

We note that for applicants that do not yet have FDA approval, once the FDA approves a label for the product, certain aspects regarding, for example, vial fill, labeled therapeutic dose, or estimated discarded amounts may change after the time the application for increased applicable percentage was submitted and when the product is FDA-approved. As stated above, we are requiring that applicants notify CMS by September 1 when the product is FDA-approved. At that time, CMS will evaluate the FDA-approved label and compare it with the application for determination of the increased applicable percentage. In the case the approved label is no longer in accord with the submitted justifications, we will consider the submitted justifications as invalid and the application as both incomplete and ineligible for consideration for a proposed increased applicable percentage. The manufacturer will have an opportunity to apply for an increased applicable percentage for the following year's application cycle.

Comment: Several commenters disagreed with the proposed exclusion of weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity as bases for a unique circumstance. Commenters described the challenges involved in achieving consistency of vial sizes for individual patients, such as step-in doses that will vary for a patient as they adjust to treatment, and the identification of optimal vial sizes for these types of drugs. One commenter requested an applicable percentage increase of 10 percent for drugs that are indicated as loading doses as vial sizes are typically selected for subsequent maintenance doses. Commenters added that the introduction of additional vial sizes to limit discarded amounts may be impractical due to great variance in patient needs, and for some manufacturers, economically infeasible. In addition, one commenter stated that example of Kyprolis vial sizes in the proposed rule confirms how long it can take manufacturers to mitigate discarded drug refund liability, as its two additional vial sizes were approved 4 and 6 years after the product's initial approval.

Response: We thank the commenters for their comments on the difficulties of reconciling highly varied patient characteristics into a limited set of vial or container sizes, as well as those for drugs with loading doses. While we acknowledge these challenges posed by these circumstances, we do not consider them to be similar to products that require filtration during preparation as described in section 1847A(8)(B)(ii) of the Act because the drug loss in the former cases is not unavoidable. In each case, we believe manufacturers can, with vial size optimization studies, identify a set of container sizes for which less than ten percent of the labeled amount is usable and not necessary for the reliable and safe delivery of the labeled therapeutic dose for all patients, on average. Regarding the economic feasibility of introducing a new vial size or multiple new sizes, we do not have sufficient information about individual manufacturers' circumstances to address whether introducing new vial sizes or optimizing vial sizes would be economically feasible in each circumstance.

As shown in Table 22 and generally during our analysis of drugs from single-dose containers, a vast majority of single-dose drugs are manufactured in package sizes that are efficient enough to keep the percentage of discarded amounts to less than 10 percent. In the case of Kyprolis, we are not aware of the specific circumstances under which the manufacturer chose to increase the number of vial sizes. Without additional information about the specific circumstances, we cannot speculate on particular business decisions of the manufacturer, when the development of each vial size began, or how long it took for a new vial size to be approved and marketed.

Comment: One commenter requested that CMS clarify how long increased applicable percentages apply when increased through the individual drug application process and subsequent rulemaking. The commenter noted that a drug's unique circumstance on which an applicable percentage increase is based is unlikely to change year to year, and therefore requiring annual applications for the same drug should not be required.

Response: We thank the commenter for their request for clarification of the duration of the unique circumstances and increased applicable percentages. We clarify that an increased applicable percentage, once finalized through rulemaking, continues to apply until modified through subsequent rulemaking. We note that drugs meeting the criteria for unique circumstances of low volume doses or rarely utilized orphan drugs could fluctuate, and we discuss communications of which drugs meet such criteria above in this section.

Comment: Two commenters requested clarification regarding what kinds of justifications, including supporting evidence, CMS will consider bases of unique circumstances for which increased applicable percentages are appropriate. The commenter also requested examples of each.

Response: We thank the commenter for their request for clarification of appropriate bases for unique circumstances and increased applicable percentages. While we cannot anticipate future drug development or what unique circumstances might arise, we can offer our analysis of the unique circumstances we consider involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act for drugs that are reconstituted in hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69727 through 69731), drugs with low volume doses, and rarely utilized orphan drugs (both discussed in section III.A.3.d.(3) of this final rule). Regarding examples of evidence, we noted minimum vial fill studies and dose preparation studies in the proposed rule, both of which are suitable for justifying increased applicable percentages because they can establish that certain unusable amounts of a product are necessarily included in a container to safely and consistently administered the labeled therapeutic dose to a patient.

After consideration of public comments, we are finalizing our proposal regarding the application process for increased applicable percentages, including the application deadline of February 1 and, in addition, we are finalizing a modification of our proposal by adopting a deadline for the FDA-approved labeling of August 1 and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would apply, in new § 414.940(e).

e. Clarification for the Definition of Refundable Drug

As discussed in the CY 2023 PFS final rule (87 FR 69650 through 69655), we aim to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. In the CY 2024 PFS proposed rule (88 FR 52395), we noted CMS anticipates addressing coding and payment for skin substitutes in future rulemaking. We explained that while we considered making changes to the Medicare Part B payment policies for such products, we proposed that billing and payment codes that describe products currently referred to as skin substitutes are not counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to not consider skin substitutes as refundable drugs for 2023 and 2024. One commenter added that the exclusion is appropriate because payment for skin substitutes is inconsistent across settings and because claims edits for appropriate JW and JZ modifier use were not in place for the first three quarters of calendar year 2023 to ensure accurate accounting of discarded amounts. Two commenters that agreed with the proposal disagreed with CMS' assertion that CMS had discretion to count these products in the first place, as they fall outside the statutory definition of a refundable drug in section 1847A(h)(8)(A) of the Act, which applies to products that are either a single-source drug or biological (as defined in subsection (c)(6)(D)) or a biosimilar biological product (as defined in subsection (c)(6)(H)), neither of which describe skin substitutes. The commenters requested that CMS acknowledge that skin substitutes are statutorily precluded from the policy.

Response: We thank commenters for their feedback as we continue to consider refinements to skin substitute policies. The comment solicitation in the CY 2024 PFS proposed rule will inform future policy development for the payment of skin substitutes.

Regarding the lack of enforcement of JW and JZ modifier use through the first three quarters of 2023, section 1847A of the Act only speaks to the use of JW data for the calculation of reporting discarded amounts and assessing refund obligations. In the CY 2023 PFS final rule (87 FR 69712 through 69728) we established the JZ modifier and finalized plans to edit for JW and JZ modifier use, which are described more fully in program instruction,[160] to improve the quality of discarded amount data. Although we proposed in the CY 2023 PFS proposed rule to require the JZ modifier beginning January 1, 2023, we delayed the requirement in the final rule to October 1, 2023, in response to comments to allow a transition period for providers, billing software vendors, and MACs to adjust billing and claims review processes (87 FR 69717). For these reasons, we disagree that this delay prevents us from using JW modifier data to calculate discarded drug refunds for the first three quarters of 2023.

Comment: One commenter requested that we clarify how CMS will handle claims for skin substitutes reported with the JW modifier in a future payment methodology.

Response: In the CY 2024 PFS proposed rule (88 FR 52357 through 52358), we solicited comment on potential approaches to billing but did not propose any revisions to the payment approach for skin substitutes under Part B for CY 2024. Therefore, we cannot comment on how claims for skin substitutes that report JW data, or the reported JW data, will be processed under a future payment approach.

Further discussion of a potential future billing approach for skin substitute products is in section II.H of this final rule. For this final rule, for CY 2023 and 2024, we are finalizing that JW units of skin substitutes will not be used for the discarded drug refund calculations and we will not issue reports to manufacturers with respect to skin substitutes.

Comment: One commenter requested that CMS explicitly confirm the statutory exclusion for imaging agents in section 1847A(h)(8)(B)(i) of the Act includes contrast agents.

Response: We point the commenter to the discussion in CY 2023 PFS final rule (87 FR 69724). In response to two commenters requesting the same confirmation, we stated that we recognize contrast agents as a category of imaging agents as described in FDA's Guidance for Industry. Therefore, we

[160] *https://www.cms.gov/files/document/r12067cp.pdf.*

clarified that contrast agents are excluded from the definition of refundable single-dose container or single-use package drug.

Comment: Two commenters requested that we treat drugs or biologicals that are regarded as multiple source drugs under section 1847A(c)(6)(C)(ii) of the Act as multiple source drugs for purposes of the discarded drug refund.

Response: The definition of refundable drug under section 1847A(h)(8)(A) of the Act requires that such drugs are single source drugs or biologicals (as defined in subsection (c)(6)(D)) or a biosimilar biological product (as defined in subsection (c)(6)(H)). The definition of single source drug or biological requires that the drug is not a multiple source drug, which is defined at section 1847A(c)(6)(C) of the Act. Therefore, we agree with the commenter and clarify that, under section 1847A(c)(6)(C)(ii) of the Act, single source drugs or biologicals that were within the same billing and payment code as of October 1, 2003, will be treated as multiple source drugs for the purposes of the discarded drug refund.

f. Clarification for the Determination of Discarded Amounts and Refund Amounts

Section 1847A(h) of the Act specifies that discarded amounts of refundable drugs are to be determined using a mechanism such as the JW modifier used as of the date of enactment of the Infrastructure Act or any successor modifier that includes such data as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69718 through 69719), we finalized our previously existing policy that required billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023.

In the CY 2024 PFS proposed rule (88 FR 52395), we discussed the applicability of the JW modifier in Medicare Advantage claims. We stated that since the JW modifier, the mechanism described in section 1847A(h) of the Act, is not required in Medicare Advantage claims for drugs payable under Medicare Part B and there is not a similar mechanism to identify discarded units of such drugs that are billed to Medicare Advantage plans, we proposed to clarify that the JW modifier requirement does not apply to units billed to Medicare Advantage plans and that the refund amount calculations under section 1847A(h)(3) of the Act will not include units billed to Medicare Advantage plans.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal to exclude units for refundable drugs billed to Medicare Advantage plans from the calculation of refund amounts.

Response: We thank the commenters for their support.

Comment: While agreeing that the JW modifier is not required for units billed to Medicare Advantage plans, one commenter requested that we clarify that the definition of a refundable drug as described in section 1847A(h)(8) limits the scope of the provision to Part B fee-for-service claims.

Response: We thank the commenter for their feedback. As finalized in in the 2023 PFS final rule (87 FR 69710 through 69734), our policy is to determine the total number of discarded units using the JW modifier (or any successor modifier that includes the same data). This policy results in the exclusion of units billed to Medicare Advantage plans. We do not believe it is necessary to evaluate additional arguments for excluding units billed to MA plans in this final rule.

Comment: One commenter requested clarification regarding whether Medicare Advantage plans are permitted to require the reporting of the JW modifier. The commenter cited Chapter 4, Section 10.2 of the Medicare Managed Care Manual, which states that Medicare Advantage plans have discretion to establish their own billing and payment procedures, both for contracted and uncontracted providers, and such discretion extends to the option to adopt fee-for-service billing modifiers.

Response: We thank the commenter for their request for clarification. We are clarifying that since the JW modifier, the mechanism described in section 1847A(h)(1) of the Act, is not necessarily required by all Medicare Advantage plans, we cannot ensure that any JW modifier data gathered by Medicare Advantage plans is consistently done so in accordance with our JW and JZ modifier use policy, the refund amount calculations under section 1847A(h)(3) of the Act will not include units billed to Medicare Advantage plans.

After reviewing all comments, we are finalizing the clarification that we will not include units billed to Medicare Advantage plans in calculations under section 1847A(h)(3) of the Act because we cannot ensure data for refundable drugs billed to plans is consistently collected in accordance with the same reporting requirements. We are finalizing the additional clarification that Medicare Advantage plans are not required, but are permitted, to adopt the Medicare fee-for-service JW and JZ modifier requirements for single-dose container drugs that are separately payable under Part B; however, those units will not be included in the refund amount calculations.

g. Technical Changes

In the CY 2023 PFS final rule (87 FR 70227) we finalized the regulation text for the calculation of the manufacturer refund requirement. That text contained an error in two places, § 414.940(c)(3) and (d), which incorrectly referenced paragraph (c)(1)(ii) of that section in reference to the applicable percentage, rather than paragraph (c)(2). In the CY 2024 PFS proposed rule (88 FR 52395), we proposed to correct the textual reference in both paragraphs and make additional technical changes to streamline the text.

We did not receive any comments on these proposed technical corrections and are finalizing as proposed.

h. Use of the JW Modifier and JZ Modifier Policy

In the CY 2023 PFS final rule (87 FR 69723), we discussed the applicability of the JW and JZ modifier policy to drugs that are not administered by the billing supplier, including drugs furnished through a covered item of DME that may be administered by the beneficiary. In such cases, suppliers who dispense drugs payable under Medicare Part B do not actually administer the drug, as the claim is typically submitted prior to the administration of the drug, and the billing provider or supplier is not at the site of administration to measure discarded amounts. We stated that since we do not believe it would be appropriate to collect data about discarded amounts from beneficiaries, the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the patient's home. In the updated FAQ for the JW/JZ modifier policy [161] released on January 5, 2023, we reiterated that suppliers who dispense but do not actually administer a separately payable drug are not expected to report the JW modifier.

In the CY 2024 PFS proposed rule (88 FR 52395) we discussed that beginning

[161] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

October 1, 2023, we will begin editing for correct use of both the JW and JZ modifiers for billing and payment codes for drugs from single-dose containers (87 FR 69719). However, because currently there is no claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier, we were concerned that the policy finalized last year exempting self-administered drugs from the JW/JZ modifier policy may result in claims rejections absent a modification. Therefore, we proposed to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier, since we continued to believe it is unreasonable to collect discarded drug data from beneficiaries.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters expressed support for the proposal to not to apply the discarded drug refund to units of single-dose container drugs that are furnished but not administered by the billing supplier. The commenters echoed our position that it is not feasible for Medicare beneficiaries to track and accurately report discarded amounts.

Response: We thank the commenters for their support.

Comment: Two commenters stated they oppose the requirement to report the JZ modifier for drugs furnished but not administered by the biller. One commenter recommended that instead of requiring the use of the JZ modifier, CMS instead improve compliance with the JW modifier policy by enhancing provider and supplier education efforts. Two commenters suggested another alternative in which CMS develops a new modifier to be reported on claims for these drugs to separate them from the calculation of discarded drug refund amounts. One commenter added that a new modifier would be more appropriate because the supplier cannot in fact determine that there were no discarded amounts when the patient self-administers the drug for which the supplier is submitting a claim, as the reporting of the JZ modifier suggests; rather, the JZ modifier's use in this instance in fact means that the discard drug refund policy does not apply to these drugs.

Response: As we noted in the CY 2023 PFS final rule (87 FR 69716 through 69717), the Committee on Implications of Discarded Weight-Based Drugs found compliance with the JW modifier requirement not only varied among providers and suppliers, but even providers and suppliers who use the modifier do not do so consistently and vary in their reporting from one drug to another and across claims for the same patient and drug.[162] We do not believe that provider and supplier education alone can obtain the consistent reporting of JW modifier data needed for the implementation of this provision.

Regarding the establishment of a new modifier for drugs covered under the DMEPOS benefit, we agree this approach would accomplish the same objective in avoiding the rejection of claims for which we do not expect to receive JW modifier data. We do not, however, see how the requirement that suppliers of drugs covered under the DMEPOS benefit report a new modifier rather than the JZ modifier would reduce administrative burden on the supplier. One potential benefit to the program would be, rather, that billing units of such drugs are not automatically counted as administered with zero discarded amounts, but we do not have any reason, at this time, to believe this would result in additional refund obligations. We may revisit this suggestion in future rulemaking.

Comment: One commenter requested that CMS take efforts to minimize the discarded drug refund policy's compliance burden on providers and suppliers. One commenter stated that because discarded amounts for drugs covered under the DMEPOS benefit are consistently far below 10 percent, the JZ modifier requirement for these drugs does not provide a program benefit that justifies the administrative burden it would place on suppliers.

One commenter described the issuance of contradictory guidance by DME MACs that has created confusion about whether providers and suppliers are required to report the JZ modifier for single-dose container drugs that are dispensed but not administered to patients beginning July 1, 2023 or October 1, 2023, or not at all. The commenter requested that CMS direct DME MACs to update their external fusion pump local coverage articles to clarify the JW and JZ modifier policy for single-dose drugs that are dispensed, but not administered to patients for dates of service between July 1 and October 1, 2023 and for dates of service after October 1, 2023, regardless of whether the local coverage article is updated in time to reflect the new billing requirement.

Response: As we stated in the CY 2023 PFS final rule discussion on provider burden (87 FR 69716), we believe that in most cases the JW and JZ modifier requirements impose no new burdens on providers beyond the requirement of measuring and reporting discarded amounts by use of the JW modifier that predates the enactment of the discarded drug refund policy under section 1847A(h) of the Act. Providers and suppliers who have been complying with the JW modifier requirement effective January 1, 2017 have already been assessing and documenting what is needed for the JZ modifier, and the new requirement of reporting the JZ modifier is minimal and justifiable for the purposes of obtaining more complete discarded amount data.

Regarding the confusion about the billing requirements for suppliers who dispense, but do not administer a single-dose drug to patients, since we did not finalize the requirement to report the JZ modifier in this situation in the CY 2023 PFS final rule, we cannot require it to be reported for dates of service in CY 2023. On October 16, 2023, we updated the JW and JZ Modifier FAQ[163] to provide additional clarity and resolve concerns about processing claims for single-dose drugs that are self-administered by a patient or caregiver in the patient's home before CY 2024 billing requirement updates take effect. The updated FAQ provides reference to a published list of specific billing and payment codes to which only single-dose containers are assigned, and thus, may require use of the JW or JZ modifiers depending on the setting of use. The identified codes should not be considered an all-inclusive list of codes that are subject to the JW and JZ modifier policy. The list is available on the ASP Billing Resources website.[164]

Comment: One commenter stated that CMS has long stated that it expects providers and suppliers to use drugs in a clinically appropriate manner and has consistently advised that all procedures for drug reconstitution and administration should conform to applicable FDA guidelines, one of which states that any extra amount of the drug remaining after the dose is administered must be discarded.

[162] National Academies of Sciences, Engineering, and Medicine. 2021. Medications in single-dose vials: Implications of discarded drugs. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25911*. National Academies of Sciences, Engineering, and Medicine. 2021. Medications in Single-Dose Vials: Implications of Discarded Drugs. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25911.*

[163] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[164] *https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-billing-resources.*

Another commenter requested clarification of correct JZ modifier use when drugs from a single-dose containers are used for multiple patients.

Response: The JW Modifier and JZ Modifier Policy Frequently Asked Questions document [165] reiterates language in Chapter 17 of the Medicare Claims Processing Manual,[166] which states that CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. In the resources section of the FAQ document, there is a link to a memorandum from the Survey and Certification Group at CMS regarding entitled *Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections.*[167] In this memorandum CMS clarified guidance regarding the various infection control regulatory requirements to indicate that when previously unopened single-dose vials are repackaged consistent with aseptic conditions under the requirements of USP <797>, and subsequently stored consistent with USP <797> and the manufacturer's package insert, it is permissible for healthcare personnel to administer repackaged doses derived from single-dose vials to multiple patients, provided that each repackaged dose is used for a single patient in accordance with applicable storage and handling requirements. We reiterate the JZ modifier policy that the modifier is used to attest that no amount of drug was discarded from single-dose container drugs. To align with the JW modifier policy, the JZ modifier is required when there are no discarded amounts of a single-dose container drug for which the JW modifier would be required if there were discarded amounts. In addition, we clarify that JZ modifier policy does not require that the claim line with the JZ modifier account for only whole vials of the drug and the JW modifier policy does not require that the two claim lines (as described in the modifier FAQ document [168]) account for only whole vials of the drug.

Comment: One commenter requested clarification regarding the JW/JZ reporting requirements for drugs that are excluded from the definition of ''refundable drug'' and are therefore exempt from refunds for discarded amounts. The commenter requested that such drugs that do not meet the definition of a refundable drug be billed with the JZ modifier, similar to those that are furnished but not administered by a supplier.

Response: As stated in the CY 2023 PFS final rule (87 FR 69724), even if a drug is excluded from the definition of refundable single-dose container or single-use package drug (and not subject to refunds), for example, multiple source drugs, claims for such drugs furnished from a single-dose container are still required to use the JW and JZ modifiers in accordance with the policy.

After reviewing all comments, we are finalizing as proposed the requirement that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier.

i. General Comments

We received several public comments on these proposals, generally. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for CMS' ongoing efforts to implement section 90004 of the Infrastructure Act by continuing to refine the process for manufacturers to provide a refund to CMS for certain discarded amounts from refundable drugs. The commenter stated that implementation of the discarded drug refund will help reduce waste and spending within the Medicare program by discouraging drug manufacturers from overfilling single-dose containers.

Response: We thank the commenter for their support.

Comment: One commenter states that the discarded drug refund exacts financial penalties due to a drug's FDA-approved labeling and efficacy and safety profile, and administration of the product by healthcare providers, over which a manufacturer exerts no control.

Response: Section 1847A(h)(3) of the Act requires that the refund calculation use the total number of units of the billing and payment code of such drug, if any, that were discarded for a given calendar quarter for which a refund is due, as determined using a mechanism such as the JW modifier. CMS is implementing the law.

Comment: One commenter noted that for biosimilar biological products (hereafter, biosimilars), introducing new vial sizes would not be feasible, because manufacturers of biosimilars must offer the same vial sizes as the reference product.

Response: To date, we have not observed any biosimilars that have discarded amounts exceeding 10 percent. However, we will continue to monitor discarded drug data for biosimilars. We also note that section 90004 of the Infrastructure Investment and Jobs Act requires the Office of Inspector General (OIG), after consultation with CMS and FDA, to submit a report to Congress on any reported impact that section 90004 may have on the licensure, market entry, market retention, or marketing of biosimilars. The OIG is expected to issue a report to Congress in fiscal year (FY) 2024.[169]

Comment: One commenter expressed concern that the discarded drug refunds will impact provider reimbursement.

Response: Since Medicare pays for units of single-dose drugs that are administered to the patient as well as units that are discarded (and billed using the JW modifier), we do not expect the refund to affect reimbursement to providers.

j. Out of Scope Comments

Comment: We received comments on several topics that were outside the scope of the proposed rule. Those topics included the following: the contents of the preliminary report (87 FR 69725) and the annual refund report described in § 414.940(a)(1) and manufacturers' ability to use them to identify potential calculation errors; a request that the window for submitting an error report be extended to 60 days; several requests for the establishment of an appeals process including for calculated refund amounts and for unique circumstance applications; support for our reaffirmation of the exclusion of radiopharmaceuticals and imaging agents from the definition of refundable drugs; requests that all non-refundable drugs or just radiopharmaceuticals and imaging agents be excluded from the JW and JZ modifier reporting policy; a request that we clarify that all non-refundable drugs single-dose container drugs be reported with the JZ modifier; a request for clarification on correct JZ modifier use when drugs from a single dose vial are used for multiple patients; a request that CMS develop a mechanism to automate the reporting of discard amounts in claims systems; a request that Medicare compensate provider and suppliers for the discarded

[165] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[166] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[167] *https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-12-35.pdf.*

[168] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[169] *https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000743.asp.*

amount reporting burden; support for the JW and JZ modifier edits; offers to collaborate with CMS on provider education for the JW and JZ modifier requirements; a statement of concern about complications for reporting JW and JZ modifier data in systems in which EHR recording for single-dose container drugs is automated; a request for a delay in the beginning of edits for correct JW and JZ modifier use; a request for additional provider education on the discarded drug refund policy; a request for a requirement that all skin substitute products report ASP data; a request that CMS affirm the 18-month exclusionary period for Leqembi begins on October 1, 2023; a request for drugs whose use is required by an unrelated manufacturer over which the product's manufacturer has no control and the establishment of new HCPCS codes for products based on alternative utilization methods to be considered to have unique circumstances; a request for newly approved drugs when the manufacturer is actively carrying out post-market optimization activities to be considered to have unique circumstances; two requests that we confirm that certain drugs meet the definition of the rarely utilized orphan drugs for which we proposed a unique circumstances; a request from several commenters that we extend through rulemaking the 18-month exclusion period for newly marketed drugs, as described in section 1847A(h)(8)(B)(iii) of the Act, to 36 months; a request from several commenters for cell and gene therapies and other personalized therapies to be considered to have a unique circumstance and have an increased applicable percentage, as well as a request that in considering future HCPCS applications for these therapies we consider the implications of any decision on its potential discarded drug refund obligations; and a request for drugs that treat multiple indications across unique patient types and characteristics to be considered to have unique circumstances.

Response: While these comments are out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. We note, as discussed in section III.B.2.b. of this final rule, effective January 1, 2024 RHC and FQHC practitioners can also be licensed marriage and family therapists or mental health counselors. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to new payment limits on the AIR, and this limit will be determined for each RHC in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket reduced by a productivity adjustment.

2. Implementation of the Consolidated Appropriations Act (CAA), 2023

a. Section 4113 of the Consolidated Appropriations Act, 2023

In the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. In addition, we revised the regulation

under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

We also revised the regulation under § 405.2469, FQHC supplemental payments, to state that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. At § 405.2469, we also revised paragraph (d) to describe the same in-person visit requirement referenced in § 405.2463.

As discussed in the CY 2023 PFS final rule (87 FR 69738), the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) included the extension of a number of Medicare telehealth flexibilities established during the public health emergency (PHE) for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE for COVID–19. Specifically, Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19. Therefore, in the CY 2023 PFS final rule (87 FR 69737), we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions.

As discussed in the CY 2024 PFS proposed rule (88 FR 52396 through 52397), the CAA, 2023 (Pub. L. 117–328, December 29, 2022) extends the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ends prior to that date. Specifically related to RHCs and FQHCs, section 4113(c) of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the period beginning on the first day after the end of the COVID–19 PHE and ending on December 31, 2024, if the PHE ends prior to that date. We noted that payment continued to be made under the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. We also noted that we did not believe it necessary to conform the regulation to this temporary provision. Rather, we used our authority in section 4113(h) of the CAA, 2023 to issue program instructions or other subregulatory guidance to effectuate this provision to ensure a smooth transition after the PHE.[170]

We explained that section 4113(d) of the CAA, 2023 continues to delay the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in-person visits will not be required until January 1, 2025 or, if later, the first day after the end of the PHE for COVID–19. Therefore, we stated that we will continue to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs. We noted, the Department of Health and Human Services declared an end to the Federal PHE for COVID–19 under section 319 of the Public Health Service Act on May 11, 2023.[171]

Accordingly, we proposed to make conforming regulatory text changes based on CAA, 2023 to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we proposed to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we proposed to amend paragraph (d) to include the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025. We noted that we are not revising the regulation text to reflect ''or, if later, the first day after the end of the PHE for COVID–19'' as the legislation states since the end of the PHE was May 11, 2023.

We noted that in the CY 2023 PFS final rule (87 FR 69738), we listed the several other provisions of the CAA, 2022 that apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. For details on the other Medicare telehealth provisions in the CAA, 2022, see section II.D. of this final rule. We also noted that the CAA, 2023 extended the telehealth policies mentioned above and enacted in the CAA, 2022 through December 31, 2024.

We received many comments on the extension of telehealth flexibilities under section 4113 of CAA, 2023. The following is a summary of the public comments received and our responses:

Comment: Many commenters generally supported the extension of telehealth flexibilities for RHCs and FQHCs and the delay of the in-person requirements for mental health services, as required under section 4113 of CAA, 2023.

Response: We thank commenters for their support.

Comment: We received several comments requesting that the COVID–19 telehealth flexibilities be made permanent. Although one commenter acknowledged that CMS does not have the authority to make the changes related to payment of FQHCs and RHCs for telehealth services beyond December 31, 2024, several commenters requested that CMS work with Congress to ensure the telehealth flexibilities remain in place indefinitely. One commenter explained that this would include telehealth flexibilities related to continuing payment for telehealth services, removing the in-person visit requirements for mental health visits, expanding the originating site requirements to include any site in the U.S. the beneficiary is located (for example, the individual's home) and extending coverage and payment of telehealth services that are furnished via audio-only communications. Commenters explained that they believe if FQHCs and RHCs are no longer able to furnish telehealth services to patients after December 31, 2024, this will limit access to care and may negatively impact patient health.

[170] *https://www.cms.gov/files/document/rural-health-clinics-and-federally-qualified-health-centers-cms-flexibilities-fight-covid-19.pdf.*

[171] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

Response: We thank commenters for their input. The CAA, 2023 does not extend these policies beyond December 31, 2024. We do not have the authority to make these flexibilities permanent.

Comment: We received comments from the RHC and FQHC community requesting CMS revise the definition of a medical visit so that these services can be furnished via telecommunication technologies similar to what CMS finalized in the CY 2022 PFS final rule (86 FR 65208 through 65211) for mental health visits furnished via telecommunication technologies. A few commenters urged CMS to revise the ''medical visit'' definition before January 1, 2025, stating that they believe that this action would avoid significant gaps in care for some of the most vulnerable Medicare patients. The commenter suggested that CMS consider these consequences if Medicare patients cannot receive virtual medical services due to a lapse in coverage and payment. The same commenters stated that they believe CMS has the authority to revise § 405.2463(b)(1) to define a medical visit as a face-to-face encounter or encounter where services are furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of or do not consent to, the use of devices that permit a two-way audio/video interaction for the purposes of diagnosis, evaluation or treatment of services under § 405.2463(b)(2). Commenters further stated that if CMS were to revise the definition of a ''medical visit'' so that these services can be furnished via telecommunication technologies, CMS should also amend cost reporting instructions to ensure the costs associated with these services are included as ''FQHC services'' on the cost report.

Response: Since we did not make any proposals in this rulemaking related to revising the regulatory definition of a ''medical visit'' to permit these services be furnished via telecommunication technologies, these comments are out of scope. However, we anticipate that the extension of payment for distant site telehealth services furnished by RHCs and FQHCs through December 31, 2024, as established in the CAA, 2023, would mitigate concerns regarding gaps in care since it could provide time for patients transitioning from virtual to in-person services to come into the RHC or FQHC.

Comment: A commenter stated that given the extension of current RHC medical telehealth policy through December 31, 2024, and they requested that CMS permit normal coding instead of billing G2025 for all allowable Medicare telehealth services. The commenter believes that the payment can be achieved through appending the modifier code (95) to these services which could better facilitate data collection of RHC services performed via telehealth, including proper counting of Annual Wellness Visits and other preventive services.

Response: We thank the commenter for bringing this to our attention. We agree that transparency in the services furnished can improve data collection and inform payment policies and can explore options that may provide RHCs and FQHCs the ability to report the HCPCS code that describes the service furnished instead reporting G2025. If we were to implement such changes in the claims processing systems, we do not believe that it would change the payment policy, that is, overall payment would be the same. Therefore, changes in the way RHCs and FQHCs would report these services and how CMS pays would be effectuated through sub-regulatory guidance.

Comment: A commenter requested guidance from CMS to clarify for the RHC community if distant site telehealth services may be provided outside of the RHC's hours of operations. The commenter stated that RHCs should not be limited to only offering telehealth during the physical RHC's hours of operation. The commenter further explained that they believe this policy limits access to care for safety-net patients.

Response: Currently, RHCs and FQHCs are required to furnish services during their hours of operation and if services are furnished at times other than the RHC's or FQHC's posted hours of operation, they may not be billed to Medicare Part B if the practitioner's compensation for these services is included in the RHC/FQHC cost report. This policy is discussed in Pub. 100–02 Medicare Benefit Policy Manual, Chapter 13, section 40.2 ''Hours of Operation.'' [172] We appreciate the commenter bringing this concern to our attention and we can consider for future rulemaking.

Comment: One commenter encouraged CMS to not impose requirements for in-person services beyond what is statutorily required. The commenter stated that for patients seeking mental health treatment, the issues which prevent them from accessing care existed prior to the pandemic and will continue to exist beyond its duration. The commenter further stated that it is important to ensure the provisions intended to maintain program integrity do not inhibit patient access to care. The commenter also stated that providers can utilize their clinical judgment to assess if a patient requires an in-person visit.

Response: We appreciate the feedback from commenters regarding how requirements for in-person service when mental health visits are furnished by RHCs and FQHCs through telecommunication technology may have on access to care. In the CY 2022 PFS final rule (86 FR 65210) we finalized a policy that an RHC or FQHC patient must have an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that in general, there must be an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders. We stated that this is consistent with policies finalized for mental health services furnished via telehealth under the PFS, and that the in-person service requirements apply only to telehealth services furnished to a patient receiving the service at home.

Regarding concerns that the in-person requirements would pose a challenge for some beneficiaries, we would like to direct you to § 405.2463(b)(3) that describes the exceptions to the in-person visit requirements. That is, if the patient and practitioner consider the risks and burdens of an in-person service and agree that, on balance, these outweigh the benefits, and the practitioner documents the basis for that decision in the patient's medical record, then the in-person visit requirement is not applicable for that 12-month period. Situations in which the risks and burdens associated with an in-person service may outweigh the benefit could include, but are not limited to, instances when an in-person service is likely to cause disruption in service delivery or has the potential to worsen the patient's condition(s) (86 FR 65211).

After consideration of public comments, we are finalizing our proposal to make conforming regulatory text changes based on CAA, 2023 to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we are finalizing revisions to paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we are finalizing revisions

[172] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf.*

to paragraph (d) to include the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025, as proposed.

b. Direct Supervision via Use of Two-way Audio/Video Communications Technology

In the CY 2024 PFS proposed rule (88 FR 52397), we discussed direct supervision. Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. See section II.D.2.a. for the discussion regarding direct supervision for services under the PFS. For RHCs and FQHCs, services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care management services which may be furnished under general supervision (§ 405.2415(a)(5)). The ''incident to'' policy for RHCs and FQHCs is discussed in Pub. 100–02, chapter 13, section 120.1. Similar to physician services paid under the PFS, outside the circumstances of the PHE, direct supervision of RHC and FQHC services does not require the physician to be present in the same room. However, the physician must be in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished to a beneficiary.

In the CY 2024 PFS proposed rule, we explained that during the COVID–19 PHE, the modifications that we made to the regulatory definition of direct supervision for services paid under the PFS were also applicable to RHCs and FQHCs. We explained in the April 6, 2020 IFC that given the circumstances of the PHE for the COVID–19 pandemic, we recognized that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. We believed that the same concerns existed for RHCs and FQHCs. In the April 6, 2020 IFC, we allowed the supervising professional to be immediately available through virtual presence using two-way, real time audio-visual technology, instead of requiring their physical presence (85 FR 19245 and 19246).[173] When discussing direct supervision in RHCs and FQHCs, we noted that in general, we have modified the requirements for direct supervision to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.[174]

We also explained that we believed that extending this definition of direct supervision for RHCs and FQHCs through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023 and we were concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2023, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believed that RHCs and FQHCs will need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. For RHCs and FQHCs, we proposed to continue to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024.

In the absence of evidence that patient safety is compromised by virtual direct supervision, we stated that we believe that an immediate reversion to the pre-PHE definition of direct supervision may present a barrier to access services, such as those furnished incident-to a physician's service. Therefore, we solicited comments on whether we should consider extending the definition of ''direct supervision'' to permit virtual presence beyond December 31, 2024. We explained that when compared to professionals paid under the PFS, RHCs and FQHCs have a different model of care and payment structure. Therefore, we solicited comments from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Commenters noted that they believe direct supervision has become increasingly challenging and the option to provide virtual direct supervision has enhanced the quality and provision of healthcare services beneficiaries have received in medically underserved, rural communities. They also noted using audio-visual technology for supervision during the COVID–19 PHE did not create significant clinical safety concerns and subsequent formal assessments will confirm the safety of virtual direct supervision. As workforce challenges exist and are pronounced in some of their rural communities, commenters believe this allows RHCs and FQHCs to have a larger community presence, including longer hours or more days, and stated that they may not be able to maintain these schedules if a physical presence for direct supervision is required. Commenters stated that virtual direct supervision facilitates timely access to services that on-site personnel could effectively deliver.

Response: We appreciate the commenters' support of extending the definition of direct supervision to permit virtual presence in RHCs and FQHCs though December 31, 2024. With regard to extending this flexibility past December 31, 2024, we may address in future rulemaking. We also appreciate the positive feedback received from commenters regarding any potential patient safety, quality, or program integrity concerns when direct supervision occurs virtually in RHCs and FQHCs.

After consideration of public comments, we are finalizing our proposal to extend the definition of direct supervision to permit virtual presence in RHCs and FQHCs through December 31, 2024.

c. Section 4121 of the CAA, 2023

Section 1861(aa) of the Act provides authority under Medicare Part B to cover and pay for RHC and FQHC services. Section 1861(aa)(1) of the Act defines these services as those furnished by physicians, physician assistants, nurse practitioners, nurse-midwives, qualified clinical psychologists, clinical social workers, and services and supplies furnished incident to

[173] *https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf.*

[174] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

professional services of these practitioners. The conforming regulation text to these provisions are provided in 42 CFR part 405, subpart X where we define RHC and FQHC visits as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished.

Before passage of CAA, 2023, there was no separate benefit category under the statute that recognized the professional services of licensed marriage and family therapists (MFTs) or mental health counselors (MHCs). As discussed in the CY 2023 PFS final rule (87 FR 69546), payment for MFTs was only made under the PFS indirectly when an MFT or MHC performed services as auxiliary personnel incident to the services of a physician or other practitioner and under general supervision. This was also true for RHCs and FQHCs, in that MFTs and MHCs were considered auxiliary personnel and the services they provided were considered incident to the services of the RHC or FQHC practitioner (§ 405.2413).

Section 4121 of Division FF, Title IV, Subtitle C of the CAA, 2023, entitled ''Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program'', amended section 1861(s)(2) of the Act to establish coverage of MFT and MHC services (section 1861(s)(2)(II) of the Act). We noted that section II.J. of this final rule provides a detailed discussion of the provisions in section 4121(a) of CAA, 2023 including the authority for coverage of MFT and MHC services, definitions of these professionals and their services, and payment under the PFS. Section 4121(b) of CAA, 2023 amended section 1861(aa)(1)(B) of the Act by extending the scope of RHC services to include those furnished by MFTs and MHCs as eligible for payment, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. We proposed to codify payment provisions for MFTs and MHCs under 42 CFR part 405, subpart X beginning January 1, 2024. That is, RHC and FQHCs will be paid under the RHC AIR and FQHC prospective payment system (PPS), respectively, when MFTs and MHCs furnished RHC and FQHC services defined in §§ 405.2411 and 405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs will follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

In addition, as discussed in section II.J. of this final rule, we proposed to allow addiction counselors that meet all of the applicable requirements to enroll in Medicare as MHCs. Therefore, to remain consistent with payment policies for professionals billing Medicare under the PFS, we proposed that the definitions established for MFTs and MHCs under the PFS would also apply for RHCs and FQHCs. In the CY 2023 PFS final rule (87 FR 69735 through 69737), we discussed the coding and payment for HCPCS code G0323 which describes general BHI services performed by CPs and CSWs under the PFS. We noted CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs under sections 1861(aa)(1) and (3) of the Act, respectively, and as described by § 405.2411(a)(6). We also explained, the payment rate for HCPCS code G0323 is based on the payment rate for the current general BHI code, 99484. Therefore, in the CY 2023 PFS final rule (87 FR 69737) we clarified that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. We further stated RHCs and FQHCs that furnish general BHI services are able to bill for this service using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023.

We noted that in section II.J. of this final rule, we proposed to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. Since MFTs and MHCs are statutorily authorized to furnish services in RHCs and FQHCs effective January 1, 2024, we proposed to clarify that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill for this service using HCPCS code G0511. We believe that this policy aligns with our efforts to be consistent with new services that are proposed for practitioners billing under the PFS.

We proposed to make several conforming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically:

- At § 405.2401, Scope and definitions, we proposed to amend the section to add definitions for MFT and MHC;
- At § 405.2411, Scope of benefits, we proposed to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2415, Incident to services and direct supervision, we proposed to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2446, Scope of services, we proposed to amend the section to include MFT and MHC services to the scope of services;
- At § 405.2448, Preventive primary services, we proposed to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2450, Clinical psychologist and clinical social worker services, we proposed to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2452, Services and supplies incident to clinical psychologist and clinical social worker services, we proposed to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2463, What constitutes a visit, we proposed to amend the section to add MFT and MHC to the list of eligible practitioners; and
- At § 405.2468, Allowable costs, we proposed to amend the section to add MFTs and MHCs where other RHC and FQHC practitioners are listed.

We received many comments on section 4121 of the CAA, 2023. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters supported the proposals related to MFTs and MHCs. Commenters stated that health centers commonly employ LMHCs and LMFTs to expand their behavioral health services and that the proposed regulatory changes will enable health centers to maximize their workforce to meet their patients' needs. Another commenter suggested that CMS use the definition of MHC that would include all appropriately trained and qualified health professionals currently licensed by States or recognized by the National Health Services Corps (NHSC).

Response: We thank the commenters for their support. Regarding licensure, we note that while section 1861(lll)(4) of the Act establishes the term ''Mental Health Counselor,'' this statutory benefit category also includes those who are licensed or certified as a clinical professional counselor or, as a professional counselor by the State in which the services are furnished to qualify as a mental health counselor along with the individuals who are licensed or certified by the State as a mental health counselor. Additionally, we proposed and are finalizing our provisons to allow addiction counselors who meet all applicable requirements to enroll as MHCs. In response to the

comments received on the variation in nomenclature used across States for mental health counselors, we clarify that mental health practitioners who meet all of the applicable statutory qualifications for the mental health counselor benefit category but are licensed by their State under a different title, are eligible to enroll in Medicare under the Part B ''Mental Health Counselor'' statutory benefit category. We refer to the discussion in section II.J of this final rule for more information.

Comment: One commenter requested that CMS confirm that MFTs and MHCs will not be subjected to a productivity standard as is required for physicians, NPs, PAs, and CNMs in the RHC setting.

Response: We thank the commenter for raising this issue. As described in the Medicare Benefit Policy Manual, Chapter 13, Section 80.4, ''RHC Productivity Standards'', ''productivity standards are used to help determine the average cost per patient for Medicare reimbursement in RHCs. The current productivity standards require 4,200 visits per full-time equivalent physician and 2,100 visits per full-time equivalent non-physician practitioner (NP, PA, or CNM)''. Additionally, in the Form CMS 222–17, Worksheet B, Part I of the Independent RHC Cost Report, and Form CMS–2552–10, Hospital and Hospital Care Complex Cost Report, Worksheet M–3, productivity standard information is entered for physician, PA, NP, and CNM. Productivity standards are not in place for RN, LPN, CP, or CSWs. As discussed in this rule, MFTs and MHCs are mental health practitioners and more closely aligned with CPs and CSWs and as such we believe that the productivity standards also do not apply to MFTs and MHCs.

Comment: Some commenters requested that CMS consider the inclusion of Certified Community Behavioral Health Centers (CCBHCs) in the Medicare program, which they stated would offer incredible value to beneficiaries. While CCBHCs are not a specific provider type in Medicare, CCBHCs are required to establish care coordination with entities such as with FQHCs and RHCs. Given this pre-existing relationship, the overlap for MFT and MHC services that could be furnished in either location, and because behavioral health services are optional at FQHCs, advancing a relationship and partnership through these entities in the Medicare program could be a point for CMS' further exploration as efforts to improve behavioral health care for beneficiaries' advance.

Response: New provider types must be authorized by statute; CMS does not have the authority to create new provider types. We did not propose adding CCBHCs as a provider type for Medicare, and therefore, this comment is out of scope.

Comment: Some commenters recommended CMS consider broadening the FQHC mental health visit by adding health and behavior assessment and intervention services (HBAI) codes to the Medicare FQHC mental health visit.

Response: Currently, HBAI services are covered services and can be furnished in an FQHC, but they do not qualify as stand-alone billable visits in a FQHC. That is, if an HBAI service is furnished during a FQHC qualifying visit, the service(s) are included in the visit. Since we did not make any proposals related to updates to the FQHC qualifying visit list and we note that there are recent coding changes for HBAI services, we wish to consider this topic further.

After consideration of public comments, we are finalizing our proposal as proposed to codify payment provisions for MFTs and MHCs under 42 CFR part 405, subpart X beginning January 1, 2024. That is, RHC and FQHCs will be paid under the RHC AIR and FQHC PPS, respectively, when MFTs and MHCs furnish RHC and FQHC services defined in §§ 405.2411 and 405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs should follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

In addition, we are finalizing as proposed a provision to allow addiction counselors that meet all of the applicable requirements of clinical supervised experience in mental health counseling, and that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the State in which the services are furnished) to enroll in Medicare as MHCs. In remaining consistent with payment policies for professionals billing Medicare under the PFS, we are also finalizing as proposed a provision applying the definitions established for MFTs and MHCs under the PFS to RHCs and FQHCs. Since MFTs and MHCs are statutorily authorized to furnish services in RHCs and FQHCs effective January 1, 2024, we are finalizing as proposed the clarification that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. Finally, we are finalizing as proposed several conforming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, §§ 405.2401, 405.2411, 405.2415, 405.2446, 405.2448, 405.2450, 405.2452, 405.2463, and 405.2468.

d. Section 4124 of the Consolidated Appropriations Act, 2023

Section 4124 of Division FF of the CAA, 2023 establishes coverage and payment under Medicare for the Intensive Outpatient Program (IOP) benefit, effective January 1, 2024. IOP may be furnished by hospitals, Community Mental Health Centers (CMHCs), FQHCs and RHCs. Payment for IOP services furnished by RHCs and FQHCs is to be made at the same payment rate as if it were furnished by a hospital.

In addition to existing mental health services furnished by RHCs and FQHCs, this new provision establishes coverage for IOP services furnished in RHCs and FQHCs and includes occupational therapy, family counseling, beneficiary education, diagnostic services and individual and group therapy.

Please see section VIII.F. of the CY 2024 Hospital Outpatient Prospective Payment System and the Ambulatory Surgical Center payment system final rule with comment for discussion of the new IOP scope of benefits, requirements, physician certification, and payment policies.

3. Updates to Supervision Requirements for Behavioral Health Services Furnished at RHCs and FQHCs

In the CY 2023 PFS final rule (87 FR 69545 through 69548), we amended the direct supervision requirement under the ''incident to'' regulations for services payable under the PFS to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. Several commenters expressed support for CMS allowing behavioral health services to be furnished under general supervision in the RHC and FQHC settings in addition to services paid under the PFS. In response to the public comments, we noted that for CY 2023, the proposed change to the level of supervision for ''incident to'' behavioral health services from direct to general was applicable only to services payable under the PFS, as services furnished in the RHC and FQHC settings were not addressed in the relevant proposal in the CY 2023 PFS proposed rule (87 FR 46062 through 46068). We stated we may consider changes to the regulations regarding services furnished at RHCs and FQHCs in the future.

Currently, behavioral health services furnished in the RHC and FQHC settings require direct supervision. However, in order to be more consistent with applicable policies under the PFS, for CY 2024, we proposed to change the required level of supervision for behavioral health services furnished ''incident to'' a physician or NPP's services at RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023. Accordingly, we proposed to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner). Additionally, as discussed in the CY 2023 PFS final rule (87 FR 69547), we noted that at § 410.26(a)(1) we define ''auxiliary personnel'' as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other Federally-funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

We received a few comments on our proposal to update the supervision requirements for behavioral health services furnished in RHCs and FQHCs. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of our proposal to change the required level of supervision for behavioral health services furnished in RHCs and FQHCs ''incident to'' a physician or NPP's services to general supervision rather than direct supervision. Commenters stated that these revisions are necessary to ensure FQHCs can bill ''incident to'' services furnished by auxiliary personnel on the cost report and that the provision will help better meet the health needs of vulnerable patient populations.

Response: We appreciate the commenters' support of our proposal.

After consideration of public comments, we are finalizing our proposal to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner), as proposed.

4. General Care Management Services in RHCs and FQHCs

a. Background

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to independently recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

As we discussed in the CY 2016 PFS final rule (80 FR 71081 through 71088), to address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for CCM services when CCM service requirements are met. We explained that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Although many RHCs and FQHCs pay for coordination of services within their own facilities and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are generally not included in the RHC or FQHC payment. Therefore, separate payment was established in the CY 2016 PFS final rule (80 FR 71080 through 71088) for RHCs and FQHCs that furnish CCM services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule (82 FR 53169 and 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018. We also initiated the use of HCPCS code G0511, a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. In the CY 2019 PFS final rule (83 FR 59683), we explained for CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised HCPCS code G0511 were CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*).

We also explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487 (83 FR 56983). Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that the requirements described by the codes for Principal Care Management (PCM) services were similar to the requirements for the services described by HCPCS code G0511; therefore, we added HCPCS codes G2064 and G2065 to HCPCS code G0511 as general care management services for RHCs and FQHCs. Consequently, effective January

1, 2021, RHCs and FQHCs are paid when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. The payment rate for HCPCS code G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS codes G2064 and G2065). We noted that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the payment rate for HCPCS code G0511 was the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, 99491, 99424, and 99425).

Most recently, in the CY 2023 PFS final rule (87 FR 69735 through 69737), we included Chronic Pain Management (CPM) services described by HCPCS code G3002 in the general care management HCPCS code G0511 when at least 30 minutes of qualifying non-face-to-face CPM services are furnished during a calendar month. We explained since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there was no change made to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services.

Additional information on care management requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html* and on the CMS RHC and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*.

b. Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) Services Furnished in RHCs and FQHCs

In recent years under the PFS, we have finalized payment for five CPT codes in the RPM code family. RPM services include the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan (84 FR 62697). Within the suite of services that comprise RPM, there is a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data.

After analyzing and interpreting a patient's remotely collected physiologic data, we noted that the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or other practitioner develops a treatment plan with the patient and/or caregiver (that is, develops a patient-centered plan of care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care.

TABLE 23: RPM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
99453	Rem mntr physiol param setup	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial set-up and patient education on use of equipment
99454	Rem mntr physiol param dev	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99457	Rem physiol mntr 1st 20 min	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Rem physiol mntr ea addl 20	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)
99091	Collj & interpj data ea 30 d	Collection and interpretation of physiologic data (e.g. Blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days

Remote Therapeutic Monitoring (RTM) is a family of five codes finalized for Medicare payment in the CY 2022 PFS final rule (86 FR 65114 through 65117). RTM services involve remote monitoring of respiratory system status, musculoskeletal status, therapy adherence, or therapy response. There is also a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data within the suite of services that comprise RTM.

TABLE 24: RTM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
98975	Rem ther mntr 1st setup&edu	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Rem ther mntr dev sply resp	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Rem ther mntr dv sply mscskl	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98980	Rem ther mntr 1st 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Rem ther mntr ea addl 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (list separately in addition to code for primary procedure)

As discussed in the CY 2024 PFS proposed rule (88 FR 52401), RPM and RTM services are not stand-alone billable visits in RHCs and FQHCs. When these services are furnished incident to an RHC or FQHC visit, payment is included in the RHC's AIR subject to a payment-limit or the per visit payment under the FQHC PPS which is the lesser of the PPS rate or the FQHC's actual charges.

In recent years, we have updated RHC and FQHC policies to improve payment for care management and coordination. We have provided a separate payment to RHCs and FQHCs in addition to the billable visit in part for monthly care management and behavioral health integration codes, as described in the general care management code, HCPCS code G0511, because these are inherently non-face-to-face services that may not be accounted for in the per-visit payment for an in-person encounter.

RHCs and FQHCs have inquired about receiving a separate payment for RTM and RPM services. They have stated that CMS should expand HCPCS code G0511 to include RPM treatment management services to provide Medicare beneficiaries in rural and underserved areas access to these services or establish G-codes to reimburse RHCs and FQHCs for RPM set-up and patient education on use of equipment (CPT code 99453) and monthly data transmission (CPT code 99554) and do not believe that these services are captured in the RHC AIR or FQHC PPS and as such are impeding access to these services.

Therefore, upon further review and in line with our thinking about non-face-to-face services previously, we proposed to include the CPT codes that are associated with the suite of services that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs since the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. We explained that allowing a separate payment for RPM and RTM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of these services.

We explained in the CY 2024 proposed rule, that the care coordination included in services, such as office visits, does not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. As RPM and RTM services are described, particularly, collection and transmission of data and then further analysis and interpretation of the data are happening outside of the face-to-face visit. RPM and RTM also have principles which are consistent with other care management principles, such as, an established patient-physician relationship is required, patient consent is required at the time that RPM services are furnished, and services allow the monitoring of acute conditions and chronic conditions. We noted that under the proposal, RPM and RTM services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. As such, we proposed that RHCs and FQHCs that furnish RPM and RTM services would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters expressed support for our proposal to allow RHCs and FQHCs to bill separately for RPM and RTM services. Commenters noted they believe allowing RHCs and FQHCs to bill RPM and RTM codes outside of the all-inclusive rate or prospective payment systems would prevent disparities in care. Commenters also noted the ability to bill separately for RPM and RTM services will empower RHCs and FQHCs to leverage remote monitoring technologies effectively, ensuring better patient outcomes and more efficient healthcare delivery, expanding access to innovative care models and improving patient engagement and self-management.

Response: We appreciate the commenters' support of allowing RHCs and FQHCs to bill separately for RPM and RTM services.

Comment: Some commenters stated that adding RPM and RTM services to the general care management code is not sustainable or equitable and would like CMS to create a separate code(s) for RPM and RTM services that can be billed outside of the RHC AIR or FQHC PPS. Commenters noted the proposed payment methodology for HCPCS code G0511 does not fully reflect the costs of providing RPM and RTM services in the RHC and FQHC settings and requested that CMS modify the reimbursement rate to match the national average payment rates for comparable RPM and RTM services under the PFS, which would better reflect the complexity of delivering RPM and RTM services.

Response: As we discuss in more detail later, in the CY 2024 proposed rule, we proposed a revised methodology for the calculation of HCPCS code G0511 by analyzing the actual utilization of the services using a weighted average of the services that comprise HCPCS code G0511. Regarding separate coding and a separate calculation of RPM and RTM services, we note that the non-facility rates of the codes describing RPM and RTM range from $43.04 to $133.18. As shown in Table 27, the utilization of the CPT codes with the higher reimbursement rates tend to be much lower than the CPT codes with the lower reimbursement rates. When we take into account the utilization of all the services that comprise HCPCS code G0511, the weighted average is $72.98. We believe RPM and RTM services fall squarely into the rate for G0511.

We believe allowing a separate payment for these services along with our revised methodology for calculating the rate for G0511 will provide adequate payment and support access to these services; however, we plan to continue to monitor and explore other options for future rulemaking to address any sustainability and efficiencies of these policies.

After consideration of public comments, we are finalizing as proposed to add the suite of services that comprise RPM and RTM services to the general care management code, G0511 beginning January 1, 2024 as the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs.

c. Services Addressing Health-Related Social Needs: Community Health Integration Services and Principal Illness Navigation Services

(1) Background

As discussed in the CY 2024 PFS proposed rule (88 FR 52401), in recent years, we have sought to recognize significant changes in health care practice and have been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS (see section II.E.4.(27) for the discussion regarding these services under the PFS). In congruence with services paid under the PFS, we have similarly provided separate payment for transitional care management services, chronic care management services, and behavioral health care management services to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations. In this effort to improve payment accuracy for care coordination in RHCs and FQHCs, in the CY 2024 PFS proposed rule we stated we are exploring ways to better identify the resources for helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with their ability to execute a medically necessary plan of care. RHCs and FQHCs sometimes obtain information about and help address, social determinants of health (SDOH) that significantly impact their ability to diagnose or treat a patient. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity. Additionally, RHCs and FQHCs sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, considering the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in the RHC AIR or under the FQHC PPS payment amount for visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe RHCs and FQHCs are performing them more often.

However, this work is not explicitly identified in current coding, and as such, we believe it is underutilized and undervalued. Accordingly, we proposed to create new coding to expressly identify and value these services for PFS payment and distinguish them from current care management services. Therefore, we considered the new coding for purposes of payment to RHCs and FQHCs.

(2) Payment for Community Heath Integration (CHI) Services in RHCs and FQHCs

As discussed in the CY 2024 PFS proposed rule (88 FR 52402), there were two new HCPCS codes proposed to describe CHI services performed by certified or trained auxiliary personnel, which may include a Community Health Worker (CHW), incident to the professional services and under the general supervision of the billing practitioner for services paid under the PFS. We stated that the requirements for the proposed CHI services are similar to the requirements for the general care management services furnished by RHCs and FQHCs. As such, we explained that we believe the level of care coordination resources required in addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit were not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with CHI as described in the proposed HCPCS code below, for example, coordination of care, facilitation of access to services, communication between settings.

GXXX1—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes,*

including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

• *Practitioner, Home-, and Community-Based Care Coordination*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).

• *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*

• *Health care access/health system navigation*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

• *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

• *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*

• *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

(3) Payment for Principal Illness Navigation (PIN) Services in RHCs and FQHCs

As discussed in the CY 2024 PFS proposed rule (88 FR 52403), there were two new HCPCS codes proposed to describe PIN services for services paid under the PFS. These services describe when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. We explained that the requirements for the proposed PIN services were also similar to the requirements for the general care management services furnished by RHCs and FQHCs.

As such, we explained that we believe the resources required to provide the level of care coordination needed for individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with PIN as described in the proposed HCPCS code below.

GXXX3—Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

• *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the practitioner's treatment plan.

• *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*

• *Practitioner, Home, and Community-Based Care Coordination*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

• *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*

• *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

• *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting*

patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

We explained that allowing a separate payment for CHI and PIN services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. Therefore, in an effort to have consistency with the new services that were being proposed for practitioners billing under the PFS, we proposed to include PIN services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs.

We noted that under the proposals to expand the billable services under HCPCS code G0511 to include CHI and PIN, each of these services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. We expected that our proposal to add the new codes for CHI and PIN to the general care management code would also support the CMS pillars [175] for equity, inclusion, and access to care for the Medicare population, and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to allow RHCs and FQHCs to bill separately for CHI and PIN services. Commenters noted this will allow auxiliary personnel like CHWs to furnish key SDOH interventions after an evaluation/management visit and allow RHCs and FQHCs to bill for specific care services to patients with high-risk conditions.

Response: We appreciate the commenters' support of allowing RHCs and FQHCs to bill separately for CHI and PIN services.

Comment: Commenters recommended that CMS consider a standalone HCPCS code for CHI and PIN services in RHCs and FQHCs because of the potential for increased claim denials for duplicate billing when numerous care management services are included in HCPCS code G0511 that would potentially require RHCs and FQHCs to bill for more than one care management service on the same day for the same beneficiary or duplicate claims denied when multiple care management services are filed on successive days for the same beneficiary.

Response: We appreciate the commenter's concerns regarding the ability of RHCs and FQHCs to bill for more than one care management service per month for the same beneficiary. As we stated in the CY 2024 PFS proposed rule (88 FR 52403), each of the services included in the general care management code must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. That is, an RHC or FQHC may bill HCPCS code G0511 multiple times in a calendar month as long as all requirements are met and there is not double counting. For example, RHCs and FQHCs can bill HCPCS code G0511 twice for 20 minutes of qualifying CCM services and 30 minutes of qualifying PCM services, as long as, the clinical staff minutes do not overlap. Regarding separate coding, we believe allowing a separate payment for these services along with our revised methodology for calculating the rate for HCPCS code G0511 will provide adequate payment and support access to these services; however, we plan to continue to monitor and explore other options for future rulemaking to address any sustainability and efficiencies of these policies.

Comment: Some commenters stated there should be a provision for RHCs and FQHCs to receive additional compensation based on actual time spent because CHWs are compensated based on time and not encounters.

Response: RHCs and FQHCs are paid a per visit amount. We believe the commenters concern is being addressed in the revised methodology of the calculation for the RHC and FQHC general care management HCPCS code G0511 which takes into account the additional time spent in care coordination by incorporating all of the applicable add-on codes for these services.

After consideration of public comments and in an effort to be consistent with the new services finalized in section II.E.4. of this final rule for practitioners billing under the PFS, we are finalizing as proposed to include CHI and PIN services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. We are also clarifying that RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements for each service are met. Finally, we note that the placeholder HCPCS codes GXXX1 through GXXX4 that describe CHI and PIN services are replaced with HCPCS codes G0019, G0022, G0023, and G0024 respectively.

In section II.E.4. of this final rule, we discuss the proposals and final policies under the PFS for the SDoH Risk Assessment. In section III.S. of this final rule, we discuss proposals and final policies for a SDOH Risk Assessment as an optional, additional element of the AWV. We received comments from interested parties on how the SDoH Risk Assessment will be paid in the RHC and FQHC settings.

Comment: Commenters supported CMS' proposal to reimburse for an SDOH Risk Assessment as part of the Annual Wellness Visit (AWV). Many commenters requested clarification on the payment mechanics for the SDOH Risk Assessment as an additional element of the AWV in relation to the FQHC and RHC bundled payment mechanisms. Commenters also requested that we revise § 405.2463(c)(1)(iii) and add the AWV along with the initial preventive physical exam as an exception to the FQHC and RHC single visit payment when a separate medical or mental health visit is made by the patient on the same day. Another commenter also supported CMS' proposal to reimburse for the SDOH through the creation of a standalone G code under the PFS, but urged CMS to clarify language to ensure FQHCs can benefit from this proposal.

Response: FQHCs and RHCs are currently eligible to furnish the AWV and as such, they will also be eligible to furnish a SDOH Risk Assessment as an additional element of the AWV. As stated in section III.S of this final rule, Medicare will pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (beneficiary cost sharing would not be applicable) when this risk assessment is furnished to a Medicare beneficiary as an optional element within an AWV (as part of the same visit with the same date of service

[175] CMS Strategic Plan. *https://www.cms.gov/cms-strategic-plan.*

as the AWV). This is analogous to the current approach to the ACP service, which is an optional service for which beneficiary cost sharing is not applicable when furnished as part of the same visit and on the same date of service as the AWV. Beneficiary cost sharing is not applicable to the AWV and, because the SDOH Risk Assessment will be an optional element within the AWV, there will not be any beneficiary cost sharing for the SDOH Risk Assessment either when furnished as part of the same visit and on the same date of service as the AWV. When ACP is furnished as an element of the annual wellness visit (AWV) in an RHC or FQHC, only one visit is paid. Maintaining consistency, therefore, when SDOH is furnished as an optional element of the AWV, only one visit is paid, that is, it will be paid under the AIR or the lesser of charges or the PPS rate with the AWV adjustment.

Consequently, when the SDOH Risk Assessment is furnished with a billable visit (other than an AWV) on the same day in an RHC, only the visit will be paid under the AIR and coinsurance and deductible will be applied. For FQHCs, the SDOH Risk Assessment is not considered a qualifying visit. When the assessment is furnished in conjunction with a qualifying visit (other than an AWV) on the same day in a FQHC, only the visit will be paid under the FQHC PPS and coinsurance will be applicable. Additional information on RHC and FQHC billing of the SDoH Risk Assessment will be available in subregulatory guidance.

Regarding the public comments that recommend that § 405.2463(c)(1)(iii) be revised to add the AWV along with the initial preventive physical exam as an exception to the FQHC and RHC single visit payment when the patient has a separate medical or mental health visit on the same day is out of scope for this rule, this recommendation has been informative and we will take it into consideration for possible future rulemaking.

d. Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511

Currently, HCPCS code G0511 is based on the PFS national average non-facility payment rate for each of the services identified as billable general care management services. We then add each payment rate and divide by the total number of codes to arrive at the payment amount for HCPCS code G0511. This payment amount is a flat rate that is not subsequently adjusted for locality. As we noted in the CY 2023 PFS final rule (87 FR 69735), when determining which services are billable under HCPCS code G0511, we do not include the add-on HCPCS codes payable under the PFS because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners. Instead, we generally include the base codes.

In the CY 2023 PFS final rule (87 FR 69736), we mentioned that we may consider other approaches for calculating the payment rate for HCPCS code G0511 as the number of services included in the general care management code is growing each year and provided examples. We thought to consider in the future valuing HCPCS code G0511 using a weighted average of the services that comprise HCPCS code G0511 or using the national average of the top three services comprising HCPCS code G0511. We welcomed comments on potential methodologies, but noted we did not receive any comments.

As we discussed in the CY 2024 PFS proposed rule (88 FR 52403 through 52406), we have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to separately recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. Through the last few payment rules, we have expanded the general care management services billable using the HCPCS code G0511 to be consistent with the policies implemented under the PFS.

In the CY 2024 PFS proposed rule, we noted our proposal to expand the billable services under HCPCS code G0511 to include RPM, RTM, CHI, and PIN. We explained that if we continue to calculate HCPCS code G0511 using our current approach, we believed that the value may no longer be appropriate payment for those services since we are simply dividing by the number of codes that comprise HCPCS code G0511 and as that number of services with lower payment rates increases, the value diminishes. Therefore, we proposed to revise our method for calculating HCPCS code G0511 so that payment for general care management is more appropriate. We provided a comparison of our current method to the proposed revised approach in the proposed rule and below for ease of reference.

Based on the current methodology for HCPCS code G0511 as shown in Table 25, general care management services are paid at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, 99491, 99424 and 99426.

TABLE 25: CY 2023 National Non-Facility PFS Payment Rate for G0511

CPT Code	National Non-Facility PFS Payment Rate
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$77.94[1]**

[1] Noting when averaging the six codes, the total RVU for HCPCS code G0511 is 2.295. Multiplying that by the conversion factor of 33.8872 results in $77.77. However, RVUs on the PFS file are expressed in two decimal places. Thus, we round the 2.295 average to 2.30 which yields 2.30 * 33.8872, resulting in $77.94, the current payment rate for HCPCS code G0511.

As shown in Table 26, when we include RPM and RTM services in the national non-facility average as discussed above, the payment rate for HCPCS code G0511 is reduced to $64.13 based on the national non-facility PFS payment rates for CY 2023.

TABLE 26: CY 2023 National Non-Facility PFS Payment Rate for G0511 with RPM and RTM Base Codes

CPT Code	National Non-Facility PFS Payment Rate
99454	$50.15
99457	$48.80
99091	$54.22
98976	$50.15
98977	$50.15
98980	$49.48
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$64.13***

*Noting when averaging the 12 codes, the total RVU for HCPCS code G0511 is 2.30. Multiplying that by the conversion factor of 33.8872 results in $64.13.

As demonstrated by comparing Table 25 to Table 26, using the current method of calculating the average of the non-facility rates but adding in RPM and RTM services base codes would result in a lower payment amount for HCPCS code G0511 compared to the current payment amount. We noted our belief that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, we considered and proposed a revised methodology for the calculation by looking at the actual utilization of the services. That is, we proposed to use a weighted average of the services that comprise HCPCS code G0511. In order to use a weighted average, there needed to be data on the utilization of the services. We stated we did not have data on utilization of the services that comprise HCPCS code G0511 for RHCs and FQHCs since HCPCS code G0511 accounts for a variety of services. Therefore, we would use the most recently available utilization data from the services paid under the PFS, that is, in the physician office setting. We explained that we believed that the physician office setting provides an appropriate proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services furnished in RHCs and FQHCs since they typically furnish primary care.

In order to analyze utilization for services paid under the PFS and to ensure we accounted for payments accurately, we used CY 2021 claims data to look at utilization of the base code for the service and any applicable add-on codes used in the same month as well as any base codes reported alone in a month for all of the services encompassing general care management (that is, the array of services that made up HCPCS code G0511). We believed we needed to account for the payment associated with the base code along with an applicable add-on code in our calculation as this demonstrates a complete encounter. Until actual utilization becomes available, RHCs and FQHCs that furnish CPM, GBHI, CHI and PIN services would report HCPCS code G0511 when those services are furnished; however, they would not be included in the weighted average at this time. We stated that once more data is available, we will revisit the valuation of HCPCS code G0511 to include CPM, GBHI, CHI, and PIN as necessary.

Table 27 shows the payment amount using the proposed calculation. We explained in the proposed rule that the national non-facility payment rate associated with each code that comprises HCPCS code G0511 could be found in Addendum B of the proposed rule. We noted that the revised methodology reduces the payment rate for HCPCS code G0511 from its current rate for CY 2023, although not significantly.

TABLE 27: Weighted Average Payment Rate for G0511 with RPM, RTM, CHI, and PIN Services Using CY 2023 Rates and Conversion Factor

CPT Code	2021 NF Utilization	Weighted Average
99454	931,411	46,710,262
99457	492,286	24,023,557
99457+99458	398,209	35,221,586
99474	1,581	24,110
99091	55,435	3,005,686
98976	93,141	4,671,028
98977	93,141	4,671,028
98980	14,112	698,243
98980+98981	119,463	10,647,711
99424	13,719	1,115,766
99424+99425	4,573	638,482
99426	28,858	1,770,134
99426+99427	9,619	1,046,382
99484	151,808	6,533,816
99487	26,441	3,521,412
99487+99489	229,004	46,641,245
99490	3,436,429	215,429,734
99490+99439	802,656	88,396,505
99491	29,665	2,523,322
99491+99437	118,661	17,210,562
G0511		**$72.98**

Therefore, we proposed to take the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. The number on the right side of Table 27 is a weighted average which grants more relative weight to the codes in proportion to their utilization in 2021 claims data. To calculate the weighted average, we multiple the non-facility payment rate times the non-facility utilization for each code, sum this total, then divide by the summed non-facility utilization for the codes included in the average. In an effort to be consistent with practitioners billing under the PFS and to account for the additional time spent in care coordination, we determined that this approach was a more accurate representation of the payment. We stated that we would update HCPCS code G0511 annually based on current data available in the PFS.

We proposed revisions at § 405.2464(c) to reflect the revised methodology for calculating the payment amount for general care management services beginning January 1, 2024 which would be based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data. We welcomed comments on this proposed methodology.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed methodology for calculating the payment amount for general care management services, as long as the utilization data was pulled from traditional fee-for-service for physician offices.

Response: We appreciate the commenters' support of the proposed revision methodology for calculating the payment amount for general care management services and confirm we will be utilizing the data from the PFS for updates.

Comment: A few commenters expressed concerns that, since the code can only be billed once per calendar month, the increased payment rate may not sufficiently account for the resources required to provide chronic care management, CHI and/or PIN, as well as remote monitoring when several of these services are provided in the same month. One commenter stated that they believed that CMS does not allow RHCs to bill more than one care management service per month for the same beneficiary. The commenter stated that fee-for-service providers are able to bill for all of these services for one beneficiary during the same month, yet RHCs can only provide one of these suites of services and bill G0511 once per month per beneficiary. Some commenters requested that CMS increase the payment rate for HCPCS code G0511 to account for these circumstances when a beneficiary receives multiple care management services in a month but they are only able to bill the code once per month.

Response: We appreciate the commenters' raising these concerns. As we clarified above, RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met and resource costs are not counted more than once. We will continue to review these services for consideration in future rulemaking.

Comment: One commenter suggested various approaches to billing for multiple iterations of HCPCS code G0511 during a calendar month. Suggestions included: using modifiers to identify the service; creating a more comprehensive set of HCPCS codes separated by service type or by time; or allowing RHCs and FQHCs to bill the full suite of care management codes the same way traditional fee-for-service providers or hospital outpatient

departments bill for care management services.

Response: We appreciate the commenter's recommendations on how to operationalize and track HCPCS code G0511 when billed multiple times in a calendar month. We did not propose these options in the CY 2024 PFS proposed rule; however, we will take these options into consideration for future rulemaking.

Comment: Some commenters requested that CMS add the General Behavioral Health Integration (GBHI) code and the Chronic Pain Management (CPM) codes into the weighted average for the calculation of HCPCS code G0511.

Response: As we stated in the CY 2024 PFS proposed rule, until actual utilization becomes available, RHCs and FQHCs that furnish CPM, GBHI, CHI and PIN services would report HCPCS code G0511 when those services are furnished. Once more data is available, we will revisit the valuation of HCPCS code G0511 to include CPM, GBHI, CHI, and PIN as necessary.

After consideration of public comments, we are finalizing the proposal to revise our method for calculating HCPCS code G0511, as proposed. That is, on an annual basis we will obtain actual utilization of the services that comprise HCPCS code G0511 using the most recently available data for the services paid under the PFS. Next, we will take the utilization of the base code for the service and any applicable add-on codes used in the same month, as well as any base codes reported alone in a month, for use in calculating the weighted average. To calculate the weighted average, we multiple the non-facility payment rate times the non-facility utilization for each code, sum this total, then divide by the summed non-facility utilization for the codes included in the average. This results in the payment amount for HCPCS code G0511. We will continue to publicly post the updated payment rate for G0511 on the RHC and FQHC center web pages.

For CY 2024, and as we demonstrated in the proposed rule, we obtained actual utilization of the base code and add-on code pairs, in addition to the individual base codes for CCM, PCM, RPM, and RTM by using the CY 2021 PFS utilization to calculate the weighted average and determine the payment rate for HCPCS code G0511. We will post the final CY 2024 payment rate for the general care management HCPCS code G0511 on the RHC and FQHC center web pages.[176]

e. Chronic Care Management Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent

(1) Chronic Care Management Services

RHCs and FQHCs have been authorized to bill for Chronic Care Management (CCM) services since January 1, 2016. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies. In fact, in the CY 2017 PFS final rule (81 FR 80256–80257) to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we finalized revisions to the requirements for CCM services furnished by RHCs and FQHCs similar to revisions to the requirements for CCM services finalized under the PFS (81 FR 80243 through 80251). Information regarding CCM services is available on the CMS Care Management Site.[177]

In the CY 2022 PFS proposed rule (86 FR 39175), we solicited public comment on the standard practice used by practitioners to obtain beneficiary consent for CCM services. We stated that we have received questions from interested parties regarding the consent requirements for CCM services. We explained that these questions may have arisen because of the many flexibilities allowed in response to the PHE for COVID–19. In particular, during the PHE for COVID–19, we allowed interested parties to obtain beneficiary consent for certain services under general supervision (85 FR 19230, April 6, 2020). We noted that before the PHE for COVID–19, we required that beneficiary consent be obtained either by a primary care practitioner or a staff member or contract employee under the direct supervision of such primary care practitioner. We noted that this requirement was consistent with the conditions of payment for this service under the PFS. We stated that as we consider what policies implemented during the PHE for COVID–19 should remain in effect beyond the PHE, we were interested in understanding how billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and how different levels of supervision impact this activity. We welcomed public comment on the issue, specifically on what levels of supervision of employees or third party contractors are necessary to obtain beneficiary consent when furnishing CCM services and said that we will consider such comments in future rulemaking.

We received 52 comments regarding the standard practice used by practitioners to obtain beneficiary consent for CCM services from a variety of interested parties including but not limited to individuals, hospitals, physicians, RHCs, FQHCs, software companies, and care management companies.

Comment: All commenters supported obtaining consent for care management under general supervision. Many commenters requested that CMS make this supervision level permanent after the expiration of the COVID–19 PHE. They stated that their practice would be unable to maintain its current CCM program without the assistance of a third-party partner. CCM vendors have trained enrollment staff which are vital to obtaining proper consent from their patients. Their staff are able to educate and inform our patients regarding the CCM program as they have been specifically trained to explain the benefits of CCM. They explained that vendors have the capacity to call patients and receive calls when it is convenient for the patient. They expressed concern that they could not replicate these services using only their employed staff and that allowing a third party to obtain consent from their patients for CCM under general supervision is vital to their CCM program.

One commenter explained that CCM programs are a challenging and heavy lift for all providers, regardless of size and available resources, and the providers that offer CCM services to their patient populations do so because they recognize and value CCM's capacity to improve patient outcomes. The commenter stated that they have seen the administrative burdens of successful and compliant CCM programs fall hardest upon RHCs and FQHCs and noted if CMS were to establish general supervision as the guideline for beneficiary consent, this would ease those burdens. The commenter noted that CCM codes describing clinical staff activities are assigned general supervision and if CMS were to carve out beneficiary consent

[176] *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center and https://www.cms.gov/medicare/payment/prospective-payment-systems/federally-qualified-health-centers-fqhc-center.*

[177] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

from the rest of CCM and impose a heightened administrative burden by imposing direct supervisions, RHCs and FQHCs that service the most vulnerable and underserved patient populations, would encounter challenges that could have negative consequence for their existing CCM programs.

Several commenters stated that they believed an efficient Medicare system requires CCM services to leverage the potential of non-face-to-face modalities, such as EHR systems, patient portals, texting/SMS services, chatbot technologies, interactive mobile medical apps, and direct patient calls. The commenters explained that while they understood CMS' concerns, it is long past due that CMS do away with the requirement for a provider to directly obtain consent. Virtual modalities more than adequately enable a patient to gain an understanding of what they are consenting to at the same level or better than an in-person consent process, making the direct consent requirement outdated and overburdensome. The commenters encouraged CMS to permanently allow providers to obtain beneficiary consent under general supervision.

Response: As discussed in the CY 2024 PFS proposed rule (88 FR 52406), for the purposes of CCM services furnished under the PFS, we require that practitioners obtain informed consent before furnishing a beneficiary with CCM services. During the COVID–19 PHE, we clarified existing policy about how practitioners could obtain beneficiary consent. We explained that practitioners could obtain beneficiary consent either at the required initiating visit for CCM (many of which Medicare allows to be furnished virtually), or at the same time that the CCM service is initiated by auxiliary staff (often independent third-party entities) who work to furnish the CCM services. When the beneficiary's consent is separately obtained, it may be obtained under the general supervision of the billing practitioner and may be verbal as long as it is documented in the medical record and includes notification of the required information. We noted that now that the COVID–19 PHE has ended, we expect that practitioners will continue to appropriately obtain informed consent before they start furnishing CCM services to a beneficiary.

In the CY 2024 PFS proposed rule, for purposes of CCM services furnished by RHCs and FQHCs, we proposed to clarify the policy of how RHC and FQHC practitioners could obtain beneficiary consent. That is, while we have stated our intent since allowing RHCs and FQHCs to furnish CCM services, is to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we believed our guidance could be clearer. After a review of commenters' concerns, we proposed to clarify when, how and by whom beneficiary consent for CCM services could be obtained. We explained, informed consent to receive CCM services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. That is, beneficiary consent can be obtained at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. Further, there need not be an employment relationship between the person obtaining the consent and the RHC or FQHC practitioner. That is, the clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC.

We noted, it was important to reiterate that the importance of obtaining advance beneficiary consent to receive CCM services was to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. In addition, querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. We stated CMS requires the beneficiary be informed on the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of the right to stop the CCM services at any time (effective at the end of the calendar month). Again, we believed that it is important that the beneficiary grant the consent at the onset of CCM services to have the opportunity to understand what services are being billed and note it is important for CMS to take a balanced approach between administrative burden and potential program integrity concerns. That being said, we clarified that we understand that the sequencing and mode of consent can take various forms since the beneficiary is given notice and verbally consents.

(2) Virtual Communication Services

In the April 6, 2020 IFC (85 FR 19253 through 19254), we implemented on an interim final basis the expansion of services that can be included in the payment for virtual communications in RHCs and FQHCs. We explained that in order to minimize risks associated with exposure to COVID–19, and to provide the best care possible during the PHE for the COVID–19 pandemic, we believed that RHCs and FQHC practitioners, like many other health care providers, should explore the use of interactive communications technology in the place of services that would have otherwise been furnished in person and reported and paid under the established methodologies.

To ensure these services would be available to beneficiaries who otherwise would not have access to clinically appropriate in-person treatment, we placed in our interim final rule a provision stating that all virtual communication services billed by HCPCS code G0071 would be available to new patients not seen by the RHC or FQHC within the previous months and modified requirements regarding when patient consent was required for these services, in order to promote timely provision of care. Specifically, we allowed consent to be obtained when the services were furnished instead of prior to the service being furnished and before the services were billed. Consent could also be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication codes during the PHE for COVID–19.

We received several comments on these policies and subsequently finalized the provisions of the April 6, 2020, IFC without modification. However, we stated that when the PHE for COVID–19 ended, beneficiary consent for these services would revert back to direct supervision and clarified this in the CY 2023 PFS final rule with comment period (87 FR 70127 through 70128).

As discussed in the CY 2024 PFS proposed rule (88 FR 52407), we believe the same philosophy applies to consent for virtual communications as it does for CCM. In an effort to continue promoting access to timely, quality care for Medicare beneficiaries and to align with the PFS, we proposed to clarify that the consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. While we continue to believe that beneficiary consent is necessary so that the beneficiary is

notified of cost sharing when receiving these services, we do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services.

We received a few comments on our proposal to clarify beneficiary consent for CCM and virtual communications services. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to clarify obtaining beneficiary consent related to CCM and virtual communications services. Commenters stated that this flexibility will continue to allow health centers to enhance their efficiency by tailoring their operational processes and workflows to continue focusing on patient care. Commenters also appreciated CMS permitting third-party vendors to obtain consent from patients, stating that utilizing technological third-party vendors helps decrease administrative burden, allowing health center personnel more time to focus on patient care while ensuring patients understand the services rendered.

Response: We appreciate commenters' support of our clarification of the policy for obtaining beneficiary consent for CCM and virtual communications services.

After consideration of public comments, we are finalizing our clarification as proposed.

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs)

1. Background and Statutory Authority

This section of the final rule sets out changes to the RHC and FQHC CfCs as required by section 4121 of division FF of the Consolidated Appropriations Act (Pub. L. 117–328, December 29, 2022) (CAA 2023). Specifically, we are implementing provisions that modify the existing RHC and FQHC CfCs at § 491.8(a)(3) to include marriage and family therapists (MFTs) and mental health counselors (MHCs) as part of the collaborative team approach to provide services under Medicare Part B. We also proposed to include definitions of other healthcare professionals who are already eligible to provide services at RHCs and FQHCs. Lastly, we proposed to update the definition of ''nurse practitioner'' to align with current standards of professional practice.

Section 1861(aa) of the Act establishes requirements that RHCs and FQHCs must meet to participate in the Medicare Program. These requirements are codified in regulations at 42 CFR part 491. For an RHC and FQHC to receive Medicare payment for services, it must meet the requirements at part 491, which are intended to promote the health and safety of care provided to RHC and FQHC patients.

2. Summary of the RHC and FQHC CfCs Proposed Provisions, Public Comments, and Responses to Comments

We proposed to revise the ''Definitions'' section and ''Staffing and staff responsibilities'' requirements that RHCs and FQHCs must meet to participate in the Medicare program. Commenters included individuals, health care professionals, national and State associations, patient advocacy organizations, and individual facilities that will be impacted by the rule.

a. Definitions (§ 491.2)

At § 491.2, we proposed to define certain terms that are used in the RHC and FQHC CfCs. We proposed to define the terms ''clinical psychologist (CP),'' ''clinical social worker,'' and ''certified nurse midwife (CNM)'' in the CfCs and cross-reference the definitions established in the payment requirements at §§ 410.77(a), 410.71(d), and 410.73(a) respectively. This rule also finalizes changes to the CfCs to define MFT and MHC services as proposed in section II.J of this final rule to indicate that RHC and FQHCs can offer these services under their Medicare certification by cross-referencing the definitions proposed at §§ 410.53 and 410.54.

Additionally, we proposed revising the existing ''nurse practitioner'' (NP) definition at § 491.2 to accurately reflect current professional standards by removing the reference to specific certifying bodies as they are now outdated. This revision will ensure the requirement reflects the breadth of currently available certifications. We proposed adding education requirements to paragraph (1) of the definition because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a bachelor of science in nursing (BSN), complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam.[178] We proposed to retain paragraphs (2) and (3) of the definition, which provides alternative certification and education requirements an NP can meet to furnish services in an RHC or FQHC if the education requirements in paragraph (1) are not met.

We explicitly solicited comments in the proposed rule (88 FR 52408) on whether CMS should revise the NP definition for RHCs and FQHCs. Specifically, we were interested in whether the definition of NP should specify that an NP's certification be in the area of primary care, or whether this distinction should be removed. Approximately 3,200 RHCs employ 1.25 full-time NPs per RHC, and each NP provides care for nearly 3,000 visits annually. For a total of 12,000,000 RHC visits nationally.[179] Likewise, there are 12,609 NPs in health centers funded and designated by the Health Resources and Services Administration that provided more than 30 million clinical and virtual visits in 2022.[180] [181] Removing the certification requirement for NPs would allow approximately 60,000 additional NPs to be eligible to provide care in RHCs and FQHCs.[182] NPs are instrumental in providing high-quality services to rural and underserved communities. Their services are essential in ensuring that individuals have access to the care they need, and work alongside physicians to provide comprehensive care.

The latest report from the American Association of Nurse Practitioners (AANP) indicates 88 percent of licensed NPs are educated and prepared in primary care.[183] NP students choose their patient populations at the time of entry into an NP program.[184] Doing so allows NP education to match the knowledge and skills to the needs of patients focusing their academics and clinical study on the patient population they will be working with. While NP programs have core studies everyone attends (pathology, pharmacology, and physical assessment), having a population focus-based education ensures ample education to build knowledge and skills in the area where the NP will be practicing. NP

[178] *American Association of Nurse Practitioners (2020). The Path to Becoming a Nurse Practitioner (NP). https://www.aanp.org/news-feed/explore-the-variety-of-career-paths-for-nurse-practitioners#:~:text=To%20become%20an%20NP%2C%20one,national%20NP%20board%20certification%20exam.*

[179] *https://digitalcommons.usm.maine.edu/cgi/viewcontent.cgi?article=1016&context=clinics.*

[180] *https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=5&year=2022.*

[181] *https://data.hrsa.gov/tools/data-reporting/program-data/national-lookalikes/table?tableName=5&year=2022.*

[182] *https://www.aanp.org/about/all-about-nps/np-fact-sheet.*

[183] *https://www.aanp.org/advocacy/advocacy-resource/position-statements/nurse-practitioners-in-primary-care#:~:text=Millions%20of%20Americans%20choose%20a.*

[184] *https://www.aanp.org/news-feed/explore-the-variety-of-career-paths-for-nurse-practitioners.*

population foci include adult-gerontology acute care, adult-gerontology primary care, family, neonatal, pediatric, psychiatric mental health, and women's health.[182] Of those population foci, NPs specialized in adult-gerontology acute care, neonatal, pediatric acute care, and psychiatric mental health would not be able to furnish services in an RHC and FQHC if the primary care certification requirement remained for NPs.

We sought comments on whether the specific requirement for NPs to be certified in primary care should remain in the definition at § 491.2.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed revision of the NP definition at § 491.2 to remove naming specific certifying boards for NPs and adding education requirements. Commenters also responded to the proposal supporting a broad definition of a nurse practitioner at § 491.2(1). The commenters recommend removing the primary care certification specification to allow health centers to employ the most qualified candidates who could best serve the clinic or center's patient population. One commenter supported the removal of the primary care certification requirement, with the understanding that NPs would continue to provide services only within their scope of practice. Another commenter recommended we amend the proposed definition from ''. . . and possesses a Master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree,'' to a definition that is inclusive of all NP graduate degrees. We did not receive any comments opposing our proposal.

Response: We are appreciative of these comments. Approximately 100 million individuals lack sufficient access to primary healthcare, with 65 percent of such access problems happening in rural areas.[185] Our belief is that eliminating the need for primary care certification for NPs could aid in resolving staffing shortages that healthcare facilities are experiencing in underserved and rural communities.

When hiring NPs for employment, it is important for RHCs and FQHCs to consider the specific patient population they serve, as well as the individual education, skills, and training of the NP. NPs have the ability to offer comprehensive, patient-centered care in various settings, and may have specialized expertise in fields such as addiction, psychiatric care, or cardiovascular care.[186] For new NPs providing care in FQHCs, there are opportunities to pursue fellowship, training, and residency programs to ensure they have the necessary skills to provide quality care.[187] To further ensure patient safety, states may have additional licensure requirements in place. Therefore, we are updating the standard at paragraph (1) of the NP definition at § 491.2 to require that NPs be certified by a recognized national certifying body and possess a master's or doctoral degree in nursing.

After consideration of the public comments we received, we are finalizing this provision with modification by removing language specifying that NPs must be certified in primary care. We are finalizing the requirement that NPs must be certified by a recognized certifying body and possess a master's or doctoral degree in nursing. We note that section 1861(aa)(5)(A) of the Act continues to require that NPs and PAs only provide such services as they are ''legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law).''

b. Staffing and Staff Responsibilities (§ 491.8)

Section 4121(b)(1) of the CAA, 2023, *Coverage of Certain Mental Health Services Provided in Certain Settings Rural Health Clinics and Federally Qualified Health Centers* amends section 1861(aa)(1)(B) of the Act by including MFTs and MHCs to the list of other practitioners whose services, when provided in RHCs and FQHCs, are entitled to payment under the Medicare program. We proposed to revise the RHC and FQHC CfCs to include MFTs and MHCs as recognized staff alongside other practitioners such as NPs, PAs, CPs, CSWs, and CNMs, where appropriate and as required by the statute.

At § 491.8(a)(3), we proposed to add MFT and MHC to the list of practitioners who may be the owner, employee, or furnish services under contract to the clinic or center. Section 1861(aa)(2) and (4) of the Act requires that RHC and FQHC staff include one or more physicians, and RHCs are also required to employ at least one PA or NP. There are no requirements for an RHC or FQHC to employ a CNM, CSW, CP, MHC, or MFT. To comply with this requirement, we would expect clinics and centers ensure that the needs of the patient population they serve are met. As rural areas are increasingly diverse, have significant strengths and unique challenges, RHCs and FQHCs play a key role in identifying the needs of their patients. A team of diverse professionals can take a patient-centered approach to addressing a patient's physical and mental health through counseling, case management, and provide resources and information to address social determinants of health.[188]

Additionally, we proposed to add MFTs and MHCs to § 491.8(a)(6), which determines which practitioners are required to be available to furnish patient care services at all times the clinic or center operates. This provision allows MFTs and MHCs to furnish services within their scope of practice while helping meet the needs of the clinic or center's patient population. The intent of this requirement is to ease the burden of staffing shortages in RHCs and FQHCs, which is a barrier that prevents individuals from accessing physical and mental health services.[189] MFTs and MHCs can expand the pool of mental health professionals available to address practitioner shortages in rural communities by providing reimbursable services under the Medicare program. We note the statutory provision that defines the term ''rural health clinic'' in section 1861(aa)(2)(K)(iv) of the Act states that an RHC is not a facility which is primarily for the care and treatment of mental diseases.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported expanding Medicare coverage to include MFT and MHC services in RHCs and FQHCs. Commenters expressed their appreciation for the discussion of the specific barriers to accessing mental health and substance use disorder services for people living in rural areas and areas where there are shortages of healthcare professionals.

Response: We thank the commenters for their support. We are committed to advancing health equity and increasing access to physical and mental health services. We aim to increase the number of covered behavioral health providers, bridging the gap in the accessibility of

[185] *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[186] *https://www.abn.alabama.gov/wp-content/uploads/2019/03/NP-Specialty-Certifications_03202019.pdf.*

[187] *https://www.chc1.com/what-we-do/training-the-next- generation/residency-training-programs/.*

[188] *https://www.jstor.org/stable/pdf/26554276.pdf?refreqid=excelsior%3A3437750e2633ee53aa5c0afe8caae6ea&ab_segments=&origin=&initiator=&acceptTC=1.*

[189] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1851736/.*

services to ensure that patients receive comprehensive care.

Comment: One commenter encouraged CMS to finalize the COVID–19 Public Health Emergency waiver, which modified the requirement at § 491.8(b)(1) that physicians must provide medical direction for the clinics or center's health care activities and consultation for, and medical supervision of, the health care staff with respect to medical supervision of NPs to the extent permitted by State law.[190]

Response: This comment pertains to physician supervision of NPs in RHCs and FQHCs rather than to any specific proposed changes to the policy proposals set forth in the proposed rule. Therefore, this comment is outside the scope of this final rule.

Comment: One commenter suggested that CMS propose a more permanent policy to determine RHC rural location eligibility.

Response: We did not propose any provisions related to the location requirements of RHCs or FQHCs, and therefore this comment is outside the scope of this final rule.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) and reduced by a productivity adjustment and other statutory adjustments but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. A final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), which appeared in the **Federal Register** on June 23, 2016 (81 FR 41036), implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[191]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial

[190] *https://www.cms.gov/files/document/rural-health-clinics-and-federally-qualified-health-centers-cms-flexibilities-fight-covid-19.pdf.*

[191] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule, which implemented section 1834A of the Act as required by PAMA (81 FR 41036 through 41101) and this information is also available on the CMS website.[192]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. First, section 105(a)(1) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year so that data reporting would be required during the period of January 1, 2021, through March 31, 2021, instead of January 1, 2020, through March 30, 2020. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period of January 1, 2021, through March 30, 2021, would be the period of January 1, 2019, through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022, through March 31, 2022. The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs would have been based on the data collection period of January 1, 2019, through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024 instead of CY 2023. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2022 through 2024, instead of CYs 2021 through 2023. In the CY 2021 PFS rulemaking (85 FR 50210 through 50211; 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023, through March 31, 2023) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

In the CY 2023 PFS rulemaking (87 FR 46068 through 46070; 87 FR 69741 through 69744, 70225), in accordance with section 4 of PMAFSCA, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we finalized revisions to § 414.502 to update the definitions of both the data collection period and data reporting

[192] *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/pama-educational-resources.*

period, specifying that for the data reporting period of January 1, 2023, through March 31, 2023, the data collection period is January 1, 2019, through June 30, 2019. We also revised § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 1, 2023. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the PMAFSCA amendments. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

As a result of the statutory revisions under the FCAA, CARES Act, and PMAFSCA, there have only been two data collection periods for CDLTs that are not ADLTs to date. The first data collection period for these tests occurred from January 1, 2016, through June 30, 2016, and the second occurred from January 1, 2019, through June 30, 2019. Thus far, there has been only one data reporting period for these tests, which took place from January 1, 2017, through March 31, 2017. We have established CLFS payment rates for these tests using the methodology established in PAMA only one time, effective January 1, 2018, based on the applicable information collected by applicable laboratories during the 2016 data collection period and reported to CMS during the 2017 data reporting period.

Additionally, we have applied the phase-in of payment reductions for the first 3 years of PAMA implementation, CY 2018 through CY 2020, whereby reduction of payment rates could not be more than 10 percent per year as compared to the amount established the prior year. However, the phase-in of payment reductions set forth in PAMA for years 4 through 6 of PAMA implementation, whereby payment cannot exceed 15 percent per year as compared to the amount established the prior year, has not yet occurred.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 4114 of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023, through March 31, 2023, established under the PMAFSCA. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4114(b) of the CAA, 2023, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2023; (ii) reporting is required during the period beginning January 1, 2024, and ending March 31, 2024; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4114 of the CAA, 2023 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2024, through March 31, 2024) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4114(a) of the CAA, 2023 further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2026. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. Section 4114(a) of the CAA, 2023 further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026.

5. Conforming Regulatory Changes

In accordance with section 4114 of the CAA, 2023, in the CY 2024 PFS proposed rule (88 FR 52410 through 52412), we proposed certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we proposed to revise § 414.502 to update the definitions of both the ''data collection period'' and the ''data reporting period,'' specifying that for the data reporting period of January 1, 2024, through March 31, 2024, the data collection period is January 1, 2019, through June 30, 2019. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. In addition, we proposed conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4114(a) of the CAA, 2023. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the payment amount established for that test in CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the payment amount established for that test the preceding year.

We noted that the CYs 2023 and 2024 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2025 through CY 2027 will be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2024, through March 31, 2024.

The following is a summary of the public comments received on the proposed conforming regulatory changes and our responses:

Comment: Several commenters supported our proposal to revise §§ 414.502, 414.504, and 414.507 to conform with the current statutory provisions governing data reporting and payment for CDLTs on the CLFS.

Response: We appreciate the commenters' support for these regulatory changes that reflect the recent statutory revisions required by section 4114 of the CAA, 2023.

Comment: Multiple commenters expressed concerns over the period of data collection (January 1, 2019, through June 30, 2019) that would be utilized for the next data reporting period (January 1, 2024, through March 31, 2024). Commenters noted that private payer rate data from CY 2019 would be several

years old and not reflect data on newer CDLTs that were released after this data collection period. Commenters also noted that this data collection period preceded the COVID–19 pandemic and recent trends of rising medical inflation, which has led to supply and labor challenges. Thus, commenters were concerned that private payor rates during this data collection period would be incongruent with the current economic environment and negatively impact subsequent payment under the CLFS.

Response: We note that section 4114 of the CAA, 2023 did not modify the data collection period that applies to the next data reporting period for CDLTs that are not ADLTs. Therefore, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2024, through March 31, 2024) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502. Because this requirement is statutory, we are unable to modify the data collection period.

Comment: A few commenters submitted recommendations to CMS related to outreach and education activities for data reporting purposes if these proposed policies become finalized. One commenter urged CMS to notify applicable laboratories as soon as possible if there are any future changes to the timeline for data reporting, since significant time and resources are required for entities to properly collect and report data. Another commenter suggested that CMS implement assertive outreach approaches to all applicable laboratories that need information and assistance to comply with section 216(a) of PAMA. They recommended that CMS make multi-media materials readily available to assist applicable laboratories who must fulfill data reporting obligations and should partner with national member organizations on presentations to inform applicable laboratories on the importance of reporting applicable information. They also recommended that CMS use its authority to impose civil monetary penalties (CMPs) and state publicly its intention to audit applicable laboratories and to impose penalties where warranted, in order to signal to all applicable laboratories that reporting is not voluntary, but mandatory.

Response: We appreciate commenters' recommendations related to outreach and education for data reporting. Obtaining applicable information from applicable laboratories as required under PAMA is necessary to establish payment rates for CDLTs, and outreach and education activities for applicable laboratories play an important role in achieving this objective. Accordingly, we regularly update our website and have leveraged different media platforms to disseminate various educational materials and other resources to prepare these applicable laboratories for data reporting and inform them of changes to reporting requirements. For example, we recently created a video on how to determine if a laboratory is an applicable laboratory.[193] Overall, CMS shares the commenters' interest in ensuring all applicable laboratories have the educational resources needed to report accurate and complete data to inform payment rates under the CLFS, and we may consider the submitted recommendations for upcoming data reporting periods.

Additionally, regarding the comments on CMPs, we note that section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP in cases where the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting applicable information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. We codified this provision in our regulations at § 414.504(e). As we previously stated in the CLFS final rule, which implemented section 216(a) of PAMA (81 FR 41069), in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the Office of Inspector General at the U.S Department of Health and Human Services (HHS OIG) to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances.

Comment: Multiple commenters conveyed concerns over the proposal for the phase-in of payment reductions to CLFS payment amounts that would be required to resume in CY 2024. Commenters raised that potential payment cuts to CDLTs of up to 15 percent could affect access to laboratory tests that guide medical decisions and might impact laboratories who already face resource constraints to conduct these tests. One commenter suggested capping the maximum payment reduction at 5 percent instead of 15 percent or implementing a more gradual approach to payment reductions. Another commenter noted that the CY 2016 base year that CMS intends to use for CY 2024 CDLT payment amounts under the CLFS is outdated and not representative of all applicable laboratories.

Response: We thank commenters for expressing their concerns regarding potential effects due to the phase-in of payment reductions. Nevertheless, we note that the phase-in of payment reductions to the CLFS is statutory; therefore, we are unable to alter implementation of the payment reductions or the maximum percentage by which payment can be reduced compared to the amount established for that test the preceding year. Section 1834A(b)(3)(B) of the Act explicitly states that there will be a 0 percent payment reduction for CY 2023 and, for CYs 2024 through 2026, payment may not be reduced by more than 15 percent of the amount of payment for the test for the preceding year. Additionally, the CY 2016 base year on which the CLFS payment amounts will be based for CY 2024 is also statutory. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update are to occur every 3 years. The second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019, through June 30, 2019, but a second data reporting period has not yet taken place due to the series of legislative delays passed since 2019 that modified the statutory data reporting period for such tests. Therefore, the only data collection period available for which data has been reported for CDLTs that are not ADLTs was the data collection period that occurred from January 1, 2016, through June 30, 2016, which will inform CY 2024 payment rate amounts for CDLTs that are not ADLTs under the CLFS. Lastly, promoting access to medically reasonable and necessary CDLTs for Medicare beneficiaries continues to be an important priority for CMS. Thus, we will continue to monitor cost and utilization data for CDLTs under the CLFS.

Comment: While commenters agreed with our proposal to make conforming regulatory changes to the data reporting period and phase-in of payment reductions as mandated by section 4114 of the CAA, 2023, they also stated that they would support different types of new legislation that would modify these statutory requirements for the CLFS. For example, one commenter stated that they are supporting legislation that would give CMS new authority to collect private market data through

[193] *https://youtu.be/c3eiPYeRA_U.*

statistically valid sampling from all laboratory segments for the widely available test services where previous data collection was inadequate. Another commenter mentioned that they would support legislation to eliminate the data reporting requirements or to prohibit the use of laboratory-reported information for rate-setting. Commenters also indicated they would support legislation to stabilize payment rates for CDLTs. Many commenters also urged CMS to work with Congress to address these issues.

Response: We appreciate these comments and value efforts to promote access to care to high quality laboratory services for Medicare beneficiaries. We also note that any legislative changes would require Congressional action.

Comment: We received a few comments that were out of scope for this proposal. A few of these comments included ways to improve the CLFS annual payment determination process, expansions to the laboratory date of service policy, and/or a request to reconsider requiring hospital outreach laboratories to determine their applicable laboratory status.

Response: We appreciate hearing from commenters on these issues. However, these comments are out of scope for this final rule as we did not make any proposals on these processes or policies. We could consider these requests for future rulemaking or CLFS annual payment determination processes as applicable and within our authorities under the statute.

In consideration of these public comments and in accordance with section 4114 of the CAA, 2023, we are finalizing the proposed conforming changes to the data reporting and phase-in of payment reductions at 42 CFR part 414, subpart G, as proposed.

E. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners

Conditions of coverage for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are codified at 42 CFR 410.47 and 410.49. We proposed revisions to the PR and CR/ICR regulations to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) which permit other specific practitioners to supervise the items and services effective January 1, 2024.

1. Statutory Authority

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA) amended title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B, as well as new section 1861(fff) of the Act to provide coverage of PR under Medicare part B. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in §§ 410.47 and 410.49 respectively through the CY 2010 PFS final rule with comment period (74 FR 61872 through 61886 and 62002 through 62003 (PR) 62004 through 62005 (CR/ICR)). Section 51008 of the BBA of 2018, entitled ''Allowing Physician Assistants, Nurse Practitioners, and Clinical Nurse Specialists to Supervise Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Programs,'' amended sections 1861(eee) and (fff) of the Act, effective January 1, 2024. The amendment directs us to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS).

2. Background

Under § 410.47(b), Medicare part B covers PR for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD) (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through a national coverage determination (NCD). We have not added additional medical indications for PR using the NCD process; however, we used notice and comment rulemaking through the CY 2022 PFS final rule (86 FR 64996) to establish coverage of PR for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. In the same final rule, we also updated language to improve consistency and accuracy across PR and CR/ICR conditions of coverage and removed a PR requirement for direct physician-patient contact.

Under § 410.49(b), Medicare part B covers CR and ICR for beneficiaries who have experienced one or more of the following: (1) an acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; (6) a heart or heart-lung transplant; (7) stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014, for cardiac rehabilitation and on or after February 9, 2018, for intensive cardiac rehabilitation; or (8) other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

In 2014, we established coverage of CR through the NCD process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03)) to beneficiaries with stable, chronic heart failure. Section 51004 of the BBA of 2018 amended section 1861(eee)(4)(B) of the Act to expand coverage of ICR to include patients with stable, chronic heart failure. Section 410.49 was updated to codify this expansion through the CY 2020 PFS final rule (84 FR 62897 through 62899 and 63188). The CY 2022 PFS final rule (86 FR 64996) updated language in § 410.49 to improve consistency and accuracy across PR and CR/ICR conditions of coverage.

3. Summary of Proposals for Implementation

Consistent with the amendments made by section 51008 of the BBA of 2018 to section 1861(eee) and (fff) of the Act, we proposed additions and revisions to language in §§ 410.47 and 410.49 as described below.

a. Definitions

We proposed to add a new term, nonphysician practitioner (NPP), to §§ 410.47(a) and 410.49(a), defined as a PA, NP, CNS as those terms are defined in section 1861(aa)(5)(A) of the Act.

We proposed to amend the term supervising physician at §§ 410.47(a) and 410.49(a) to supervising practitioner and amend the definition to mean a physician or NPP.

Finally, we proposed to amend the definition for pulmonary rehabilitation at § 410.47(a) and the definitions for cardiac rehabilitation and intensive cardiac rehabilitation (ICR) program at § 410.49(a) to specify that these are physician- or NPP-supervised programs.

b. Setting

We proposed to amend §§ 410.47(b)(3)(ii)(A) and 410.49(b)(3)(ii)

to specify that all settings must have a physician or NPP immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the programs.

c. Supervising Practitioner Standards

We proposed to amend language at §§ 410.47(d) and 410.49(e) by specifying that these sections include supervising practitioner standards, rather than just supervising physician standards. We also removed the third standard in each section (§§ 410.47(d)(3) and 410.49(e)(3)) because specifying that a physician or NPP is licensed to practice medicine in the state where a PR/CR/ICR program is offered, or any corresponding reference to a NPP being licensed or authorized to practice, is redundant to the definition for each practitioner type in the Act. Since the physicians and NPPs that may supervise PR/CR/ICR are defined at §§ 410.47(a) and 410.49(a) by cross-reference to the Act, we believe repeating part of that definition in these sections is unnecessary.

4. Summary

We proposed additions and revisions that are necessary to implement the amendments to section 1861(eee) and (fff) of the Act set forth in section 51008 of the BBA of 2018, which expand the types of practitioners that may supervise PR, CR and ICR. This includes changes to the regulatory language in the definitions, settings, and supervising practitioner standards sections under §§ 410.47 and 410.49. After considering the public comments on our proposed rule (discussed below), we continue to believe these amendments to §§ 410.47 and 410.49 serve to implement the provisions in the BBA of 2018 regarding the types of practitioners that may supervise PR, CR and ICR beginning January 1, 2024. As such, we are finalizing these additions and revisions as proposed. All other provisions of these regulations remain unchanged.

We received public comments on our proposals with several supporting the proposed amendments to expand the types of practitioners that may supervise PR, CR and ICR and two opposing allowing supervision by NPPs.

Comment: Of the commenters that supported expanding the types of practitioners who may supervise these programs, one commenter, who supported the allowing NPPs to supervise PR and CR, stated support specifically for the definition change and conforming revisions to the regulations to expand supervision of PR to NPPs. Another commenter supported the proposed definitions and standards. One commenter agreed with broadening the definition from supervising physician to supervising practitioner to account for additional providers. Several commenters stated that the expansion will help to expand access to these programs with a few noting that this is especially true in rural areas. Several commenters noted workforce shortages and the aging workforce to further support the proposals to expand practitioners that may supervise these programs.

Response: We appreciate these supportive comments and are finalizing the additions and revisions to §§ 410.47 and 410.49 as proposed.

Comment: One commenter supported the proposals stating that NPP supervision will continue to ensure safety and quality. One commenter asserted that advanced practice registered nurses, which include NPs and CNSs as explained by this commenter, are highly-trained and their education and licensure requirements prepare them to supervise CR and PR. Another agreed that advanced practitioners are highly experienced with complex patient populations and are fully embedded in the clinical practice making the proposed expansion an appropriate extension of their skill set in accordance with State licensure laws. One commenter stated that NPPs are highly trained to respond if emergencies arise and others noted that the ability to supervise is within PAs level of expertise. One commenter asserted that allowing NPPs to supervise these programs will help promote team-based provision of services and another stated that allowing advanced practice nurses to supervise rehabilitation services enables the overall healthcare team to function more efficiently and leads to better care coordination and patient outcomes, thus PAs, NPs and CNSs enhance the continuum of care.

Response: We appreciate these supportive comments and are finalizing the additions and revisions to §§ 410.47 and 410.49 as proposed.

Comment: One commenter requested that CMS revise the ''physician prescribed exercise'' language to include PAs. Citing the 2014 final decision memorandum for Cardiac Rehabilitation (CR) Programs—Chronic Heart Failure,[194] this commenter stated that CMS previously declined to modify language in this manner because the statute specifies that the program is under the supervision of a physician. This commenter stated that since this section of the statute has been revised to allow PAs to supervise these programs, CMS should now modify this language accordingly to ''provider prescribed exercise.'' This commenter further requested that if the exact wording cannot be modified due to statutory constraints, CMS should reinterpret the intent of this section to indicate that health professionals authorized to supervise may also prescribe exercise. Additionally, this commenter urged CMS to work with Congress to modify physician-centric language in the U.S. Code that prohibits PAs and other health professionals from ordering PR, CR and ICR.

Response: Physician-prescribed exercise continues to be a specific element of PR, CR and ICR based on the language in sections 1861(eee)(3) and 1861(fff)(2)(A) of the Act. While the BBA of 2018 expanded the types of practitioners that may supervise PR in section 1861(fff)(1) of the Act and CR/ICR in section 1861(eee)(1) of the Act, Congress did not change the items and services that these programs must furnish, so we are not adopting the commenters suggested change. Interested parties may wish to consider working with Congress to pursue statutory changes to support those requests.

Comment: Another commenter noted that under the ACO REACH model, NPs are allowed to establish, review, and sign a written care plan for PR and CR and requested that this waiver be standardized across all relevant payment models and CMS should explore regulatory avenues to remove the barrier for patients to be seen by NPs to increase PR and CR participation.

Response: We understand the commenters' request to expand the role for NPPs in prescribing, ordering PR, CR, and ICR services and establishing, reviewing and signing plans of care for these services outside of a payment model; however, we do not believe the current statutory language would support the requested changes. Interested parties may wish to consider working with Congress to pursue statutory changes to support those requests.

Comment: Some commenters disagreed with the proposed additions and revisions to our regulations because they opposed removing the requirement that physicians must supervise PR, CR and ICR services, and disagreed with expanding supervision requirements to include PAs, NPs and CNSs. One of these commenters further explained that the skillsets for physicians and NPPs are not interchangeable considering their

[194] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=270.*

differences in education and training, and NPPs do not have the education and training needed to be the head of a care team. This commenter asserted that when NPPs practice without supervision the result is lower quality, higher cost care with strong evidence that increasing scope of practice of NPs and PAs has increased healthcare costs. This commenter further stated that the proposals are counter to patient preferences as patients believe it is important for a physician to be involved in the diagnosis and treatment decisions and expect the most qualified person to supervise care to patients with severe cardiac conditions. This commenter further requested that if CMS proceeds with expanding the types of practitioners that may supervise PR, CR and ICR, CMS should not use the overarching term ''nonphysician practitioner'' and instead directly reference the specific practitioners because the term can lead to confusion. Additionally, this commenter asserted that the regulatory language should specify that NPPs must be licensed to practice medicine in the State where the PR, CR or ICR program is located and where the patient is located when receiving care, and that NPPs must adhere to State scope of practice laws.

Response: We understand that some commenters may not support the statutory changes that Congress has enacted but CMS may not simply ignore the statute. Our proposed and final rules are consistent with the statute and were supported by the majority of public commenters. Those commenters suggest that the changes will help to expand access to PR, CR, and ICR services for Medicare beneficiaries. We also disagree with the commenter's suggestion that using the overarching term ''nonphysician practitioner'' could be confusing as our proposals clearly define the term for use under §§ 410.47 and 410.49 and include a reference to the statutory definition for those practitioners as defined in section 1861(aa)(5)(A) of the Act. Furthermore, and as noted above in this final rule, we have determined that specifying that NPPs are licensed to practice medicine in the State where a PR/CR/ICR program is offered, or any corresponding reference to a NPP being licensed or authorized to practice, is unnecessary and would be redundant given the definition for each practitioner type in the statute. Since the physicians and NPPs that may supervise PR/CR/ICR services are defined at §§ 410.47(a) and 410.49(a) by cross-reference to a specific statute, we believe repeating part of that definition in these regulatory sections is unnecessary. Therefore, we are finalizing these additions and revisions as proposed.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We also established in the CY 2020 PFS final rule new codes and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. In the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone. We also revised paragraphs (iii) and (iv) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the public health emergency (PHE) for COVID–19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met (86 FR 65342).

More recently, CMS made further modifications and expansions to covered services for the treatment of OUD by OTPs in the CY 2023 PFS final rule (87 FR 69768 through 69777). Specifically, we revised our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone by using the payment amount for methadone for CY 2021 updated by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) to better reflect the changes in methadone costs for OTPs over time. Additionally, we finalized a modification to the payment rate for individual therapy in the non-drug component of the bundled payment for an episode of care to base the payment rate on the rate for longer therapy sessions that better account for the greater severity of needs for patients with an OUD and receiving treatment in the OTP setting. Moreover, for the purposes of the geographic adjustment, we clarified that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the OTP for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) guidance. We believe that this policy enables OTPs to better serve Medicare beneficiaries living in underserved areas by providing access to many of the same OUD treatment services offered at the brick-and-mortar location of the OTP. We continue to monitor utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care. For CY 2024, we proposed several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Additional Flexibilities for Periodic Assessments Furnished Via Audio-Only Telecommunications

In the CY 2024 PFS proposed rule (88 FR 52414 through 52415), we discuss several flexibilities for OTPs regarding the use of telecommunications that we have finalized, both during the PHE for COVID–19 and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the Interim Final Rule with Comment Period (IFC) entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the

COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised paragraphs (iii) and (iv) in the definition of opioid use disorder treatment service at § 410.67(b) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio-video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when audio and video communication technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. More recently in the CY 2023 PFS final rule (87 FR 69775 through 69777), we further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the COVID–19 PHE. Specifically, we allowed the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video telecommunication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met, on a permanent basis.

Furthermore, in the CY 2023 PFS proposed rule (87 FR 46093), we solicited comments on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. In response, several commenters advocated for CMS to continue to allow periodic assessments to be furnished using audio-only when video is not available after the end of the PHE. Commenters highlighted that making audio-only flexibilities permanent would further promote equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability. Additionally, a few commenters explained that there is some evidence to show higher utilization of audio-only visits for older adults. For example, one commenter stated that one analysis of claims data showed the proportion of telephonic audio-only visits increases with the age of the patient, with ''17 percent of visits delivered via audio-only interaction for patients 41–60 years of age, 30 percent for patients 61–80 years of age, and 47 percent of visits for patients over 81.'' [195] One commenter stated that periodic assessments are no less complex than intake/initial assessments, and thus are equally appropriate for audio-video and audio-only care. Lastly, several commenters expressed support for the use of telecommunications in circumstances when the provider and patient have together determined that the patient would individually benefit from telehealth services and a high quality of care is maintained. They encouraged CMS to expand flexibilities to furnish substance use disorder (SUD) services via telecommunications to allow providers and patients to decide collaboratively the best modality for individualized care. After considering these comments, CMS determined that it would be appropriate to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and, in a manner consistent with all applicable requirements. We stated our belief that this modification would allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE terminated before the end of 2023 and that it would also grant additional time for CMS to further consider telecommunication flexibilities associated with periodic assessments. Accordingly, we revised the requirements related to the periodic assessment services in paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) of the regulations to reflect these changes (87 FR 69777).

In the CY 2024 PFS proposed rule (88 FR 52415 through 52416), we explained that section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extended the telehealth flexibilities enacted in the Consolidated Appropriations Act of 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022). Specifically, it amended sections 1834(m), 1834(o), and 1834(y) of the Act to delay the requirement for an in-person visit prior to furnishing certain mental health services via telecommunications technology by physicians and other practitioners, Rural Health Clinics (RHCs), and Federally Qualified Health Centers

[195] 2021 Medicare Coverage and Payment for Audio-Only Services: *https://www.aamc.org/media/55296/download.*

(FQHCs) until dates of service on or after January 1, 2025, if the COVID–19 PHE ended prior to that date. Additionally, it extended the flexibilities available during the PHE that allow for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024, if the PHE for COVID–19 ends prior to that date. We stated that the PHE for COVID–19, which was declared under section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023, so the aforementioned flexibilities will be extended through the end of CY 2024 or CY 2025, as applicable.

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities described in section 4113 of the CAA, 2023, in the CY 2024 PFS proposed rule, we proposed to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Under this proposal, we stated that we would allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met.[196] We believe extending this flexibility would promote continued beneficiary access to these services following the end of the PHE and for the duration of CY 2024. During the COVID–19 pandemic, SUD treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[197] Notably, telephone-based (that is, audio-only) therapy and recovery support services provided by SUD programs have been found to be one of the most common modes of telehealth for treatment of opioid use disorder.[198] Therefore, extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE. Additionally, we explained that evidence has shown that Medicare beneficiaries who are older than 65 years-old, racial/ethnic minorities, dual-enrollees, or living in rural areas, or who experience low broadband access, low-income, and/or not speaking English as their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services.[199] Other evidence also has suggested that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits.[200] Therefore, minimizing disruptions to care for beneficiaries currently receiving audio-only periodic assessments may further promote health equity and minimize disparities in access to care. Lastly, we stated that extending these flexibilities another year will allow CMS time to further consider this issue, including whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs.

Accordingly, we proposed to revise paragraph (vii) of the definition of ''Opioid use disorder treatment service'' at § 410.67(b) of the regulations to state that through the end of CY 2024, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met (88 FR 52416).

We received many public comments on our proposal to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of extending the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Many commenters stated that this proposal, if finalized, would meaningfully promote efforts towards improving health equity. A few commenters noted that the audio-only extension would be beneficial for the Medicare population, as evidence has shown clinicians are experiencing a higher utilization of audio-only visits for older adults, especially as the age of the patient increases.[201] Commenters also reiterated that audio-only telehealth encounters are more prominent among individuals who are older, Black, Hispanic, American Indian/Alaskan Native, Spanish-speaking, living in areas with low broadband access, low-income, and with public insurance.[202] Additionally, several commenters raised that many underserved populations experience challenges partaking in video-based telehealth services for several reasons, including not possessing the needed technological proficiencies to operate video-based services, not having a caregiver able to assist them with appointments, feeling discomfort with the use of video, and because of the cost of high-speed internet and data required for video technologies. Furthermore, multiple commenters provided evidence demonstrating the effectiveness of audio-only telehealth services on patient outcomes. One commenter cited a recent study in which telehealth expansion implemented by CMS during the COVID–19 PHE was associated with improved treatment retention and a lower likelihood of overdose for patients receiving medications for opioid use disorder (MOUD).[203] Several other commenters shared data that audio-only visits produce many of the same benefits as video-based visits,[204] and

[196] *https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines. https://www.deadiversion.usdoj.gov/.*

[197] *https://pubmed.ncbi.nlm.nih.gov/34407631/.*

[198] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8250742/.*

[199] *https://pubmed.ncbi.nlm.nih.gov/33471458/; https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/; https://journals.lww.com/lww-medicalcare/Fulltext/2021/11000/Disparities_in_Audio_only_Telemedicine_Use_Among.10.aspx.*

[200] *https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf; https://www.cms.gov/files/document/aian-telehealthwebinar.pdf; https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub.*

[201] HHS ASPE Issue Brief: Medicare beneficiary use of telehealth visits: Early Data from the Start of the COVID–19 Pandemic (July 27, 2020). *https://aspe.hhs.gov/reports/medicare-beneficiary-use-telehealth-visits-early-data-start-covid-19-pandemic.*

[202] J.A. Rodriguez et al., ''Differences in the Use of Telephone and Video Telemedicine Visits During the COVID–19 Pandemic,'' The American Journal of Managed Care 27, no. 1 (2021), *https://www.ajmc.com/view/differences-in-the-use-of-telephone-and-video-telemedicine-visits-during-the-covid-19-pandemic;* R.P. Pierce and J.J. Stevermer, ''Disparities in Use of Telehealth at the Onset of the COVID–19 Public Health Emergency,'' Journal of Telemedicine and Telecare (2020): 1–7, *https://doi.org/10.1177/1357633X20963893;* J.E. Chang et al., ''Patient Characteristics Associated with Phone Versus Video Telemedicine Visits for Substance Use Treatment During COVID–19,'' J Addict Med 16, no. 6 (2022): 659–65; C. Shoff, T–C Yang, B.A. Shaw, ''Trends in Opioid Use Disorder Among Older Adults: Analyzing Medicare Data, 2013–2018,'' American Journal of Preventive Medicine 60, no.6 (2021): 850–855, *https://doi.org/10.1016/j.amepre.2021.01.010.*

[203] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID–19 Pandemic. JAMA Psychiatry. Published online August 31, 2022. *doi:10.1001/jamapsychiatry.2022.2284.*

[204] Danila, M.I., Sun,D., Jackson,L.E., Cutter, G., Jackson, E.A., Ford, E.W., DeLaney, E., Mudano, A., Continued

that patients often report that audio-only visits left them feeling supported and with greater privacy, provided increased access to behavioral health professionals, and helped reduce transportation barriers.[205] Moreover, many commenters shared that our proposal to extend audio-only flexibilities for periodic assessments would help facilitate collaborative decision-making and allow the provider and patient to select the modality of care that best suits the patient's needs. Lastly, a few commenters stated that an extension of these flexibilities would provide both patients and providers additional time to adjust to changes in ways appointments are conducted in preparation for a reversion to many policies preceding the COVID–19 pandemic, while minimizing potential disruptions to treatment.

Response: We appreciate the positive feedback submitted by commenters in response to our proposal to extend audio-only flexibilities for periodic assessments furnished by OTPs through CY 2024. CMS agrees that the proposed policy may further the objectives of promoting health equity among underserved populations, be consistent with evidence indicating the effectiveness of audio-only services on patient utilization and outcomes, help facilitate collaborative decision-making between the provider and patient, allow OTPs additional time to adjust their activities as flexibilities that were tied to the COVID–19 PHE termination, and minimize potential disruptions to care for Medicare beneficiaries with an OUD.

Comment: A few commenters supported extending audio-only flexibilities in OTP settings but asserted that greater regulatory flexibility must come with additional safeguards. These commenters stated that shifting additional services to telehealth settings could increase the risk of a diminished quality of care, and that telehealth modalities are not appropriate for every doctor and patient interaction. The commenters stated that even if telehealth flexibilities are extended, periodic in-person visits should be required and coupled with a compliance and monitoring process to ensure program integrity. These commenters supported extending audio-only flexibilities by an additional year in OTP settings because it would provide CMS more time to examine how various telecommunications modalities can be deployed appropriately while maintaining a high quality of care and safety before permanently extending these flexibilities.

Response: We agree with the commenters regarding the importance of maintaining standards to ensure safety and quality of care for Medicare beneficiaries. Accordingly, we continue to defer to SAMHSA and DEA clinical guidance and other applicable requirements to achieve this objective.[206] We will continue to analyze clinical evidence and guidance to ensure that any flexibilities to utilize audio-only/audio-video modalities meet all applicable requirements, and monitor claims and utilization data for program integrity purposes. We may address any concerns related to these aforementioned issues through future rulemaking as needed.

Comment: Many commenters requested that CMS make the extension for audio-only periodic assessments permanent beyond CY 2024. Commenters stated that extending this policy permanently would retain a beneficiary's right to decide with their provider how best to receive their care and would curtail existing barriers that Medicare beneficiaries with an OUD may face in accessing care. Another commenter urged CMS to work with the DEA and SAMHSA to maintain audio-only flexibilities for the treatment of OUD, as they expand access to treatment for rural populations.

Response: We thank commenters for providing this feedback. In the CY 2024 PFS proposed rule, we stated that extending these flexibilities for audio-only periodic assessments by one additional year would allow CMS time to further consider whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024. An additional year would also allow CMS time to examine whether a permanent flexibility to furnish periodic assessments via audio-only telecommunications would be appropriate for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs, and whether proper safeguards are in place so these services can be delivered in a way that would not diminish safety or quality of care for Medicare beneficiaries with an OUD (88 FR 52415). We will continue to evaluate this issue, including reviewing relevant SAMHSA and DEA guidance on this issue, and may consider additional changes through future rulemaking.

Comment: One commenter stated that they supported CMS's proposal to continue to allow OTPs to furnish substance use counseling and individual and group therapy via audio-only communications through CY 2024 when audio-video communication technology is not available to the beneficiary.

Response: We clarify that CMS previously finalized a policy in the CY 2022 PFS final rule (86 FR 65342) to allow individual and group therapy and substance use counseling to be furnished audio-only after the conclusion of the COVID–19 PHE in OTP settings in cases where audio-video communication technology is not available to the beneficiary, and all other applicable requirements are met. In the CY 2024 PFS proposed rule, the proposal was specifically related to extending current flexibilities for periodic assessments that are furnished via audio-only telecommunications through the end of CY 2024.

Comment: A few commenters acknowledged the recent approval by the Food and Drug Administration (FDA) to allow certain naloxone products to be available over the counter. These same commenters asked that CMS continue to pay for take-home supplies of naloxone provided by OTPs whether naloxone is available by prescription or over the counter to ensure continued access to this lifesaving drug.

Response: Although we did not make a proposal related to take-home supplies of naloxone, we appreciate that commenters raised this important issue. CMS shares in the commenters' interest to ensure access to naloxone when medically necessary to treat a potential overdose. CMS currently covers take-home supplies of naloxone under Medicare Part B within the OTP benefit as described by the HCPCS add-on codes G2215 (*take-home supply of nasal naloxone*), G2216 (*take-home supply of injectable naloxone*), and G1028 (*take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray*).

Comment: We received other comments on several topics that were outside the scope of the proposed rule. Those topics included the following: implementing policy changes to leverage pharmacists to deliver clinical services for patients with an OUD; clarifying that OTPs can bill Medicare for primary care services so that these

Foster, P.J., Rosas, G., Melnick, J.A, Curtis,J.R., & Saag, K.G. (2022, November). Satisfaction with modes of telemedicine delivery during COVID–19: A randomized, single-blind, parallel group, noninferiority trial. The American Journal of the Medical Sciences, 364 (5).

[205] Kang AW, Walton M, Hoadley A, DelaCuesta C, Hurley L, Martin R. Patient Experiences with the Transition to Telephone Counseling during the COVID–19 Pandemic. Healthcare (Basel). 2021;9(6):663. Published 2021 Jun 2. *doi:10.3390/healthcare9060663.*

[206] *https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines. https://www.deadiversion.usdoj.gov/.*

services can be furnished in conjunction with SUD treatment; and, creating new codes for remote therapeutic monitoring (RTM) to allow for remote observation of patients receiving take-home doses of methadone.

Response: While these comments are out of scope for this final rule as they do not relate to our proposal to allow OTPs to furnish periodic assessments audio-only through CY 2024, we appreciate commenters raising these issues and may consider these recommendations for future rulemaking.

After consideration of the public comments, we are finalizing our proposal to revise paragraph (vii) of the definition of ''Opioid use disorder treatment service'' at § 410.67(b) of the regulations to state that through the end of CY 2024, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

3. Intensive Outpatient Program (IOP) Services Provided by OTPs

In the CY 2023 PFS proposed rule, we solicited comments on intensive outpatient mental health treatment (87 FR 45943 through 45944). Commenters emphasized the importance of ensuring access to intensive outpatient program (IOP) services in OTP settings and that these services are valuable to those with SUDs (for example, OUD), including individuals who cannot stabilize at a lower level of care or require more care than can be provided in office settings and individuals who have stabilized biomedical conditions and the need for close monitoring but no longer require a higher level of care for SUD treatment, such as partial hospitalization or inpatient care.

Please see the CY 2024 Outpatient Prospective Payment System (OPPS) final rule for the full policy discussion and additional details regarding the proposal to establish Medicare payment for IOP services provided by OTPs, as well as our responses to comments and final policies on these proposals.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO), and in so, doing agree to become accountable for the total cost and quality of care provided under Original Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending.

As of January 1, 2023, 10.9 million people with Medicare receive care from one of the 573,126 health care providers in the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country.[207] While the Shared Savings Program experienced a decrease in the number of ACOs and assigned beneficiaries for 2023, the policies finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968) are expected to grow participation in the program for 2024 and beyond, when many of the new policies are set to go into effect. These policies are expected to drive growth in participation, particularly in rural and underserved areas, promote equity, advance alignment across accountable care initiatives, and increase the number of beneficiaries assigned to ACOs participating in the program by up to four million over the next several years.[208] Accordingly, we expect these recently finalized changes will support CMS in achieving its goal of having 100 percent of people with Original Medicare in a care relationship with accountability for quality and total cost of care by 2030.[209]

To further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties, we proposed changes to the Shared Savings Program as described in section III.G. of the CY 2024 PFS proposed rule (88 FR 52416 through 52498), and we sought public comments which we summarize and respond to in sections III.G.2. through III.G.8. of this final rule. We proposed changes to the quality performance standard and reporting requirements under the Alternative Payment Model (APM) Performance Pathway (APP) within the Quality Payment Program (QPP) that would continue to move ACOs toward digital measurement of quality and align with the QPP. Further, we proposed to add a third step to the step-wise beneficiary assignment methodology under which we would use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as proposing related changes to how we identify assignable beneficiaries used in certain Shared Savings Program calculations. Additionally, we proposed updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines. We also proposed refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years, to cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth; further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries; specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; and apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year. We also proposed to refine our policies for the newly established advance investment payments (AIP) and

[207] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2023, available at *https://www.cms.gov/files/document/2023-shared-savings-program-fast-facts.pdf.*

[208] See CMS Press Release, ''CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship'', January 17, 2023, available at *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable.*

[209] Ibid. See also, Seshamani M., Fowler E., Brooks-LaSure C., Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.* CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper* (Innovation Center Strategic Objective 1: Drive Accountable Care, pages 13–17).

to make updates to other programmatic areas, including the program's eligibility requirements, and make timely technical changes to the regulations for clarity and consistency. Lastly, we solicited comments on potential future developments to Shared Savings Program policies, including with respect to incorporating a new track that would offer a higher level of risk and potential reward than currently available under the ENHANCED track, refining the three-way blended benchmark update factor and the prior savings adjustment, and promoting ACO and community-based organization (CBO) collaboration.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided risk models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided risk models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020

Federal Register (85 FR 27550) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020 (85 FR 27573 through 27587).

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), and the CY 2023 PFS final rule (87 FR 69779 and 69780). In the CY 2023 PFS final rule (87 FR 69777 through 69968), we finalized changes to Shared Savings Program policies, including to: provide advance shared savings payments in the form of advance investment payments to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk; establish a health equity adjustment to an ACO's Merit-based Incentive Payment System (MIPS) quality performance category score used to determine shared savings and losses to recognize high quality performance by ACOs serving a higher proportion of underserved populations; incorporate a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, and revise the approach for determining shared losses for ENHANCED track ACOs; modify the benchmarking methodology to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks, and to support the business case for ACOs serving high-risk and high dually eligible populations to participate, as well as mitigate bias in regional expenditure calculations for ACOs electing prospective assignment; expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings; make changes to policies within other programmatic areas, including the program's beneficiary assignment methodology, requirements related to marketing material review and beneficiary notifications, the SNF 3-day rule waiver application, and data sharing requirements.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Provisions

In sections III.G.2. through III.G.7. of this final rule, we summarize and respond to public comments received on the proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2024 PFS proposed rule (88 FR 52416 through 52498). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the proposals discussed in section III.G. of the CY 2024 PFS proposed rule and will not be addressed in this section of this final rule. As a general summary, we are finalizing the following changes to Shared Savings Program policies to:

- Revise the quality reporting and the quality performance requirements (section III.G.2. of this final rule), including the following:

++ Allow Shared Savings Program ACOs the option to report quality measures under the APP on only their Medicare beneficiaries through Medicare CQMs (section III.G.2.b. of this final rule).

++ Update the APP measure set for Shared Savings Program ACOs (section III.G.2.c. of this final rule).

++ Revise the calculation of the health equity adjustment underserved multiplier (section III.G.2.d. of this final rule).

++ Use historical data to establish the 40th percentile MIPS Quality performance category score used for the quality performance standard (section III.G.2.e. of this final rule).

++ Apply a Shared Savings Program scoring policy for excluded APP measures and APP measures that lack a benchmark (section III.G.2.f. of this final rule).

++ Require Spanish language administration of the CAHPS for MIPS survey (section III.G.2.g. of this final rule).

++ Align CEHRT requirements for Shared Savings Program ACOs with MIPS (section III.G.2.h. of this final rule).

++ Revise the requirement to meet the case minimum requirement for quality performance standard determinations (section III.G.2.j. of this final rule).

- Revise the policies for determining beneficiary assignment (section III.G.3 of this final rule).

++ Modify the step-wise beneficiary assignment methodology and approach to identifying the assignable beneficiary population (section III.G.3.a of this final rule).

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.b of this final rule).

- Revise the policies on the Shared Savings Program's benchmarking methodology (section III.G.4 of this final rule).

++ Modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b of this final rule).

++ Further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries (section III.G.4.c of this final rule).

++ Specify the circumstances in which CMS will recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year (section III.G.4.d of this final rule).

++ Specify use of the CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e. of this final rule).

• Refine AIP policies, including the following (section III.G.5 of this final rule):

++ Modify AIP eligibility requirements to allow an ACO to elect to advance to a two-sided model level of the BASIC track's glide path beginning with the third performance year of the 5-year agreement period in which the ACO receives advance investment payments.

++ Modify AIP recoupment and recovery polices to forgo immediate collection of advance investment payments from an ACO that terminates its participation agreement early in order to early renew under a new participation agreement to continue its participation in the Shared Savings Program.

++ Modify termination policies to specify that CMS will immediately terminate advance investment payments to an ACO for future quarters if the ACO voluntarily terminates its participation agreement.

++ Modify ACO reporting requirements to require ACOs to submit spend plan updates and actual spend information to CMS in addition to publicly reporting such information.

++ Modify AIP requirements to permit ACOs to seek reconsideration review of all quarterly payment calculations.

• Update Shared Savings Program eligibility requirements, including the following (section III.G.6 of this final rule):

++ Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.

++ Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the five most recent performance years.

• Make technical changes to references in Shared Savings Program regulations (section III.G.7 of this final rule), including to update assignment selection references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) in subpart G of the regulations, correct typographical errors in the definitions in § 425.20, and update certain terminology used in § 425.702.

We solicited comments in the CY 2024 proposed rule regarding our intent to propose future policies aligning the APP measure set for Sharing Savings Program ACOs with the quality measures under the ''Universal Foundation'' beginning in performance year 2025 (as described in section III.G.2.b.(2). of this final rule). We also solicited comments on MIPS Value Pathway reporting for specialists in Shared Savings Program ACOs (as described in section III.G.2.i. of this final rule).

In addition, in the CY 2024 PFS proposed rule, we solicited comments on potential future developments to Shared Savings Program policies (as discussed in section III.G.8. of this final rule), including: incorporating a track with higher risk and potential reward than the ENHANCED track; modifying the amount of the prior savings adjustment through potential changes to the 50 percent scaling factor used in determining the adjustment, as well as considerations for potential modifications to the positive regional adjustment to reduce the possibility of inflating the benchmark; potential refinements to the Accountable Care Prospective Trend (ACPT) and the three-way blended benchmark update factor over time to further mitigate potential ratchet effects within the update factor; and policies to promote ACO and CBO collaboration.

In combination, the policies we are adopting for the Shared Savings Program in this final rule are anticipated to improve the incentive for ACOs to sustainably participate and earn shared savings in the program. On net, total program spending is estimated to decrease by $330 million over the 10-year period 2024 through 2033. These changes are also anticipated to support the goals outlined in the CY 2023 PFS final rule for growing the program with a particular focus on including underserved beneficiaries.

Certain policies, including both existing policies and the new policies adopted in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: the modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b of this final rule and the refinements to AIP policies as described in section III.G.5. of this final rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations will be affected by the addition of a new third step of the beneficiary assignment methodology and the revisions to the definition of ''assignable beneficiary'' described in section III.G.3. of this final rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided risk models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for ACOs under two-sided risk models); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. As described in the Regulatory Impact Analysis in section VI. and elsewhere in this final rule, the changes we are finalizing to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Quality Performance Standard and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, and 2023 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80488, 83 FR 59707 through 59715, 87 FR 69860 through 69763, respectively).

b. Option for Shared Savings Program ACOs To Report Medicare CQMs

(1) Background

In the CY 2021 PFS final rule, we finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720). For performance year 2021 and subsequent years, ACOs are required to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). Pursuant to policies finalized under the CY 2022 and CY 2023 PFS (86 FR 65685; 87 FR 69858), to meet the quality performance standard under the Shared Savings Program through performance year 2024, ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey. In performance year 2025 and subsequent performance years, ACOs must report the three eCQMs/MIPS CQMs and the CAHPS for MIPS survey.

Since the CY 2021 PFS final rule was issued, interested parties have continued to express concerns about requiring ACOs to report all payer/all patient eCQMs/MIPS CQMs via the APP due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant TINs and varying EHR systems (86 FR 65257). In the CY 2022 PFS, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQM/MIPS CQMs (86 FR 65259). Additionally, one commenter questioned how data completeness standards could be met, given the issues of deduplication and patients adding or moving insurance coverage (87 FR 65260). In public comments to the CY 2023 PFS proposed rule, some commenters expressed multiple concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMS beginning in performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837). In the CY 2023 PFS final rule, we explained these comments went beyond the scope of our proposals. These comment letters included details of the commenters' concerns. Specifically, some commenters, which included ACOs, noted the financial burden of aggregating, deduplicating, and exporting eCQM data across multiple TINs and EHRs. Commenters, including ACOs, expressed concerns that the requirement to report all payer measures ties performance to patients that the ACO does not actively manage, increases the difficulty of meeting data completeness, and may negatively impact an ACO's performance by including patients seen by specialists. We also acknowledged that as the transition to reporting all-payer eCQMs/MIPS CQMs continues, the health equity adjustment which we finalized in the CY 2023 PFS final rule (87 FR 69842) will support ACOs that may experience challenges with the new quality reporting requirement and will provide an incentive for ACOs to serve underserved populations during the transition to reporting eCQMs/MIPS CQMs. In the CY 2023 PFS final rule, we stated that we are continuing to monitor the impact of these policies as we gain more experience with ACOs reporting all payer/all patient eCQMs/MIPS CQMs and, further, that we are exploring how to address some of the concerns related to data aggregation and the all payer requirement and may revisit these and related issues in future rulemaking based on lessons learned (87 FR 69833).

Consistent with our goal to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs, in the CY 2023 PFS final rule we extended the eCQM/MIPS CQM reporting incentive through PY 2024 to provide an incentive to ACOs to report the eCQMs/MIPS CQMs, while allowing them time to gauge their performance on the eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025 (87 FR 69835). Building on our goal to provide technical support to ACOs and to help ACOs build the skills necessary to aggregate and match patient data to report all payer/all patient eCQMs/MIPS CQMS, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://youtu.be/LDrpoGnnRQs.* The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf.* We are committed to continuing to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting.

(2) Reporting the Medicare CQMs

In light of the concerns raised by ACOs and other interested parties and our commitment to supporting ACOs in the transition to digital quality measure reporting, for performance year 2024 and subsequent performance years as determined by CMS, we proposed in the CY 2024 PFS proposed rule to establish the Medicare CQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP (88 FR 52420 through 52424). As stated in the CY 2024 PFS proposed rule (88 FR 52420), Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to

report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, we believe that Medicare CQMs would address the concern raised by ACOs that—for ACOs with a higher proportion of specialty practices and/or multiple EHR systems—the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, we believe that ACOs, particularly ACOs with a higher proportion of specialty practices and/or multiple EHRs, would be able to utilize Medicare Part A and B claims data to help identify the ACO's eligible population and validate the ACO's patient matching and deduplication efforts. For these reasons, we believe that it is appropriate to establish Medicare CQMs as a new collection type for Shared Savings Program ACOs only.

In the CY 2024 PFS proposed rule (88 FR 52420), we stated that we recognized that Medicare CQMs might not be the most suitable collection type for some ACOs, particularly ACOs with a single-EHR platform, a high proportion of primary care practices, and/or ACOs composed of participants with experience reporting all payer/all patient measures in traditional MIPS. We also encouraged ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to our proposal to report quality data utilizing the Medicare CQMs collection type, in performance year 2024, ACOs would have the option to report quality data utilizing the CMS Web Interface measures, eCQMs, and/or MIPS CQMs collection types (88 FR 52420). As described in our proposal, in performance year 2025 and subsequent performance years as determined by CMS, ACOs would have the option to report quality data utilizing the eCQMs, MIPS CQMs, and/or Medicare CQMs collection types (88 FR 52420).

We stated in the CY 2024 PFS proposed rule (88 FR 52421) that our long-term goal continues to be to support ACOs in the adoption of all payer/all patient measures. We would monitor the reporting of quality data utilizing the Medicare CQMs collection type. For example, one indicator to evaluate Medicare CQMs would be to assess if there are any Medicare CQMs topped out as described at § 414.1380(b)(1)(iv). Therefore, in the 4th year the measure could be removed and would no longer be available for reporting during the performance period (83 FR 59761). Once the measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors (83 FR 59763). Separately, we may specify higher standards, new measures, or both—up to and including proposing to sunset the Medicare CQM collection type in future rulemaking—to ensure that Medicare CQMs conform to the intent of section 1899(b)(3)(C) of the Act and the priorities established in the CMS National Quality Strategy (88 FR 52421).

We also remain steadfast in our commitment to support providers in the transition from traditional MIPS to APMs and Advanced APMs. In our proposal, we acknowledged that Medicare CQMs may not be the preferred collection type for all ACOs. ACOs that are composed of participants with experience reporting all payer/all patient measures in traditional MIPS would continue to have the option to report all payer/all patient measures (88 FR 52421). In supporting providers in the transition from traditional MIPS to APMs and Advanced APMs, we also recognized the corresponding need to support ACOs in the transition to all payer/all patient reporting (88 FR 52421). In addition to the technical support that we would continue to provide ACOs, we believe that the Medicare CQM collection type would aid some ACOs in the transition to all payer/all patient measures by allowing ACOs to focus patient matching and data aggregation efforts on ACO professionals with specialties used in assignment while the ACO builds the infrastructure necessary to report on a broader eligible population (88 FR 52421).

To facilitate the reporting of Medicare CQMs, we proposed to amend the definition of ''Collection Type'' to include the Medicare CQM as an available collection type in MIPS for ACOs that participate in the Shared Savings Program (88 FR 52563). We noted that the Medicare CQMs collection type would serve as a transition collection type and be available as determined by CMS (88 FR 52421). Additionally, we proposed to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category (88 FR 52567).

A Medicare CQM is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare FFS beneficiaries, instead of its all payer/all patient population. We proposed to define a beneficiary eligible for Medicare CQMs at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs who is either of the following:

- A Medicare FFS beneficiary (as defined at § 425.20) who—

++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS).

- A Medicare FFS beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

While this definition refers to beneficiaries that have been assigned to an ACO, it nonetheless differs from our basic assignment methodology described under subpart E and from the concept of assignable beneficiary defined at § 425.20. Specifically, the use of the terms of ''claim'' (instead of primary care services) and ''measurement period'' (instead of assignment window) in the definition are synchronous with the application of all payer/all patient MIPS CQM Specifications in reporting Medicare CQMs. For example, we define primary care services as the set of services identified by the Healthcare Common Procedure Coding System (HCPCS) and revenue center codes designated under § 425.400(c). Each all payer/all patient MIPS CQM Specification identifies eligible encounters that, in part, identify patients that should be included in the measure's eligible population.

In the CY 2024 PFS proposed rule, we stated that our proposed definition for beneficiary eligible for Medicare CQMs is intended to create alignment with the all payer/all patient MIPS CQM Specifications (88 FR 52421). The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings

Program only partially overlap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications (88 FR 52421). Applying primary care service codes or deferring to the basic assignment methodology under subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of limiting the codes used to identify eligible encounters in the Medicare CQM Specification to only the codes that overlap with primary care services (88 FR 52421). Similarly, we defined the assignment window as the 12-month period used to assign beneficiaries to the ACO. In a manner that is identical to the all payer/all patient MIPS CQM Specifications, the Medicare CQM Specifications would identify the measurement period applicable to each measure (88 FR 52421). Applying the 12-month period used in assignment or deferring to the basic assignment methodology under Subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of reducing the beneficiaries eligible for Medicare CQMs to only patients that had an eligible encounter during the overlap of the assignment window as defined at § 425.20 and the measurement period as defined in the Medicare CQM Specifications (88 FR 52421).

In the CY 2024 PFS proposed rule, we proposed to establish the data completeness criteria threshold for the Medicare CQM collection type, in which a Shared Savings Program ACO that meets the reporting requirements under the APP would submit quality measure data for Medicare CQMs on the APM Entity's applicable beneficiaries eligible for the Medicare CQMs, as proposed at § 425.20, who meet the measure's denominator criteria (88 FR 52567). We also proposed the following data completeness criteria thresholds for Medicare CQMs:

- At least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, respectively.
- At least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

With the Medicare CQMs collection type serving as a transition collection type under the APP that would be available as determined by CMS, we proposed in the CY 2024 PFS proposed rule to establish the aforementioned data completeness criteria thresholds in advance of the applicable performance periods (88 FR 52567). In our proposal, we recognized that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP (88 FR 52421). We would assess the availability of the Medicare CQM as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

As described in our proposal, an ACO that reports Medicare CQMs in an applicable performance year would aggregate patient data for beneficiaries who are eligible for Medicare CQMs, as proposed at § 425.20, across all ACO participants (88 FR 52422). The ACO would then match the aggregated patient data with each Medicare CQM Specification to identify the eligible population for each measure. The ACO's aggregated ACO submission must account for 100 percent of the eligible and matched patient population across all ACO participants. Data completeness is calculated based on submitted data. We believe that the proposal to establish the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data. Specifically, our proposal to define beneficiaries eligible for Medicare CQMs aims to focus ACOs' reporting efforts on beneficiaries with an encounter with an ACO professional with a specialty used in assignment and thereby reduce the potential for missing or un-matched patient data. It is important to note that ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO. To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups described at § 414.1370.

To facilitate population-based activities related to improving health through quality measurement of Medicare CQMs and to aid ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs, we stated in the CY 2024 PFS proposed rule that we would provide ACOs a list of beneficiaries who are eligible for Medicare CQMs within the ACO. As set forth in our regulations at § 425.702, we share certain aggregate reports with ACOs under specific conditions, and this information includes demographic data that represents the minimum data necessary for ACOs to conduct health care operations work, which includes demographic and diagnostic information necessary to report quality data. We proposed that the list of beneficiaries eligible for Medicare CQMs to be shared once annually, at the beginning of the quality data submission period (88 FR 52422). Since we would not have full run-out on performance year claims data prior to the start of the quality data submission period, the list of beneficiaries eligible for Medicare CQMs would not be a complete list of beneficiaries that should be included on an ACO's Medicare CQMs reporting. ACOs would have to ensure that all beneficiaries that meet the applicable Medicare CQM Specification and also meet the definition of a beneficiary eligible for Medicare CQMs proposed under § 425.20 are included in the ACO's eligible population/denominator for reporting each Medicare CQM. We proposed to add new paragraph (c)(1)(iii) to § 425.702 as follows:

For performance year 2024 and subsequent performance years, at the beginning of the quality submission period, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its FFS population.

- The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Beneficiary name.
  - ++ Date of birth.
  - ++ Beneficiary identifier.
  - ++ Sex.
- Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

++ Demographic data such as enrollment status.

++ Health status information such as risk profile and chronic condition subgroup.

++ Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

The list of beneficiaries eligible for Medicare CQMs shared by CMS would aim to help ACOs aggregate, and match and deduplicate patient data. We proposed including the minimum data necessary to facilitate the reporting of Medicare CQMs including beneficiary identifier, gender, date of birth and

death (if applicable), chronic condition subgroup, and the NPIs of the top three frequented providers in the ACO (88 FR 52422). We also proposed to include health status information such as risk profile and chronic condition subgroup to the extent that such data would aid ACOs in identifying patients that meet the denominator criteria for the Medicare CQM Specifications (88 FR 52422). We would also provide technical assistance to ACOs when reporting the Medicare CQMs, including providing technical resource documents. Our proposal to create Medicare CQMs is intended to support ACOs through the transition to reporting the all payer/all patient eCQMs/MIPS CQMs and to facilitate quality assessment improvement activities (as described in the definition of health care operations at 45 CFR 164.501) since we would provide ACOs with a list of beneficiaries eligible for Medicare CQM reporting to aid in patient matching and data deduplication.

In the CY 2021 PFS final rule (85 FR 84733), we finalized the following three all payer/all patient eCQMs/MIPS CQMs under the APP for performance year 2021 and subsequent performance years:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

In section IV.A.4.e of the CY 2024 PFS proposed rule (88 FR 52422), we proposed to add these measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years. ACOs may report the three Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

As a result, to meet the Shared Savings Program reporting requirements:

- For performance year 2024, an ACO would be required to report the 10 measures under the CMS web interface measures, or the three eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.
- For performance year 2025 and subsequent performance years, an ACO would be required to report the three eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.

ACOs may still report via the APP using the all payer/all patient eCQM/MIPS CQM collection types and may report different collection types for each measure.

In conjunction with the proposed changes to § 425.512(a)(2), we proposed to incorporate Medicare CQMs into the existing quality performance standard policies for new ACOs at § 425.512(a)(2)(i), (ii), and (iii) (88 FR 52423). Accordingly, we proposed that for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO reports data via the APP and meets MIPS data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), the ACO will meet the quality performance standard under the Shared Savings Program, if:

- For performance year 2024. The ACO reports the 10 CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and administers a CAHPS for MIPS survey under the APP.
- For performance year 2025 and subsequent performance years. The ACO reports the three eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey under the APP.

Additionally, we proposed to incorporate Medicare CQMs into the existing policies at § 425.512(a)(5)(iii) for when an ACO would not meet the quality performance standard or the alternative quality performance standard. Accordingly, we proposed that an ACO would not meet the quality performance standard or the alternative quality performance standard if:

- For performance year 2024, if an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.
- For performance year 2025 and subsequent performance years, if an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.

We did not propose to add Medicare CQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) for performance year 2024. The eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report the all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025.

Under the goals of the CMS National Quality Strategy, we are moving towards a building-block approach to streamline quality measure across CMS quality programs for the adult and pediatric populations. This ''Universal Foundation'' of quality measure would focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. Following in the proposals under MIPS, we intend to propose future policies aligning the APP measure set for Sharing Savings Program ACOs with the quality measures under the ''Universal Foundation'' beginning in performance year 2025. These Universal Foundation measures are proposed to be adopted into the existing the Value in Primary Care MVP as discussed in Table B.11 of Appendix 3: MVP Inventory of the CY 2024 PFS proposed rule (88 FR 52423). By creating alignment with the Universal Foundation in the Value in Primary Care MVP and the APP measure set by 2025, primary care clinicians would develop familiarity with the same quality measures that are reported in the APP while in MIPS. We expect this alignment would reduce the barriers to participation in the Shared Savings Program. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to establish the Medicare CQMs as a new collection type for Shared Savings Program ACOs. Several commenters were supportive of our proposal that Medicare CQMs would be reported by Shared Savings Program ACOs on only the ACO's Medicare FFS beneficiaries. Commenters stated that reporting on Medicare patients will help ACOs bridge to all payer reporting and that the policy will encourage more ACOs to participate in the Shared Savings Program and transition into accountable care. Commenters also stated that the policy will help expand the number of beneficiaries in accountable care and support CMS' strategic direction. Another commenter shared that Medicare CQMs will ensure a more direct comparison between populations than the all-payer eCQM and will mitigate complications related to payer mix. Another commenter noted that reporting specific to Medicare beneficiaries is the most appropriate measure of ACO quality performance. One commenter stated that limiting

reporting to Medicare patients, versus all payer data, will be an important step towards reducing burden for providers in ACOs and encouraging specialist participation. Another commenter shared that CQMs for the Medicare FFS patients with a treatment relationship to ACO professionals with a primary care or related specialty ensures that CMS receives meaningful quality information on the ACO's influence on the Medicare FFS population.

A few commenters agreed that Medicare CQMs would address most of ACOs' concerns regarding all payer/all patient reporting, such as difficulties reporting for those ACOs with a higher proportion of specialty practices or groups with multiple EHRs, beneficiaries with no primary care relationship, and shouldering a greater burden when matching and deduplicating patient records. Other commenters noted Medicare CQMs reduce concerns about specialists reporting on primary care focused measures. Commenters shared that Medicare CQMs were responsive to several key concerns raised by ACOs regarding feasibility of implementing eCQMs/MIPS CQMs, including equity concerns.

One commenter agreed that Medicare CQMs would serve as an intermediary step to help ACOs build the infrastructure, skills, knowledge, and expertise required to report eCQMs/MIPS CQMs. A few commenters stated that Medicare CQMs will provide a learning period and additional time to address barriers in reporting eCQMs.

A few commenters noted that Medicare CQMs will ease the concern with the state of readiness of reporting on eCQMs and reduce administrative burden and cost relative to an all-payer reporting requirement. One commenter stated that the transition away from the Web Interface reporting has created a large resource burden on ACOs to develop new processes, hire vendors, and manage frequently changing requirements, and additional support and flexibility will allow ACOs to meet these requirements and promote digital quality measurement reporting rather than creating additional costs and unnecessary burden.

One commenter stated that Medicare CQMs are far better matched to ACOs' reporting capabilities than all-payer eCQMs, which would otherwise be required if this proposal is not finalized. Another commenter noted that ACOs with participants on multiple EHR systems may still be challenged when gathering and aggregating data to report, but the option to report using Medicare CQMs should provide ACOs with adequate opportunities to overcome this challenge and prepare them to report all payer/all patient eCQMs/MIPS CQMs.

Response: We appreciate commenters' recognition of the role that Medicare CQMs could have in advancing digital quality measurement, supporting ACOs in developing processes to gather and aggregate data for care coordination and quality improvement, and bridging the gap to all payer quality measurement.

Comment: Several commenters expressed concern about the implementation of Medicare CQMs beginning in performance year 2024. A few commenters stated that ACOs will most likely need more time to implement these changes than allotted in this proposal. One commenter stated that we should limit reporting to the list of beneficiaries eligible for Medicare CQMs provided by CMS in the initial performance year of Medicare CQMs to ensure greater uptake by ACOs given the complexity and time it will take to identify patients. One commenter suggested delaying the implementation of Medicare CQMs until performance year 2027 if reporting is not limited.

Response: We acknowledge concerns about the implementation of Medicare CQMs. Implementing Medicare CQMs in performance year 2024 is appropriate as Medicare CQMs are an optional collection type. Medicare CQMs are intended to support ACOs in transitioning to all payer/all patient measures and to address concerns about the feasibility of reporting eCQMs/MIPS CQMs that requires aggregating and deduplicating an even larger volume of patient data, which would otherwise have been required starting in 2025. We recognize that Medicare CQMs might not be the suitable collection type for some ACOs. In performance year 2024, ACOs would have the option to report quality data utilizing the CMS Web Interface measures, eCQMs, and/or MIPS CQMs collection types. Under our proposal, in performance year 2025 and subsequent performance years, ACOs would have the option to report quality data utilizing the eCQMs, MIPS CQMs, and/or Medicare CQMs collection types. We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure.

In response to comments which suggest limiting reporting, as discussed later in this section of the final rule, we are modifying our proposal to provide a quarterly list of beneficiaries eligible for Medicare CQMs which will provide ACOs with more frequent cumulative list of beneficiaries eligible for the measure to facilitate population-based activities related to improving health through quality measurement and to aid ACOs in the process of patient matching and data aggregation necessary for reporting quality measures.

Comment: One commenter applauded us for our willingness to assist ACOs that might be struggling to operationalize payer-agnostic reporting solutions but disagreed with Medicare CQMs being unilaterally offered to only Shared Savings Program ACOs and not to organizations that may struggle with the exact same reporting barriers on the MIPS reporting side. The commenter questioned why the Medicare CQM reporting option was not also made available in the form of a (modified) eCQM and noted that there are organizations participating in either the Shared Savings Program or MIPS who report via eCQMs that may face the same barriers of multiple EHR systems and/or high proportions of specialty practices that we have cited as an impetus for the proposal of Medicare CQMs.

Response: We refer the reader to past MIPS rules, where CMS has consistently stated that it would use all-payer measures in MIPS where possible to create a more comprehensive picture of the practice performance (81 FR 77098). Alongside that goal, we also stated that we aim to simplify reporting and reduce administrative burden (81 FR 77098). ACOs face unique challenges in matching patients and aggregating their data for quality measures. These challenges are not commonly shared by MIPS eligible clinicians. Further, we did not propose to establish a Medicare eCQM because of the complexity and potential technical burden ACOs and their vendors would face in implementing eCQMs for a Medicare-only population. As discussed in the CY 2024 PFS proposed rule (88 FR 52420), we proposed Medicare CQMs in light of concerns raised by ACOs and other interested parties and our commitment to supporting ACOs in the transition to digital quality measure reporting. Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, Medicare CQMs would address the concern raised by ACOs that for ACOs with a higher proportion of specialty practices the

broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, given ACOs are commonly made up of multiple practices using multiple EHRs, ACOs would be able to utilize Medicare Parts A and B claims data to help identify the ACO's eligible population and to validate the ACO's patient matching and deduplication efforts. For these reasons, it is appropriate to establish Medicare CQMs as a new collection type for Shared Savings Program ACOs only.

Comment: Many commenters raised questions and concerns regarding how CMS will determine the appropriate Medicare CQM population for these measures. Some commenters noted that the proposed denominator eligibility criteria are similar to but differ in timeline from the current assignment methodology and that this creates unnecessary complexity, potentially leading to confusion in identifying the appropriate Medicare ACO population. A few commenters suggested we combine the new Medicare CQM assignment methodology with the existing assignment methodology, which would mitigate potential challenges and ensure a smoother implementation process. A few commenters recommended that CMS limit the list of beneficiaries eligible for Medicare CQMs to beneficiaries that are attributed to the ACO. One commenter stated that depending on an ACO's selected assignment methodology, they may not be fully aware of their full assignable population and that we should limit reporting under Medicare CQMs to the ACO's assigned population rather than the assignable. Several commenters asked that we clarify if the list of beneficiaries eligible for Medicare CQMs is limited to assigned beneficiaries or if it includes all assignable beneficiaries eligible for the measure. A few commenters suggested using the existing ACO population base to create less confusion.

Response: In response to commenters' suggestions that we align the definition of beneficiary eligible for Medicare CQM with our assignment methodology, we note that our proposal aims to align Medicare CQMs with the all payer/all patient measure specifications because Medicare CQMs are intended to support ACOs in the transition to all payer/all patient measures. For reasons previously mentioned, our proposal would limit Medicare CQM reporting to beneficiaries that had an encounter with an ACO professional with a specialty used in assignment or who were voluntarily assigned to the ACO. Our proposed approach balances our commitment to the transition to all payer/all patient measures and the need to provide additional support to some ACOs as they build the skills and infrastructure necessary to report digital quality measures.

In addition, the term ''attributed'' means that the patient had the plurality of their care with the ACO. The definition of a beneficiary eligible for Medicare CQM does not require that a patient had the plurality of their care with the ACO and, as such, the list of beneficiaries eligible for Medicare CQMs is broader than the ACO's attributed population.

Comment: One commenter recommended that we limit the list to Medicare patients who have an encounter with a physician with a specialty utilized in step 1 of attribution under the current assignment methodology. A commenter stated that the proposal limits quality reporting to Medicare patients with a primary care visit instead of all patients with any type of visit.

Response: As discussed in the June 2015 final rule, primary care services can generally be defined based on the type of service provided, the type of provider specialty that provides the service, or both (80 FR 32748). The list of provider specialties used in assignment was based on public comments and recommendations by CMS medical officers knowledgeable about the services typically performed by physicians and non-physician practitioners (80 FR 32750). In finalizing the list of specialties used in assignment, we attempted to limit the list of physician specialty types that would be excluded from the assignment process to those physician specialties that would very rarely, if ever, provide primary care to beneficiaries (80 FR 32750). Tethering the Medicare CQM population to claims encounters with ACO professionals with specialties used in assignment limits the ACO's quality reporting to patients with a care relationship with the ACO and is responsive to feedback from ACOs and other interested parties.

Further, our proposed definition for a beneficiary eligible for Medicare CQMs does not require a primary care visit in order to create alignment with the all payer/all patient MIPS CQM Specifications. The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program only partially over-lap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications. Applying primary care service codes or deferring to the basic assignment methodology under subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of limiting the codes used to identify eligible encounters in the Medicare CQM Specification to only the codes that overlap with primary care services.

Medicare CQMs are an all beneficiary Medicare measure (not just ACO assigned beneficiaries) and is designed to help ACOs address challenges with aggregating patient data required to report Medicare CQMs and the all payer/all patient MIPS CQMs and eCQMs in the future.

Comment: One commenter asked how the assignable Medicare population reporting requirements will apply to ACOs that have elected prospective versus retrospective assignment.

Response: Our proposed definition for beneficiary eligible for Medicare CQM is the same for ACOs under preliminary prospective assignment with retrospective reconciliation and ACOs under prospective assignment. In a manner that is identical to the all payer/all patient MIPS CQM Specifications, the Medicare CQM Specifications would identify the measurement period applicable to each measure along with the beneficiary encounters for inclusion in the measure regardless of the ACO's assignment election.

Comment: One commenter requested that CMS provide further technical specifications on the eligibility of beneficiaries who meet the CQM requirement, the process for identifying these beneficiaries within EMRs/Vendor systems, and the impacts of FQHC/RHC in quality score as these entities would not traditionally be included in MIPS. This commenter added that this will allow ACOs to better determine next steps for moving away from the Web Interface reporting, while allowing better stewardship of resources to do this work.

Response: As stated in our proposal, ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO (88 FR 52422). To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups described at § 414.1370 (88 FR 52422). It may be helpful to note that the three quality measures (for example, eCQMs, MIPS CQMs, Medicare CQMs) included

in the APP measure set for PY 2024 overlap with measures that health centers report via the Uniform Data System (UDS). This experience reporting quality measures may be helpful for health centers that participate in the Shared Savings Program as they transition to the APP measure set.

Further, we will provide technical guidance and specifications to ACOs to support ACOs in the identification of beneficiaries eligible for Medicare CQMs. Specifically, parameters for the list of beneficiaries eligible for Medicare CQMs will be included along with the list of beneficiaries eligible for Medicare CQMs in the ACO's Quarterly Informational Report Packages.

Comment: A few commenters were concerned that ACOs reporting Medicare CQMs would need to collect data from specialist practices that do not care for any Shared Savings Program attributed patients.

Response: Medicare CQMs include beneficiaries who had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician, who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS or is assigned to the ACO through voluntary alignment (88 FR 52421). We note that in the proposed definition of beneficiary eligible for Medicare CQMs under § 425.20, we incorrectly used the phrase ''certified nurse specialist'' (88 FR 52754). In this final rule, we are finalizing our proposed definition of beneficiary eligible for Medicare CQMs under § 425.20, with a modification for clarity, and to ensure consistency of terminology across provisions, to reference ''clinical nurse specialist'' instead of ''certified nurse specialist.''

We recognize the care delivered to beneficiaries by a range of clinicians. ACOs that include specialists included in the Medicare CQM definition would need to collect data from those specialists in order to submit true, accurate, and complete data when reporting Medicare CQMs. ACOs and other interested parties can access the list of specialty designations used in assignment in Table 9 of the ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications.'' This document is updated annually and can be access on the Shared Savings Program website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations*. As discussed elsewhere in this section of the final rule, we will provide ACOs with a list of beneficiaries eligible for Medicare CQMs that can be used by ACOs in identifying encounters with specialists that should be included in quality measure reporting and improvement.

Comment: Several commenters had concerns related to data aggregation and deduplication when submitting Medicare CQMs. One commenter stated that, because the eligible population for Medicare CQMs would be broader than the ACO assigned population, many ACOs must still hire data aggregation vendors. A few commenters noted that most ACOs will require significant process workflow and software development if targeting only Medicare beneficiary data. A few commenters stated that ACOs face an initial reporting burden of collecting data from member practices on disparate EMRs and that this burden exists regardless of the scale of data collected. Commenters stated that Medicare CQMs do not resolve underlying challenges with electronic quality measurement and require significant manual data aggregation and patient matching across many tax identification numbers (TINs) and electronic health records (EHRs) types. One commenter stated that eliminating the all payer/all patient approach is helpful for large ACOs with multiple participants and EHR systems, but that the Medicare CQM option is still complex and requires data aggregation, patient matching and deduplication.

Response: We acknowledge commenters concerns related to data aggregation and deduplication when submitting Medicare CQMs and recognize ACOs will have to develop these capabilities to aggregate and exchange data either in-house or through vendors but that the movement toward digital quality data will help further enhance ACOs' care coordination and quality improvement capabilities. As discussed elsewhere in this section of the final rule, we will provide ACOs with a list of beneficiaries eligible for Medicare CQMs to support ACOs in the aggregation and deduplication of patient data.

In our proposal, we recognized that that Medicare CQMs may not be the suitable collection type for some ACOs (88 FR 52420). We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to our proposal to report quality data utilizing the Medicare CQMs collection type, in performance year 2024, ACOs would have the option to report quality data utilizing the CMS Web Interface measures, eCQMs, and/or MIPS CQMs.

To support ACOs in the transition to digital quality measures, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Specifically, the webinar focused on the APP, guidance and resources for reporting via the APP, and questions and answers from ACOs and their vendors. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://youtu.be/LDrpoGnnRQs* and *https://qpp.cms.gov/resources/webinars*. The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf*. The guidance describes how ACOs should identify an appropriate combination of data variables to achieve consistent and replicable patient matching that provides the most complete and accurate data to meet the measure specification and valid and reliable measure performance. The guidance highlights these common variables that ACOs have used to achieve patient matching rates of 90 percent or higher, which is sufficient for quality reporting, and goes on to indicate that ACOs should use 100 percent of this matched, deduplicated population to determine the eligible population for each measure.

Comment: Some commenters noted that the Medicare CQM proposal does not advance digital quality measurement as it leaves the eCQM reporting option unchanged, while one commenter noted that that Medicare CQMs do not advance digital quality measurement because CQMs do not use CEHRT. A commenter urged CMS to focus on addressing the existing gaps in digital infrastructure and equity—a prerequisite to advancing digital measurement—and to continue working with the Office of the National Coordinator for Health IT (ONC) to advance consensus-based standards for digital quality measurement and interoperability.

Another commenter stated that Medicare CQMs will not inherently advance their capabilities to report on eCQMs such as the adoption of CEHRT across ACO participants, processes to

enable aggregation of quality measurement data across all ACO participants, the ability to assess data completeness and efficiently calculate quality measures outcomes or the generation of QRDA–III files. Another commenter advocated for CMS to identify an alternative pathway to transmit data in a standardized way to enable successful patient matching, such as use of a national patient identifier or revisions to QRDA I formats. One commenter stated that incorporating additional demographics in the data (QRDA I or FHIR) may improve patient matching and support deduplication and suggested that CMS consider introducing extra demographic criteria in their CMS Implementation Guide or QRDA I specifications to enhance patient matching accuracy.

Response: Medicare CQMs would help ACOs build the infrastructure, skills, knowledge, and expertise necessary to aggregate patient data consistent with our goals described in our Digital Quality Measurement (dQM) Strategic Roadmap, which can be accessed at *https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*. Improving data aggregation skills will support ACOs in their adoption of all payer/all patient eCQMs/MIPS CQMs and the transition to dQMs.

As discussed in Domain Three: Optimize Data Aggregation of the dQM Strategic Roadmap, data aggregators currently play a vital role in the acquisition, processing, transmission, analysis, and application of digital health information. Aggregation of digital data is critical for measures that depend on information from multiple providers or sources. However, a solution that requires CMS to serve as the only data aggregator is neither cost effective nor desirable for our goals for accountable care. We recognize that providers and care settings are at different stages of readiness to adopt dQMs and that the timeframe for transition to dQMs across different quality reporting programs varies. As stated in our dQM Strategic Roadmap, we anticipate the transition may be paced with the uptake of FHIR API technology.

In response to suggestions regarding QRDA I or other file formats, QRDA I is based on the Health Level Seven International® (HL7®) Clinical Document Architecture (CDA) and does include demographic specifications. However, we note we did not propose QRDA I for Medicare CQMs and, further, that implementation guide updates are beyond the scope of our proposal. As described elsewhere in this section of the final rule, to support ACOs in the aggregation and deduplication of patient data, we will provide ACOs with a quarterly list of beneficiaries eligible for Medicare CQM.

Comment: One commenter stated that Medicare CQMs will still require creating a QRDA file, which increases the administrative burden and cost for ACOs.

Response: Medicare CQMs conform to the measure specifications included on MIPS CQMs, not eCQMs. Thus, there is no data type designation determination requiring QRDA. We anticipate providing technical guidance to ACOs and their vendors to support successful adoption of Medicare CQM reporting in accordance with the use of multiple data submission types as permitted under the MIPS data submission standards.

Comment: A couple commenters requested clarification as to whether a third party intermediary is required to submit Medicare CQMs if an ACO has multiple electronic health record systems, or if an ACO can collect, match, and de-duplicate their own data if they have the expertise.

Response: Medicare CQMs may be submitted by the ACO or a third party intermediary. Medicare CQMs would be subject to the data submission requirements detailed at § 414.1325 which provide, ''[e]xcept for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician or group by a third party intermediary described at § 414.1400.''

Comment: We received several comments in support of our proposal to provide ACOs a list of beneficiaries who are eligible for Medicare CQMs within the ACO. However, many commenters stated that it will add significant burden for ACOs to ensure that the list is complete, and that we should limit reporting of Medicare CQMs to the list of beneficiaries provided by CMS. One commenter stated ACOs will struggle to comprehensively identify the patient population for which they must report Medicare CQMs. Another commenter noted that ACOs operating under prospective assignment with retrospective reconciliation may not have the data necessary to determine their assignable populations. Several commenters suggested that limiting the reporting of Medicare CQMs to the patients provided on the CMS-issued list at the beginning of the reporting period would reduce the burden associated with reporting significantly and make the option a more feasible one for 2024. One commenter asked how ACOs could use the list of beneficiaries eligible for Medicare CQMs with incomplete claims data at the start of the reporting year. The commenter stated that CMS should ensure that the population is clear and knowable to ACOs during the reporting period.

One commenter noted that sharing data once annually may lead to missing data points and may compromise data completeness, while another commenter expressed that the proposal creates confusion, and CMS would not be able to provide timely beneficiary information to ACOs for reporting purposes. One commenter suggested that we limit reporting requirements to beneficiaries that are aligned at both the beginning and the end of the performance period, while another commenter recommended that calculations be performed on the back end of the reporting trail by CMS and that the list is automatically furnished biannually. Other commenters suggested that CMS should establish the set of beneficiaries for which ACOs report Medicare CQMs based on third quarter roster file it provides to ACOs and the beneficiaries that have a claim in the last quarter and reduce burden by adding additional demographic data elements. The commenter requested that we work with interested parties to come up with a process to ensure ACOs know/can report on their eligible patients.

Response: We acknowledge the concerns and challenges raised by commenters regarding ACOs needing to ensure that the list of beneficiaries eligible for Medicare CQMs is complete. To support ACOs in reporting Medicare CQMs, we are modifying our proposal to provide ACOs with a list of beneficiaries eligible for Medicare CQMs once annually, at the beginning of the quality data submission period. Instead, we will provide each ACO with a list of beneficiaries eligible for Medicare CQMs each quarter throughout the performance year as part of the ACO's Quarterly Informational Reports Packages in order to give ACOs access to the full 12 months of encounters necessary to report Medicare CQMs. The list will be cumulative and updated quarterly to reflect the most recent quarter's data. For example, encounters with dates of service January 1st through March 31st of the performance year will be included in the first quarter list. First quarter report packages are typically delivered to ACOs in May of the performance year. The second quarter list will include encounters with dates of service January 1st through June 30th of the performance year. Second quarter report packages are typically delivered to ACOs in August of the

performance year. The third quarter list will include encounters with dates of service January 1st through September 30th of the performance year. Third quarter report packages are typically delivered to ACOs in November of the performance year. Lastly, the fourth quarter list of beneficiaries eligible for Medicare CQMs will include encounters with dates of service January 1st through December 31st of the performance year. Fourth quarter report packages are typically delivered to ACOs in February of the year following the performance year. The Quarterly Informational Reports Packages are delivered to ACOs via the data hub in the ACO Management System (ACO–MS). This list will reduce burden relative to the proposed annual list by giving ACOs a complete list of beneficiaries eligible for Medicare CQMs. The fourth quarter list will allow ACOs to verify that they have accounted for all beneficiaries eligible for Medicare CQMs.

The cadence of updating the list throughout the performance year will enable ACOs to aggregate data throughout the performance year. ACOs may use the fourth quarter list to ensure that all beneficiaries eligible for Medicare CQMs are captured in the ACOs' reporting. Sharing data throughout the performance year will allow ACOs to prepare the majority of their submission data in advance of the submission period and then use the fourth quarter list to ensure that all beneficiaries that are eligible for Medicare CQMs are captured in the ACOs' reporting.

Additionally, the quarterly list will reduce reporting burden relative to the proposed annual list by including beneficiary-level age, diagnosis, encounter, and exclusion flags on the list of beneficiaries eligible for Medicare CQMs to aid ACOs in identifying the denominator eligible population for each measure to the extent that such data can be identified through claims and Medicare administrative systems. It is important to note that these flags are meant to assist ACOs in the aggregation of data and do not replace the need for ACOs to evaluate their patient population against each Medicare CQM Specification prior to submission, including confirming the beneficiaries meet the denominator criteria for the measure. In a manner identical to MIPS CQM Specifications, the Medicare CQM Specifications will allow for the use of multiple sources of data (for example, multiple EHRs, paper records, registries, patient management systems) to compile a measure's numerator and denominator. ACOs should use all available data, including the list of beneficiaries eligible for Medicare CQMs provided by CMS, to ensure that the ACO's quality data is true, accurate, and complete.

Comment: Several commenters had concerns about the timing of the claims run-out that would be used to determine the complete list of beneficiaries eligible for Medicare CQMs. A commenter shared that it would be helpful for CMS to define what is considered the recommended time to allow for claims run out for the patient list to be considered completed and to identify on the list patients that have been ''excluded'' from the reporting denominator. One commenter suggested that we extend the reporting window such that ACOs will have full 90-day claims run out for Medicare CQM data; for example, move the reporting deadline from March 31 to at least April 30, providing this can be done without delaying ACO financial reconciliations. The commenter added that ACOs should have confidence they can access the full and accurate list of patients whose data is used in quality measurement. One commenter asked if we considered a claims run-out period prior to the submission window for Medicare CQMs to ensure that the ACO can determine the appropriate and accurate measure population prior to calculation and submission.

A few commenters noted that the proposal's focus on claims during the measurement period could lead to discrepancies due to claims reporting delays of up to a year.

Response: We clarify our use of the phrase ''run-out'' at 88 FR 52422 of our proposal. We intended to use the phrase ''run-out'' to indicate that the list of beneficiaries eligible for Medicare CQMs that we proposed to share prior to the start of the quality data submission period would not include a full 12-months of encounter data. Medicare CQM Specifications would be identical to MIPS CQM Specifications. As such, ACOs would be able to utilize multiple sources of information (for example, multiple EHRs, paper records, registries, patient management systems) to aggregate Medicare CQM performance data. ACOs would not be limited to the use of claims data to report Medicare CQMs. While ACOs would be required to report on a full 12-months of performance data for Medicare CQMs, unlike Part B claims measures, no claims run-out would be required to report Medicare CQMs.

Comment: One commenter recommended that we apply the incentive to report eCQMs/MIPS CQMs to Medicare CQMs. The commenter noted that we should reward maximum savings to ACOs that achieve the quality performance standard.

Response: As stated in the CY 2024 PFS proposed rule (88 FR 52423), we did not propose to add Medicare CQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) for performance year 2024. The incentive is for all payer/all patient eCQM/MIPS CQM reporting. Since Medicare CQMs would include only Medicare FFS beneficiaries, Medicare CQMs are not a form of all payer/all patient reporting. As such, they are not included in the eCQM/MIPS CQM reporting incentive. We note that the alternative quality performance standard, which we finalized in the CY 2023 PFS final rule (88 FR 69831), would be applicable to ACOs that report Medicare CQMs when those ACOs are otherwise eligible for scaled savings/losses.

Comment: Several commenters opposed the Medicare CQM proposal. One commenter stated that creating an ACO-specific measure specification creates additional burden on both practices and health care vendors (that is, EHR vendors, registry vendors, and health care IT vendors) to maintain the same measure based off multiple specifications. The commenter added that the measure benchmark will not be the same across the different collection types, leading to confusion and non-comparable results. Another commenter concluded that reporting Medicare CQMs would require a third-party vendor resulting in an increased reporting expense because their current vendor does not support CQM.

Another commenter shared that they do not believe that introduction of new types of quality measures advances the goals of the Quality Payment Program and will likely lead to confusion among clinicians and administrative staff working on the program since Medicare CQMs are only available to Shared Savings Program ACOs and should not be categorized the same as MIPS CQMs/eCQMs available to all MIPS-eligible clinicians.

Another commenter opposed the proposal and stated that we are moving backwards by allowing ACOs to report on assigned and ''assignable'' Medicare beneficiaries. The commenter stated that ACOs should be required to report all payer data. This commenter stated they believe that the proposal will devalue the utility of publicly reported information and fall short of providing useful information to consumers about ACOs. They added that the proposal would create another point of disparity between MIPS, MVPs, and the Shared

Savings Program: making fair comparisons across each impossible. The commenter questioned whether the proposal would meet the standard established section 1899(b)(3)(C) of the Act which states that, the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care as it would seem that limiting the ACO's reporting to only Medicare Patients is lowering the standards not ''specifying higher standards.''

Response: We acknowledge commenters concerns regarding the creation of the Medicare CQM Specifications and direct readers to this section of this final rule for discussion on this topic. A measure specification for the Medicare CQMs collection type must be established in order for such collection type to have its own benchmark separate from the other collections, for example, MIPS CQMs collection type or eCQMs collection type. We direct readers to our discussion of benchmarks in this section of the final rule to address concerns related to Medicare CQM benchmarking. Lastly, we direct readers to the discussion in this section of the final rule where we clarify that third-party intermediaries are permitted, but not required for reporting Medicare CQMs.

As discussed in our proposal, our long-term goal continues to be to support ACOs in the adoption of all payer/all patient measures (88 FR 52421). The Shared Savings Program has historically permitted an ACO to report on a sample of attributed Medicare beneficiaries through the CMS Web Interface. While we have encouraged and incentivized ACOs to transition to the reporting of all payer data for MIPS CQMs and/or eCQMs, many have commented on the complexity of doing so due to their difficulty matching and aggregating patient data across the various EHR systems used by their constituent clinician practices (88 FR 52420). We previously extended the availability of the CMS Web Interface in the Shared Savings Program to provide relief for these practices (86 FR 65262). Medicare CQMs provide a transition path for ACOs that have difficulty reporting patient data by limiting the beneficiaries for which an ACO must match and aggregate data to only Medicare beneficiaries that are eligible to be included. This is the logical next step in the reporting of digital quality measures as it is inclusive of the ACO's broader Medicare FFS population, which is larger than the sample currently used in the CMS Web Interface, but not as large as the all payer/all patient population that must be reported for an eCQM or MIPS CQM.

Comment: Many commenters suggested that we establish Medicare CQMs as a permanent option that is in place until digital quality measurement and reporting is feasible for all ACOs. Commenters outlined several benefits for making Medicare CQMs permanent, including reducing the ACOs need to choose, invest in, and implement multiple reporting types prior to digital quality measurement and reporting options becoming available, and that while the requirements for reporting are challenging, Medicare CQMs will still be an improvement over the other reporting options currently available. Another commenter noted that their EHR vendor does not plan to support Medicare CQMS because it is a temporary reporting option not in alignment with or contributing to the adoption of eCQMs. One commenter stated that understanding the timeline for sunsetting Medicare CQMs will help ACOs take the necessary steps to prepare for eCQM reporting and make decisions about continued participation in the program.

Another commenter urged CMS to maintain the Medicare CQM reporting option for ACOs until digital quality measurement and reporting is feasible for all ACO participants, especially small and independent providers who will need more technical assistance, resources, and support during this transition. Many commenters stated that Medicare CQMs should be a permanent collection types due to issues transitioning to all payer/all patient measures.

Response: We have heard that ACOs need a better understanding of how long Medicare CQMs will be an available collection type as they prepare to report quality measures for future performance years. Medicare CQMs are intended to serve as a transition to all payer/all patient reporting and not as a permanent collection type. We acknowledge that ACOs are at different stages of readiness to adopt all payer/all patient measures and we intend for Medicare CQMs to be available to ACOs during their transition to all patient/all payer reporting. We expect that the sunsetting of the Medicare CQM collection type may be paced with the uptake of FHIR API technology, but this will be assessed on industry readiness and CMS requirements.

Comment: Many commenters suggested that we to consider a data completeness requirement lower than 75 percent for ACOs reporting eCQMs, MIPS CQMs, or Medicare CQMs due to the complexities of multiple practices and EHRs involved in a single ACO, and the significant burden and investment required by ACOs and participant providers to be able to complete any one of these reporting options.

One commenter suggested that we apply the same data completeness thresholds utilized for MIPS CQMs and Medicare CQMs to eCQMs and recommended that data completeness thresholds be applied at the ACO-level. A few commenters recommended that we maintain a 75 percent data completeness requirement for ACO quality measure reporting. The commenter stated that CMS should require ACOs to report on 100 percent of their assigned beneficiaries only and that this would be consistent with other payers' quality reporting methodology and allows all quality measures to utilize a uniform denominator set, while another few commenters expressed concern about the impact of potentially requiring 100 percent data completeness for any of the measure types in the future.

One commenter noted that it is unclear which data completeness standard the agency proposes to adopt, and that the proposal mentions both establishing data completeness at 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods, as well as 100 percent data completeness in terms of aggregating, matching, and de-duplicating data. One commenter stated that our methodology and baseline for determining data completeness is unclear, so ACOs and others lack insight into whether they are submitting appropriately complete data.

Response: The data completeness criteria threshold of at least 75 percent for the Medicare CQMs aligns with the data completeness criteria threshold established for eCQM and MIPS CQM collection types for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years as discussed in section IV.A.4.f.(1)(d) of this final rule. It is appropriate for Medicare CQMs, eCQMs, and MIPS CQMs to have the same data completeness criteria in order to prevent confusion and complexity and to maintain a level of consistency in the program. Additionally, CMS will provide all ACOs with a list of beneficiaries eligible for Medicare CQMs each quarter, which will aid ACOs in satisfying data completeness by enabling ACOs to aggregate data throughout the performance year and use the fourth quarter list to ensure that

all beneficiaries eligible for Medicare CQMs are captured in the ACOs' reporting.

To meet the data completeness criteria, ACOs must report quality performance data (''Performance Met,'' ''Performance Not Met,'' or denomination exclusions/exceptions) for at least 75 percent of the eligible and matched denominator population for the performance year. In our proposal, we stated that, ''The ACO's aggregated ACO submission must account for 100 percent of the eligible and matched patient population across all ACO participants'' (88 FR 52422). By this we mean that ACOs must aggregate quality performance data from all of their ACO participants. Once patient data are matched and de-duplicated across all of the ACO's participants, the ACO would then match the aggregated patient data with each Medicare CQM Specification to identify the eligible population for each measure. To aid ACOs in meeting data completeness, CMS will provide each ACO with a list of beneficiaries eligible for Medicare CQMs each quarter in order to give ACOs access to the full 12 months of encounters necessary to report Medicare CQMs.

In response to commenters suggestion that CMS should require ACOs to report on 100 percent of their assigned beneficiaries, we direct readers to the discussion in this section of the final rule regarding the alignment of beneficiaries eligible for Medicare CQMs and the all payer/all patient measure specification.

Comment: Many commenters expressed concern regarding our larger goal to require all ACOs to report all payer eCQMs/MIPS CQMs. Many commenters noted concerns that the current state of data standards and interoperability will not yet fully enable ACOs to meet the eCQM reporting requirements successfully.

Some commenters supported the transition to eCQM/MIPS CQM reporting. One commenter shared their belief that reporting eCQMs is a better reflection of overall quality, while another commenter encouraged CMS to continue working with providers to facilitate the transition to all payer/all patient measures even as/if the provider or ACO chooses to report Medicare CQMs.

Response: We did not propose any changes to the previously finalized policies regarding all payer eCQMs/MIPS CQMs. We note that the Medicare CQM collection type that we are finalizing in this rule addresses many of concerns about all payer/all patient shared by ACOs and other interested parties. Specifically, because beneficiaries eligible for Medicare CQMs must have had a claim encounter with an ACO professional with a specialty used in assignment, Medicare CQMs would address the concern raised by ACOs that for ACOs with a higher proportion of specialty practices and/or multiple EHR systems, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, ACOs, particularly ACOs with a higher proportion of specialty practices and/or multiple EHRs, would be able utilize Medicare Part A and B claims data to help identify the ACO's eligible population and to validate the ACO's patient matching and deduplication efforts. For these reasons it is appropriate to establish Medicare CQMs as a new collection type for Shared Savings Program ACOs.

After consideration of the public comments received, we are finalizing our proposal to define a beneficiary eligible for Medicare CQMs at § 425.20. As discussed elsewhere in this section of the final rule, we are finalizing our proposed definition of beneficiary eligible for Medicare CQMs under § 425.20, with a modification for clarity, and to ensure consistency of terminology across provisions, to reference ''clinical nurse specialist'' instead of ''certified nurse specialist.'' Specifically, we are finalizing the definition of a beneficiary eligible for Medicare CQMs at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs) who is either of the following:

- A Medicare FFS beneficiary (as defined at § 425.20) who—
  - ++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and
  - ++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.
- A Medicare FFS beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

Additionally, we are finalizing our proposal with modifications to reflect that the list of beneficiaries eligible for Medicare CQMs will be shared more than once annually to add new paragraph (c)(1)(iii) to § 425.702 as follows:

For performance year 2024 and subsequent performance years, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its FFS population.

- The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Beneficiary name.
  - ++ Date of birth.
  - ++ Beneficiary identifier.
  - ++ Sex.
- Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Demographic data such as enrollment status.
  - ++ Health status information such as risk profile and chronic condition subgroup.
  - ++ Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

As discussed in section IV.A.4.e of this final rule, we are finalizing our proposal to establish Medicare CQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

As discussed in section IV.A.4.f.(1)(d) of this final rule, we are not finalizing the proposal to establish the data completeness criteria threshold of at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

(3) Benchmarking Policy for Medicare CQMs

As the Shared Savings Program adopted the APP (see, for example, § 425.512(a)(3)(i)), benchmarks for quality measures used by the program are those established under the MIPS policies at § 414.1380(b)(1)(ii). We proposed that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking

policies (88 FR 52423). As historical Medicare CQM data would not be available at the time of the proposal, we proposed for performance year 2024 and 2025 to score Medicare CQMs using performance period benchmarks. Similarly, as quality performance data are submitted via Medicare CQM and baseline period data become available to establish historical benchmarks, we proposed for performance year 2026 and for subsequent performance years to transition to using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii).

The following is a summary of the comments we received on these proposals and our responses.

Comment: A few commenters supported CMS' proposal to use performance period benchmarks for performance years 2024 and 2025 before transitioning to historical benchmarks starting with performance year 2026.

Response: We thank the commenters for their support.

Comment: Several commenters were concerned about the proposal to score Medicare CQMs in performance years 2024 and 2025 using performance period benchmarks. One commenter stated that the use of same year percentile rankings is in direct conflict with CMS' stated desire to have all Traditional Medicare beneficiaries in accountable relationships by 2030 as in-year percentile calculations would result in a percent of participants to fail. The commenter also noted that the use of a historical period would create the opportunity for improvement. Another commenter stated that ACOs need Medicare CQM benchmarks to understand the impact of reporting Medicare CQMs compared to CMS Web Interface. A few commenters stated that benchmarks should be established prior to the start of the performance year and that having unknown benchmarks will discourage ACOs from reporting Medicare CQMs. One commenter added that benchmarks should be based on historical performance on which everyone can improve.

Response: As discussed in the CY 2024 PFS proposed rule (88 FR 52423), we proposed that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. Since Medicare CQMs would be subject to MIPS scoring policies, the application of MIPS benchmarking policies to Medicare CQMs is both logical and necessary for implementation of the new collection type. MIPS benchmarks are specific to each collection type (for example, eCQM, MIPS CQM, Medicare CQM, CMS Web Interface, Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey measures, and Part B claims measures). Because benchmarks are specific to collection type, a measure reported as an eCQM will be compared to a different benchmark than the same measure reported as a MIPS CQM or Medicare CQM.

In response to commenters concerns regarding the use of performance period benchmarks, as described in the MIPS Quality Benchmark Overview which is updated for each performance year and posted in the Quality Payment Program Resource Library, if a quality measure or collection type does not have a historical benchmark, we will attempt to calculate benchmarks based on data submitted for the performance period. The PY 2023 MIPS Quality Benchmark Overview can be accessed at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*. We can establish performance period benchmarks when at least 20 instances of the measure are reported through the same collection type and meet data completeness and case minimum requirements and have a performance rate greater than 0% (or less than 100% for inverse measures). Consistent with MIPS benchmarking policies, since historical data would not be available for the Medicare CQM collection type in the first and second year of implementation, we proposed for performance years 2024 and 2025 to score Medicare CQMs using performance period benchmarks. In further alignment with MIPS benchmarking policies, we proposed for performance year 2026 and subsequent performance years to transition using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii). Benchmarks for the Medicare CQMs will be updated annually and posted on the Quality Payment Program Resource Library at *https://qpp.cms.gov/resources/resource-library.*

Comment: Several commenters expressed concerns about the use of MIPS benchmarking policies to establish benchmarks for Medicare CQMs. Commenters stated that the use of 20 entities reporting at least 20 patients was not a reliable basis for benchmarks, and benchmarks would vary year-to-year based on changes in the number of entities reporting. A few commenters stated that, on review of the existing benchmarking process for MIPS CQMs, eCQMs, and now Medicare CQMs, they do not believe that the process for distributing performance across deciles is transparent nor does this approach as constructed produce information that is meaningful. The commenters stated that the approach also assumes that all measures should be scored with the potential to achieve 100% (or 0% if it is an inverse measure) and may not reflect clinical knowledge or practical considerations of quality. A few commenters stated that CMS needs to revise the benchmark methodology to increase transparency, consider the impact of random fluctuation, and adjust for practical considerations of comparison and relative performance. One commenter noted that ACOs have virtually no opportunity to improve scores based on data due to the current benchmarks and data lags. One commenter was concerned that that some ACOs could receive zero points or at most seven points.

Response: The MIPS benchmarking requirement of 20 submissions of at least 20 cases was established in the CY 2017 Quality Payment Program final rule as the minimum standard for establishing a benchmark to reliably score measures (81 FR 77277). In order for a benchmark to be established for the Medicare CQMs collection type, there would need to be a minimum of 20 Shared Savings Program ACOs with at least 20 cases reporting the measure and such submissions would need to meet the data completeness criteria requirement and have a performance rate greater than zero in order for a reliable benchmark to be established (42 CFR 414.1380(b)(1)(ii)(A)). For the CY 2024 performance period, benchmarks have not yet been established for the Medicare CQMs collection type since CY 2024 will be the first year in which such collection type will be available and as a result, performance period benchmarks will be established for the Medicare CQMs collection type if the benchmarking requirement of 20 submissions of at least 20 cases is met (§ 414.1380(b)(1)(ii)). With the number of Shared Savings Program ACOs reporting under the APP in order to meet the Shared Savings Program's quality performance standard, there is little variation in the volume of Shared Savings Program ACOs reporting data. As a result, we do not expect the establishment of reliable benchmarks for Medicare CQMs to be an issue.

To ensure that we establish robust benchmarks, each benchmark must have

a minimum of 20 submissions that meet the data completeness requirement and meet the required case minimum criteria (20 cases) for scoring (§ 414.1380(b)(1)(ii)(A)). The benchmarking methodology relies on assigning points based on decile distributions with decimals. A decile distribution requires at least 10 observations. We doubled the requirement to 20 to be able to assign decimal point values and minimize cliffs between deciles (81 FR 77277). We establish benchmarks using a percentile distribution, separated into deciles, because it translates measure-specific score distributions into a uniform distribution of those reporting the measure based on actual performance values. For each set of benchmarks, we calculate the decile breaks for measure performance and assign points for a measure based on which benchmark decile range the clinician's measure performance rate is between (81 FR 77286). For the quality performance category measures, we use the case minimum requirements for the quality measures used in the 2018 Value Modifier (VM) program (see § 414.1265): 20 cases for all quality measures (81 FR 77287). We referred readers to Table 46 of the CY 2016 PFS final rule (80 FR 71282), which summarized the analysis of the reliability of certain claims-based measures used for the 2016 VM payment adjustment. The benchmarking policy and decile scoring system allow the program to score clinicians on quality performance in the program relative to care as it is provided in actual clinical settings by scoring according to data submitted through participants. This allows us to drive improvements in clinical care that is more considerate of real-world practice and responsive to changes over time.

Comment: A few commenters suggested that we apply the MIPS scoring rules for new measures which establish a 7-point scoring floor, provided data completeness requirements are met, and a 5-point floor in year two. Commenters noted that, during this 2-year phase, ACOs would be better able/willing to allocate limited resources to technical development and workflows associated with the transition. Stratifying Medicare only data without a ''point floor'' guarantee, according to commenters, may result in ACOs choosing to simply submit all payer data versus Medicare only data as it will be a lighter lift. In addition, committing to performance against unknown benchmarks for this new collection type, ACOs would have no way to gauge near real-time performance which has been a staple of the program.

Response: We note that the scoring policy providing measure achievement points of a 7-point scoring floor and a 5-point scoring floor pertains to the submission of new MIPS quality measures during their first 2 years in MIPS. Specifically, under the scoring policy for new MIPS quality measures in § 414.1380(b)(1)(i)(C), the measure achievement points available for the submission of a new MIPS quality measure (having a benchmark, and meeting case minimum and data completeness requirements) in its first year of MIPS are between 7 and 10 measure achievement points and the submission of a new MIPS quality measure (having a benchmark, and meeting case minimum and data completeness requirements) in its second year of MIPS are between 5 and 10 measure achievement points. The scoring policy for new MIPS quality measures is not applicable to the establishment of a new collection type or the application of a newly available collection type to an existing MIPS quality measure. In the CY 2022 PFS final rule, we noted that such policy will not apply to measures that have existed as a MIPS quality measure but are being introduced for a new collection type (86 FR 65500). For example, if a MIPS quality measure is currently available as a MIPS CQM and it becomes newly available as an eCQM or Medicare CQM, the application of the newly available collection type to an existing MIPS quality measure would not be considered a new measure under such scoring policy.

To operationalize the implementation of the Medicare CQMs collection type, specifically the capability to distinguish between the submission of data for a Medicare CQM and a MIPS CQM to CMS, we created an identifier that reflects the Quality number associated with a quality measure (that is, Q001, Q134, and Q236) followed by the letters ''SSP.'' For the reporting of Medicare CQMs, the identifiers are as follows: 001SSP, 134SSP, and 236SSP. We note that the Medicare CQM identifiers must be included in the submission files. We will take these comments into consideration for future rulemaking.

In response to the comment that ACOs would have no way to gauge near real-time performance which has been a staple of the program, we note that Medicare CQMs would transition to historical benchmarks when sufficient base period data are available to establish historical benchmarks in a manner that is consistent with MIPS benchmarking policies. We also direct readers to the discussion in section III.G.2.e. of this final rule regarding our finalized policy to adopt a historical 40th percentile quality performance standard for performance year 2024 and subsequent performance years. In section III.G.2.e of this final rule, we are finalizing, as proposed, the proposal to provide ACOs with the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior by the start of the performance year, which supports the ability for ACOs to understand and meet quality goals, allocate resources effectively, and ultimately support patients and improve quality outcomes. Lastly, as described at § 425.512(a)(4)(ii) and (5)(ii), in performance years beginning on or after January 1, 2023, ACOs that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and are otherwise eligible to share in savings would share in savings on a sliding scale (87 FR 69832). This alternative quality performance standard will help to mitigate impacts on shared savings and losses as ACOs transition to a new collection type.

Comment: Several commenters asked how benchmarks would be developed if fewer than 20 ACOs report Medicare CQMs.

Response: In the unlikely event that fewer than 20 instances of a Medicare CQM are reported that meet the data completeness and case minimum requirements, the MIPS scoring policy for measures that lack a benchmark would apply to that Medicare CQM. *See* § 414.1380(b)(1)(i)(A).

Comment: Since the Medicare CQMs would be available only to Shared Savings Program ACOs, a few commenters were concerned about ACOs being compared only to other ACOs that report Medicare CQMs. One commenter stated their preference to have their quality performance compared to all other participants on these measures. Another commenter stated that CMS should stop measuring ACOs against each other and instead measure ACOs on a national standard so that all ACOs can pass and do not lose out on savings due to arbitrary quality decile cut points.

Response: Given that benchmarks are specific to each collection type and that we proposed to establish Medicare CQMs as a new collection type for only Shared Savings Program ACOs, only ACO data will be available to benchmark Medicare CQMs.

Additionally, the health equity adjustment would be applicable to Medicare CQMs for purposes of determining shared saving payments/losses. The application of the health equity adjustment would help improve performance when ACOs deliver high quality care to underserved patient populations. For these reasons, it is appropriate to establish benchmarks for Medicare CQMs that are consistent with MIPS benchmarking policies. ACOs that prefer to be compared to clinicians at large may do so by reporting eCQMs or MIPS CQMs, for which CMS calculates a benchmark using data reported by MIPS eligible clinicians reporting under the chosen collection type.

Comment: Commenters suggested the following alternative recommendations regarding establishing benchmarks for Medicare CQMs: A1c control and blood pressure control measures be considered topped out measures and depression screening be considered pay-for-reporting until benchmarks can be set for Medicare CQMs; for performance years 2024 and 2025, use CMS Web Interface benchmarks or make Medicare CQM measures pay-for-reporting; consider a process similar to the recent benchmarking of the CMS Web Interface measures where benchmarks would be defined based on pre-determined distributions of performance and thresholds are not dependent on random fluctuations in performance or on the fact that a measure is new to the program.

Response: We thank commenters for their feedback. The Shared Savings Program sunset our pay for reporting policy in PY 2020, and MIPS scoring policies do not include pay for reporting. As such, we would not apply pay for reporting to Medicare CQMs.

To address commenters suggestion that we consider a process similar to benchmarking of CMS Web Interface measures, we wish to underscore that MIPS benchmarking policies establish benchmarks for CMS Web Interface using historical data. Performance on CMS Web Interface measures are based on a sample of the ACO's beneficiaries and ACOs that have performed high on CMS Web Interface measures. We anticipate that ACO performance may fluctuate as ACOs transition to new collection types, like Medicare CQMs. Once historical data are available for Medicare CQMs consistent with MIPS benchmarking policies, we proposed to transition to using historical benchmarks.

After consideration of public comments, we are finalizing our proposal to establish new benchmarks for scoring ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies. As historical Medicare CQM data would not be available, we are finalizing that for performance years 2024 and 2025, we will score Medicare CQMs using performance period benchmarks. We are also finalizing that, for performance year 2026 and subsequent performance years, when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we will score Medicare CQMs using historical benchmarks.

(4) Expanding the Health Equity Adjustment to Medicare CQMs

In the CY 2023 PFS final rule (87 FR 69838 through 69858), for performance year 2023 and subsequent performance years, we finalized a health equity adjustment to upwardly adjust the MIPS Quality performance score for ACOs that report eCQMs/MIPS CQMs, are high performing on quality, and serve a higher proportion of underserved beneficiaries. As we stated in the CY 2023 PFS final rule, the goals of the health equity adjustment include rewarding ACOs serving a high proportion of underserved beneficiaries and supporting ACOs with the transition to eCQMs/MIPS CQMs (87 FR 69841).

Consistent with the goal of supporting ACOs in their transition to all payer/all patient eCQMs/MIPS CQMs, we proposed that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments (88 FR 52423). We proposed to revise § 425.512(b) to specify that, for performance years 2024 and subsequent performance years, we would calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). This proposal would advance equity within the Shared Savings Program by supporting ACOs that deliver high quality care and serve a high proportion of underserved individuals. Applying the health equity adjustment to an ACO's quality performance category score when reporting Medicare CQMs would encourage ACOs to treat underserved populations.

The following is a summary of the comments we received on these proposals and our responses.

Comment: We received several comments in support of our proposal to expand the health equity adjustment to Medicare CQMs. One commenter stated that the adjustment is necessary to correct the unintended consequence of disincentivizing the care of underserved populations in value-based payment systems. Another commenter noted the importance of a health equity adjustment in recognition of ACOs serving a high proportion of underserved beneficiaries who have traditionally lacked access to care or non-clinical resources that significantly impact their health.

One commenter supported our focus on health equity but stated these changes and financial implications are occurring too rapidly and urged a delay of at least one year. The commenter was concerned that the proposed calculation may not account for all components of health equity and noted the need for more funding and time for analysis and development. Another commenter supported our proposal, but they did not believe that a health equity adjustment is sufficient to address the underlying discrepancies in all-payer/all-patient measurement across vastly different patient populations. Another ACO concluded that it is unfair to compare a multispecialty group against other groups that either do not have specialists or have carved their specialists out of their ACOs, and that a more viable solution would be to require primary care services to have been provided to patients before they are eligible for eCQM reporting for measures that are intended to track performance of primary care.

One commenter was opposed to our proposal to expand the health equity adjustment to Medicare CQMs and questioned the legality of providing financial incentives to ACOs (providers) to provide more services to people of certain races, sexualities, and religions.

Response: In response to the commenter that alluded to providing financial incentives to ACOs (providers) to provide more services to people of certain races, sexualities, and religions, our proposal to expand the health equity adjustment to Medicare CQMs does not incentivize ACOs, ACO providers/suppliers, or ACO professionals to provide more services to individuals based on race, sexuality, religion, or any other protected class. By applying the health equity adjustment to ACO's MIPS Quality performance category score when determining shared savings and shared losses for ACOs,

ACOs are rewarded for delivering high quality care and serving a high proportion of underserved individuals. Here, the proportion of underserved beneficiaries is determined using the Area Deprivation Index, enrollment in the Medicare Part D low-income subsidy, and dual eligibility for Medicare and Medicaid (42 CFR 425.512(b)(2)(iv)(A)). For a fuller discussion of how we found these factors to represent a method for determining the proportion of underserved beneficiaries, please see the CY 2023 PFS final rule (87 FR 69838 through 69842). This approach is agnostic of race, gender, sexuality, and religion. As stated in Executive Order 13985, ''Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' by advancing equity across the Federal Government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. Extending the health equity adjustment to Medicare CQMs is consistent with our goal of promoting health equity across the health care system.

To address commenter's concern that the proposed calculation may not account for all components of health equity and may need more funding and time for analysis and development, we note that the health equity adjustment is designed to upwardly adjust the ACO's quality performance score and will not financially penalize ACOs. The health equity adjustment promotes health equity in a value-based care program, while simultaneously avoiding the pitfalls of other pay-for-equity type approaches. This health equity adjustment will not risk adjusting away disparities (thereby masking them) and does not set lower quality standards for underserved populations—rather, this provision will reward those providers who provide excellent care for underserved populations. Furthermore, these bonus points represent the sole motivation for ACOs seeking to improve quality and health equity.

In response to commenters' suggestion that we require primary care services to have been provided to patients before they are eligible for eCQM reporting for measures that are intended to track performance of primary care, we direct readers to this section of the final rule where we discuss the alignment of beneficiaries eligible for Medicare CQMs and the all payer/all patient Measure Specifications.

After consideration of public comments, we are finalizing our proposal that ACOs reporting Medicare CQMs will be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments. We are also finalizing our proposal to revise § 425.512(b) to specify that, for performance years 2024 and subsequent performance years, we will calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).

(5) Summary of Final Policies

In Table 28 of this final rule, we summarize the changes to the regulation at § 425.512(a)(4) and (5) to reflect the changes we are finalizing to the quality reporting requirements and quality performance standard for performance year 2024 and subsequent performance years. Performance benchmarks for performance year 2024 used to determine the 10th, 30th, and 40th percentiles for purposes of evaluating the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) will be posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library.*

We direct readers to the MIPS measure benchmarking policies described at § 414.1380(b)(1)(ii) and to both the quality benchmark and performance period benchmark documentation posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library* for more details. Performance benchmarks differ by collection type (that is, eCQM, MIPS CQM, Medicare CQM (as finalized), CMS Web Interface) and are updated for each performance year.

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TABLE 28: Final APP Reporting Requirements and Quality Performance Standard for Performance Year 2024 and Subsequent Performance Years

	Performance Year 2024	Performance year 2025 and Subsequent Performance Years*
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface or the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.	ACOs are required to report on the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.
Shared Savings Program ACO Quality Performance Standard	For ACOs that report eCQMs/MIPS CQMs/Medicare CQMs and serve a high proportion of underserved beneficiaries, achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs and receives a MIPS Quality performance category score under § 414.1380(b)(1), achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	For ACOs that report eCQMs/MIPS CQMs/Medicare CQMs and serve a high proportion of underserved beneficiaries, achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

*The CMS Web Interface reporting option sunsets after performance year 2024 and is no longer available beginning with performance year 2025.

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c. APP Measure Set

(1) Background

We refer readers to Table 29, which lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for performance year 2023 and subsequent performance years. These are the same measures finalized in the CY 2023 PFS final rule (87 FR 69862); however, we noted that the Collection Type for each measure has been updated. As finalized in the CY 2023 PFS final rule (87 FR 69863), we included the measure type in Table 29 for each measure in the measure set to provide ACOs a list of

the outcome measures for purposes of meeting the quality performance incentive for reporting eCQMs/MIPS CQMs. This information is also relevant to the alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score at the 10th percentile on 1 of the 4 outcome measures in the APP measure set, may be eligible to share in savings on a sliding scale (87 FR 69861). We noted inclusion of this information does not change any of the measures in the measure set.

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TABLE 29: Measures included in the APP Measure Set for Performance Year 2024 and Subsequent Performance Years [a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	PRO-PM*
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 236	Controlling High Blood Pressure	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface**	APM Entity/Third Party Intermediary	Safety	Process
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Process
Quality ID#: 370	Depression Remission at Twelve Months***	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Outcome^

[a] We note that the CMS Web Interface measures: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID#: 438) and Depression Remission at Twelve Months (Quality ID: # 370) do not have benchmarks; and therefore, are not scored for performance year 2024; they are however required to be reported in order to complete the Web Interface data set.

^ Indicates this is an outcome measure.

* Patient-reported outcome-based performance measure (PRO-PM) is a performance measure that is based on patient-reported outcome measure (PROM) data aggregated for an accountable healthcare entity.

**ACOs will have the option to report via the CMS Web Interface for performance year 2024 only.

*** This measure is not included as one of the four outcome measures for purposes of the Quality Reporting Standard as this measure is not scored.

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(2) Revisions

The CMS Web Interface collection type under the APP includes 10 measures. We refer readers to Table Group E of Appendix 1 of this final rule for the proposed substantive changes to measure specifications for 9 out of 10 CMS Web Interface measures starting with performance year 2024. As proposed, the changes would update measures and align the CMS Web Interface measures with the practice workflows of the MIPS CQM collection type.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a comment expressing appreciation for not making any significant changes to the APP measure set.

Response: We thank the commenter for their support.

We received many comments about issues that were not related to the proposals included in this section of the proposed rule. The issues were related to the clinical merits of adding the three Medicare CQMs to the APP measure set, the financial, administrative, resource, and technical burden of this policy on ACOs and healthcare vendors, and the scheduled sunsetting of the CMS Web Interface in PY 2024. We refer readers to section IV.A.4.e., Reporting the Medicare CQMs, of this final rule for the disposition of our proposal to add three Medicare CQMs to the APP measure set.

Additionally, we requested information on the APP measure set and the Universal Foundation within the Medicare CQM proposal (88 FR 52423). We thank the commenters for their feedback and will take the comments under consideration in future rule making, as we evaluate the impact of aligning the APP measure set with the Universal Foundation measures and existing Value in Primary Care MVP.

In the CY 2021 PFS final rule (85 FR 84733), we finalized the following three all payer/all patient eCQMs/MIPS CQMs under the APP for performance year 2021 and subsequent performance years:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

In section IV.A.4.e of this final rule, we are finalizing our proposal to add these measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years.

d. Modifications to the Health Equity Adjustment Underserved Multiplier

(1) Background

Consistent with our goal of rewarding ACOs that include a higher proportion of underserved beneficiaries while delivering high quality care, we finalized in the CY 2023 PFS final rule (87 FR 69836 through 69857) the application of a health equity adjustment that adds up to 10 bonus points to an ACO's MIPS Quality performance category score based on certain criteria. The health equity adjustment is applied to an ACO's MIPS quality performance category score when the ACO reports the three all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(4) of this final rule, the three eCQMs/MIPS CQMs/Medicare CQMs starting in performance year 2024. To qualify for the health equity adjustment, the ACO must also meet the data completeness requirement at § 414.1340 and administer the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). The health equity adjustment is conditional on (1) high quality measure performance and (2) providing care for a proportion of underserved populations greater than or equal to a predetermined floor.

The goal of the health equity adjustment is to reward ACOs with high performance scores on quality measures and that serve a high proportion of underserved beneficiaries. Correspondingly, the health equity adjustment bonus points are calculated by multiplying the ACO's performance scaler by the ACO's underserved multiplier. An ACO's performance scaler is designed to identify top performance among ACOs reporting all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(4) of this final rule, eCQMs/MIPS CQMs/Medicare CQMs in performance year 2024. The performance scaler is an aggregated value across all eCQM/MIPS CQM measures and is determined based on if the ACO's measure performance was in the top, middle, or bottom third of ACO performance for that performance year. We refer readers to section III.G.4.b.(7).(c) of the CY 2023 PFS final rule (87 FR 69843 through 69845) for more details on the performance scaler calculation.

The underserved multiplier is designed to identify ACOs serving high proportions of underserved beneficiaries. As described in the CY 2023 PFS final rule (87 FR 69845 through 69849), the underserved multiplier is a proportion, ranging from zero to one, of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of: (1) the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85; or (2) the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid. The use of both the ADI and Medicare and Medicaid dual eligibility or LIS status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries.

The CY 2023 PFS final rule did not state how CMS intended to compute the proportion of beneficiaries with an ADI national percentile rank of at least 85 with respect to beneficiaries for whom a numeric national percentile rank value is not available. We do not believe it is appropriate to assign a zero to the beneficiaries without an ADI national percentile rank in the calculation. Doing so would unfairly disadvantage ACOs with such beneficiaries vis-à-vis those ACOs with beneficiaries that all have an ADI national percentile rank by lowering their scores. The CY 2023 PFS final rule (87 FR 69846) stated that the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 is computed using the number of assigned beneficiaries. A footnote stated that in computing the proportion of beneficiaries dually eligible for Medicare and Medicaid, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid. In response to public comment, we finalized the proposal to include LIS as a modification to the calculation of the underserved multiplier (87 FR 69849). In calculating the LIS proportion, CMS uses the same methodology it adopted for calculating dually eligible beneficiaries: person years.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52429 through 52430), we proposed to revise the underserved multiplier

calculation to specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid. Specifically, we proposed to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Beneficiaries without a national percentile ADI rank would appear neither in the numerator nor in the denominator of the proportion.

While we established a policy for the treatment of aligned beneficiaries for whom an ADI national percentile rank could not reasonably be calculated for use in the AIPs risk factors-based score (87 FR 69796 through 69797), we neither proposed nor finalized a policy for such beneficiaries with respect to the calculation of the health equity adjustment underserved multiplier—nor do we believe the policy we finalized for AIP is appropriate for calculating the health equity adjustment. In the CY 2023 PFS final rule (87 FR 69800), we finalized the use of imputing a value of 50 for the ADI national percentile rank if there is insufficient data to match a beneficiary to an ADI national percentile rank for calculating AIP risk factors-based scores. There are important differences in the implications of using an imputed value of 50 for calculating the AIP risk factors-based scores and for calculating the underserved multiplier. The imputed ADI ranking of 50 corresponds to the average national ADI ranking and would be the most neutral imputed value and would avoid biasing an ACO's payments in either direction for risk factor-based scores in the AIP calculation. The use of an ADI ranking of 50 in the underserved multiplier, however, would result in that beneficiary not counting in the numerator of the underserved multiplier proportion because only beneficiaries with an ADI of at least 85 are counted in the numerator. Therefore, we proposed to exclude beneficiaries without a national percentile ADI rank from the health equity adjustment underserved multiplier (88 FR 52429). This approach is more equitable because it will remove a beneficiary without an ADI rank from the denominator and the numerator of the calculation of an ACO's underserved multiplier instead of penalizing ACOs that have such beneficiaries.

It is in the public interest to apply this change starting with performance period 2023. Section 1871(e)(1)(A)(ii) of the Act authorizes the Secretary to retroactively apply a substantive change in Medicare regulations if the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. Here, applying this change starting with performance period 2023 is in the public interest because, absent further specification of how to treat beneficiaries without a national percentile ADI rank current policy may unfairly penalize ACOs for reasons beyond their control. Current policy counts beneficiaries with missing ADI ranks in the underserved multiplier denominator and contributes zero to the numerator, thereby reducing the health equity adjustment for ACOs with such beneficiaries and harming their ability to meet the quality performance standard and receive shared savings.

Separately, in the CY 2024 PFS proposed rule (88 FR 52430), we proposed to modify the calculation of the proportion of assigned beneficiaries dually eligible for Medicare and Medicaid and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid starting in performance year 2024. For example, when calculating the underserved multiplier component of the health equity adjustment to an ACO's quality performance score for ACOs that report the three eCQMs/MIPS CQMs/Medicare CQMs, the proportion would be equal to the number of assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by total number of assigned beneficiaries. We did not propose to alter the calculation of the proportion of beneficiaries residing in a census block group with an ADI national percentile rank of at least 85, which is already based on the number of assigned beneficiaries. Person years would continue to be used in financial calculations where beneficiary experience is stratified by Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged non/dual eligible) and where it is important to account for partial year enrollment to ensure accuracy. This policy change will bring greater consistency between the two proportions used in determining the underserved multiplier. It also acknowledges that beneficiaries with partial year as compared to full year LIS enrollment or dual eligibility are also socioeconomically vulnerable and strengthens incentives for ACOs to serve this population. Further, inclusion of beneficiaries with partial year LIS enrollment in the underserved multiplier provides increased incentive for ACOs to help facilitate LIS enrollment for beneficiaries who meet eligibility criteria.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposed modifications to the health equity adjustment underserved multiplier. Several commenters expressed their appreciation for CMS's continued focus on health equity and providing access and accountable care to underserved patients. Other commenters stated that the health equity adjustment encourages providers to continue providing high quality care to underserved beneficiaries. One commenter stated that the modifications to the underserved multiplier would improve efficacy and consistency in identifying ACOs' underserved populations.

Response: We appreciate the comments in support of the proposed modifications to the health equity adjustment underserved multiplier. As we discussed in the proposed rule, the goal of the health equity adjustment is to reward ACOs with high performance scores on quality measures and that serve a high proportion of underserved beneficiaries. We agree with the commenters that these modifications will specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid.

Comment: Several commenters expressed concern that the national ADI rank score is inadequate in identifying underserved beneficiaries living in high cost-of-living areas. Commenters' concerns with the national ADI rank score included that it overly relies on income and home values, can mask urban poverty, and may not be a good proxy for patient-level social risk factors. One commenter gave the example that all the District of Columbia has a National ADI less than the 85th percentile. Another commenter stated

that an ACO in San Francisco or Seattle will be disadvantaged by any index that uses rent and mortgage expenses to calculate a score but does not account for the large population of unhoused individuals. Two commenters recommended to remove the ADI from the health equity adjustment underserved multiplier calculation because it is weighted toward income and home values. One commenter recommended exploring other data sources as they become available for revisions to the underserved multiplier. Other commenters recommended incorporating a regional approach to identifying underserve beneficiaries such as including or replacing the National ADI rank score with State ADI rank scores in the underserved multiplier calculation. Two commenters noted that CMS Innovation models, including the ACO Realizing Equity, Access, and Community Health (REACH) and the Making Care Primary models, have announced inclusion of the State ADI rank score in their health equity adjustments for upcoming performance years.

Response: We did not propose any changes to the previously finalized policy of using the national ADI rank score in the health equity adjustment underserved multiplier; rather, we proposed to exclude beneficiaries without a national percentile ADI rank from the health equity adjustment underserved multiplier. Therefore, these comments are considered to be out of scope. However, we are continuing to assess the impact of using the national ADI in the health equity adjustment in the Shared Savings Program and the use of state ADI in the health equity adjustments used in CMS innovation models. Additionally, we note that for the purposes of the underserved multiplier, we use the ''greater of'' the percentage of individuals who are dually eligible or receiving low-income subsidies, or live in an area with an ADI of 85 or above. This means that for areas with lower average ADIs, if the ACO still serves a low-income population with a higher percentage of individuals who are dually eligible or receiving low-income subsidies, the ACO could still qualify for an upwards adjustment. CMS will continue to examine the learnings from the CMS Innovation Models and external researchers to contemplate improvements to the measures of geographic deprivation over time. We may consider these and other suggestions in future rulemaking.

Comment: Several commenters requested CMS to consider allowing all ACOs to be eligible for the health equity adjustment regardless of quality measure collection type. Specifically, commenters requested that ACOs reporting via the CMS Web Interface be eligible for the health equity adjustment.

Response: We direct commenters to our response to similar comments regarding the eCQMs/MIPS CQMs reporting requirement for health equity adjustment eligibility in the CY 2023 PFS final rule (87 FR 69841 through 69842). Specifically, we explained that while we understand the concerns raised by commenters regarding the eCQMs/MIPS CQMs reporting criteria for being eligible to receive a health equity adjustment, the health equity adjustment is designed to upwardly adjust the ACO's quality performance score and will not financially penalize ACOs that are not eligible for the adjustment such as those that do not report using eCQMs/MIPS CQMs. We further explained that as the transition to reporting all-payer eCQMs/MIPS CQMs continues, with this reporting mechanism becoming mandatory starting in PY 2025, the health equity adjustment would reinforce the timeline while supporting ACOs that may be experiencing challenges with the new quality reporting requirement and providing an incentive for ACOs not to seek to avoid underserved populations during the transition to reporting eCQMs/MIPS CQMs.

Comment: One commenter requested that CMS monitor the impact of the proposed change of dropping beneficiaries without a National ADI rank score to ensure it does not negatively affect rural ACOs already struggling to succeed in the Shared Savings Program.

Response: We acknowledge the commenter's concern. As we stated in the CY 2023 PFS final rule (87 FR 69841), the inclusion of National ADI, Medicare and Medicaid eligibility, and LIS status in the underserved multiplier calculation provides opportunity for identifying underserved populations for all providers, whether in rural or urban areas. Further, as we noted in the CY 2023 PFS final rule (87 FR 69796) in a preliminary review of Medicare beneficiary information, less than 2 percent of Medicare beneficiaries could not be matched to a census block group due to missing or insufficient mailing address data, and approximately 1 percent of Medicare beneficiaries had sufficient address data but were in a U.S. census block group without a national percentile rank due to data suppression criteria. Based on the statistical analysis provided, we do not anticipate a significant impact of the proposed change on ACOs in rural areas. We will assess the impacts of the policy in rural areas and may make refinements as needed in future rulemaking.

Comment: One commenter requested CMS clarify what is being identified as health equity in the context of performance, as well as what is being measured.

Response: We refer readers to CY 2022 PFS final rule (86 FR 65382 through 65384) for a detailed explanation of health care outcome inequities and health equity. In the CY 2022 PFS final rule, we used the definition of health equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' In response to the question of what is being measured, we direct readers to section III.G.4.b.(7)(d) of the CY 2023 PFS final rule (86 FR 69845 through 69849) where we finalized the inputs for the calculation of the underserved multiplier. Specifically, we state that we use the higher value of either the proportion of an ACO's assigned beneficiary population that is considered underserved based on beneficiaries who are from underserved neighborhoods, identified using ADI data, or the proportion of an ACO's assigned beneficiary population that are dually eligible for Medicare and Medicaid or enrolled in Medicare Part D Low-Income Subsidy (LIS).

Comment: Some commenters requested CMS consider changes that were not related to the proposals included in this section of the proposed rule. The requests included: increase the health equity adjustment bonus points to have a greater and faster impact on the lives of the most at-risk beneficiaries; instead of using Medicare Part D LIS enrolled status in the underserved multiplier calculation, CMS should use Medicare Part D LIS eligible to account for those beneficiaries who have not enrolled, but whose income is lower than 150 percent of the federal poverty level; expand the number of diagnoses allowed on Medicare claims to accommodate the use of Z-codes or otherwise allow documentation of Z-codes in addition to

the current limit of diagnosis codes on Medicare claims.

Response: We note that we did not propose any changes to these previously finalized policies in the proposed rule, and therefore, these comments are considered to be out of scope.

In conclusion, after review of the public comments received, we are finalizing at 42 CFR 425.512(b)(2)(iv)(A) our proposal to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for PY 2023 and subsequent performance years and to use the number of beneficiaries, rather than person years, for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid, starting in PY 2024.

e. Use of Historical Data To Establish the 40th Percentile MIPS Quality Performance Category Score

(1) Background

In the CY 2023 PFS final rule (87 FR 69858), we finalized that beginning performance year 2024, one of the ways for an ACO to meet the Shared Savings Program quality performance standard and share in savings at the maximum rate under its track (or payment model within a track) is for the ACO to achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring.

In the CY 2022 PFS proposed and final rules (86 FR 39274 and 86 FR 65271), we stated that, for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores would be calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. Therefore, we are not able to provide performance rate information prior to or during the performance year. Nevertheless, we stated that we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We stated that we would release this historical information on the Shared Savings Program website when it becomes available.

In the CY 2022 PFS proposed rule (86 FR 39274), we also explained that interested parties have expressed concerns regarding the lack of information on the level of quality performance that would equate to the 30th or 40th percentile MIPS Quality performance category score and that would enable an ACO to be eligible to share in savings or to avoid maximum shared losses, if applicable. We noted that interested parties have expressed concern that these data are not publicly available prior to the start of a performance year and that they do not believe that ACOs have a way of determining what quality score they would need to achieve to meet the quality performance standard.

In the CY 2022 PFS proposed rule (86 FR 39274), we also solicited comments on whether publicly displaying prior year performance scores that equate to the 30th or 40th MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the Shared Savings Program. Several commenters supported publicly displaying prior year performance scores that equate to the 30th or 40th percentile across all MIPS Quality category performance scores, and one commenter expressed concern that publicly displaying prior year performance scores is not the optimal way to address concerns of interested parties and indicated that performance is volatile and the 30th (or 40th) percentile may change significantly from year to year depending upon changes in quality performance in MIPS (86 FR 65271).

We clarified in the CY 2023 PFS proposed rule (87 FR 46148) and final rule (87 FR 69867) that we use the submission-level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Savings Program. In the CY 2024 PFS proposed rule (88 FR 52430 and 52431), we stated that in light of public comments and concerns about the predictability of the 40th percentile MIPS Quality performance category score due to changes in MIPS scoring policies over time—including MIPS scoring changes impacting measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), new sub-group reporting option as described at § 414.1318(a), and MIPS High Priority and End to End Bonus Points as described at § 414.1380(b)(1)(v)—and as a result of the concerns expressed by ACOs and other interested parties and as we gain experience with aligning Shared Savings Program reporting and scoring policies with MIPS, we believe that a revised methodology is needed to calculate the 40th percentile MIPS Quality performance category score for the quality performance standard for performance year 2024 and subsequent performance years.

Additionally, we stated in the CY 2024 PFS proposed rule (88 FR 52431) that as MIPS scoring policies evolve over time, changes in MIPS scoring policy have the potential to adjust the year-to-year comparability of MIPS Quality performance category scores. Between performance years 2022 and 2023, there were MIPS policy changes to measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), and a new sub-group reporting option as described at § 414.1318(a). Additionally, MIPS High Priority and End to End Bonus Points were sunset in performance year 2022 as described at § 414.1380(b)(1)(v). The projected 40th percentile MIPS Quality performance category score for performance year 2023 does not reflect these proposed methodological changes. To minimize reliance on a single year of performance data, the use of multiple years of historical data could be used to ''smooth'' out the impact of MIPS scoring policy changes on the quality performance standard in any 1 year. At the same time, using too many years of data to average scores may include a greater number of years that do not reflect current policies.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52431), we proposed to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score for performance year 2024 and subsequent performance years. Specifically, we proposed to use a rolling 3-performance year average with a lag of 1-performance year (for example, the 40th percentile MIPS Quality performance category

score used for the quality performance standard for performance year 2024 would be based on averaging the 40th percentile MIPS Quality performance category scores from performance years 2020 through 2022). We believe that our proposal to use a 3-year historical average is consistent with the proposal under section IV.A.4.h.(2) of the CY 2024 proposed rule that would permit, for purposes of establishing a performance threshold as identified in § 414.1405(b), a time span of up to 3 consecutive performance periods for performance year 2024 and subsequent performance years.

We would provide ACOs with the performance score that equates to the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior to the start of the performance year (for example, the 40th percentile MIPS Quality performance category score based on historical data and applicable for performance year 2024 would be released on the Shared Savings Program website in December 2023).

The use of 3 historical base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, specific to the historical base year. Additionally, the use of historical data would allow additional time for data availability and limit the potential impact of MIPS Targeted Review as described at § 414.1385 and other MIPS scoring corrections. This approach is also responsive to the concerns ACOs, and other interested parties have with the predictability of the current method of calculating the 40th percentile MIPS Quality performance category score. However, we acknowledged that by using historical benchmarks, the benchmark would not reflect the most recent policies, measure specifications, and scores (88 FR 52431). For example, the historical base years are 2–4 years removed from the performance year and could reflect data that may have anomalies specific to the base year that would render those data inconsistent with the performance year's quality performance. Additionally, changes to measure specifications for measures included in the APP measure set may result in the historical base period including measures that are different than the corresponding measures that were applicable during the performance year. This could further reduce the comparability of historic base year data with the performance year's quality performance data.

Table 29 in the CY 2024 PFS proposed rule (88 FR 52432) shows the 40th percentile MIPS Quality performance category scores for performance years 2018 through 2021 based on the current methodology as published in the CY 2023 PFS final rule (87 FR 69868). The proposed methodology would be effective for performance year 2024 and subsequent performance years. We have added to Table 30 the projected 40th percentile MIPS Quality performance category scores for performance years 2022 and 2023 based on the proposed methodology for illustrative purposes. The projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2018 through 2020, and the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2023 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2019 through 2021. The years are averaged at equal weights. For example, we would calculate the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 by first summing the 2018 (70.80), 2019 (70.82), and 2020 (75.59) 40th percentile Quality performance category score values to arrive at a value of 217.21 [70.80 + 70.82 + 75.59 = 217.21]. We would then divide the value of 217.21 by three (the number of years included in the historical reference period) to arrive at a projected 40th percentile MIPS Quality performance category score of 72.40 for 2022 [217.21 ÷ 3 = 72.40]. Note that this example illustrates averaging the 2018, 2019, and 2020 40th percentile MIPS Quality performance category score values.

In the CY 2024 PFS proposed rule (88 FR 52432), we solicited comments on our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years. Using a 1-year lag would help ensure the availability of base period data by limiting the possibility that data availability is negatively impacted by scoring, policy, and/or performance anomalies from the prior performance year. In the development of our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years, we considered another alternative methodology, which was to establish a historical quality performance standard based on the year immediately prior to the performance year's quality performance score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring (88 FR 52432). We also solicited comments on other alternative methodologies we should consider to calculate the 40th percentile MIPS Quality performance category score for the quality performance standard.

The following is a summary of the comments we received on our proposal to use historical data to establish the 40th percentile MIPS Quality performance category score and our responses.

Comment: Several commenters supported our proposal to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score for performance year 2024 and subsequent performance years and to provide ACOs with the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior to the start of the performance year. Several commenters noted that the proposal would provide ACOs with more certainty and predictability regarding what the quality targets are in advance of the performance period starting and mitigate the potential impact of annual program changes affecting the MIPS Quality performance category scores. A few commenters stated that basing the threshold on historical data will provide transparency around the threshold calculation. One commenter stated that the proposal would alleviate issues with scoring and performance anomalies as was seen during the COVID–19 pandemic and limit the impact of the MIPS Targeted Review and MIPS scoring corrections; however, the commenter noted using historical benchmarks will not reflect the most recent scores and measure specifications.

Response: We appreciate commenters' support and agree that providing ACOs with the 40th percentile MIPS Quality performance category score that would be used as the quality performance

standard for a given performance year prior by the start of the performance year supports ACOs' ability to understand and meet quality goals, allocate resources effectively, and ultimately support patients and improve quality outcomes.

Comment: A few commenters that supported the proposal also expressed concerns that data from performance years 2020 to 2022 are not likely to yield a meaningful comparison given the impact of the COVID–19 pandemic and the extreme and uncontrollable circumstances policies applied in those years and suggested that CMS could consider a weighted average approach that gives more credit to the most recent year (that is, performance year 2022). Another commenter supportive of the proposal recommended that CMS assess whether a longer or potentially different lookback period would be more appropriate for performance year 2024, given that the lookback period for performance year 2024 will reflect years heavily impacted by the COVID–19 pandemic. Another commenter supportive of the proposal stated that implementation of the proposed methodology should be delayed until after the CMS Web Interface sunsets and transition to eCQMs/MIPS CQMs/Medicare CQMs reporting occurs. The commenter further stated that the rolling 3-year performance average with a lag of 1-performance year will eventually help solve for changes in scoring policies; however, in the first year that scores are based on eCQMs/MIPS CQMs/Medicare CQMs, the historical submission-level MIPS Quality performance category score will be predominantly based on CMS Web Interface measures. Should CMS finalize the proposal, the commenter recommended CMS set guardrails during the transition period to ensure that ACOs transitioning to the eCQMs/MIPS CQMs/Medicare CQMs are not unfairly penalized against historical MIPS Quality performance standards that do not adequately consider historical eCQM/MIPS CQM/Medicare CQM submission data.

Response: The methodology we are finalizing provides a guardrail by minimizing the reliance on a single year of performance data that may have anomalies specific to the performance year, such as a pandemic, and by using multiple years of historical data to prevent a cliff and ''smooth'' out the impact of MIPS scoring policy changes on the quality performance standard in any one year. As explained in the CY 2024 PFS proposed rule, as MIPS scoring policies evolve over time, changes in MIPS scoring policy have the potential to adjust the year-to year comparability of MIPS Quality performance category scores (88 FR 52431).

Comment: One commenter opposed the proposal stating that it creates the potential for an unlevel playing field because the benchmark would not reflect the most recent policies, measure specifications, and scores as the base years used would be 2–4 years prior, and there may be significant anomalies making it more difficult to achieve that score years later. The commenter noted that in performance year 2025, when all organizations will be reporting using eCQMs, the historic percentiles, based largely on CMS Web Interface measures reported in performance years 2021 to 2023, would be more difficult to achieve with eCQM reporting. Additionally, the commenter stated that the playing field would not completely level out until performance year 2029 when all historic years used in the calculation require reporting via eCQMs, and only if there were no other significant changes to the measures and reporting requirements.

Response: In the CY 2021 PFS final rule (85 FR 84720 through 84722), we aligned the Shared Savings Program quality reporting requirements with the APP and have worked over time to align with MIPS scoring policies (see 86 FR 65253 and 65254; 87 FR 69779 and 69780 for a summary of certain finalized policies); however, we acknowledged that MIPS scoring changes could occur that may impact the predictability of the 40th percentile MIPS Quality performance category score. We acknowledged in the CY 2024 PFS proposed rule (88 FR 52431) that by using historical benchmarks, the benchmark would not reflect the most recent policies, measure specifications, and scores.

As we stated in the CY 2024 PFS proposed rule (88 FR 52431), and some commenters agreed, the use of 3 historical base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, that are specific to the historical base year. Additionally, the use of historical data would allow additional time for data availability. While we understand concerns about the transition from the CMS Web Interface in performance year 2024 and the historical data changing over time with more ACOs increasingly submitting eCQMs/MIPS CQMs/Medicare CQMs data, delaying the proposal to use a rolling 3-performance year average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score would result in a delay to mitigate potential MIPS scoring policy changes and a delay in providing ACOs with their benchmark target prior to the start of the performance year. For these reasons, the implementation of the proposed methodology should not be delayed until after the CMS Web Interface sunsets.

Additionally, the 40th percentile MIPS Quality performance category score is not based solely on Shared Savings Program ACOs. Out of the 30,000–40,000 MIPS eligible clinicians and APM entities in the MIPS Quality performance category score unweighted distribution, less than 500 are ACOs. As stated in the CY 2023 PFS final rule (87 FR 69867), the unweighted distribution of Quality performance category scores is based on the Quality performance category scores of the submitting MIPS eligible clinicians and APM entities (for example, ACOs, other APM entities, group practices, and individual clinicians). For illustrative purposes, we are providing an example using the average (instead of the 30th or 40th percentile) for the quality performance standard. In this example, there are three submitting entities: an ACO, a MIPS eligible clinician that is a group practice, and an individual MIPS eligible clinician. The MIPS Quality performance category scores for these submitting entities are 90 for the ACO, 70 for the group practice, and 50 for the individual clinician. The average of the unweighted distribution of scores is (90 + 70 + 50)/3 = 70 where each submitting entity contributes one score. The weighted distribution of scores takes into account the number of individual providers from each submitting entity. The ACO has 10 providers, the MIPS Group has four providers, and the individual MIPS provider has one provider. The average of the weighted distribution is $((90 \times 10) + (70 \times 4) + (50 \times 1))/15 = 82$. Thus, by using a weighted distribution of scores when calculating the 40th percentile MIPS Quality performance category score for the quality performance standard, each of the ACO's individual providers would be contributing to the calculation rather than the ACO itself, and the ACO's score would be counted once. As noted in the CY 2023 PFS final rule (87 FR 69867 and 69868), we use the submission-level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard. The use of the

unweighted distribution of scores aligns with the MIPS and Shared Savings Program benchmarking policies.

Furthermore, not all MIPS eligible clinicians and APM entities report the CMS Web Interface measures, and for performance years 2023 and 2024, the CMS Web Interface collection type is only available for APM Entities reporting the APM Performance Pathway, such as Shared Savings Program ACOs. Historical benchmark years are thus likely to reflect eCQM and MIPS CQM reporting more quickly than if they were based on Shared Savings Program ACOs alone, even as the CAHPS for MIPS Survey measure and the two administrative claims measures also contribute to an ACO's MIPS Quality performance category score.

Comment: One commenter noted that they supported an alternative methodology we considered during the development of our proposal, which was to establish a historical quality performance standard based on the year immediately prior to the performance year's quality performance score across all MIPS Quality performance category scores. They noted that the playing field would then be leveled in performance year 2026 under this methodology.

Response: We appreciate the commenter's response to our request for comment on alternative methodologies for consideration in calculating the historical submission-level MIPS Quality performance category score. Prior to the publication of the CY 2024 PFS proposed rule, in addition to our proposed methodology, we evaluated two alternative methodologies for calculating a historical MIPS Quality performance category score: establishing the historical quality performance standard based on the year immediately prior to the performance year; and also based on a 2-performance year rolling average with a lag of 1-performance year. Of the methodologies we considered, the 3-year historical benchmark with a 1-year lag best accounts for the anticipated learning curve that ACOs may encounter as they transition to eCQM/MIPS CQM/Medicare CQM reporting. This methodology allows ACOs to know in advance what MIPS 40th percentile Quality performance category score they will need to achieve in order to meet the quality performance standard for performance year 2024 and subsequent performance years. With this predictability, ACOs can work to meet this target as they evaluate and develop strategies to continue to improve their quality performance for performance year 2024 and subsequent performance years.

Comment: One commenter requested that CMS provide better scoring toolkits, methodologies, and sample scoring calculations to ACOs and QCDRs, similar to the MIPS scoring toolkits released annually, in advance of and during the performance period so that clear scoring predictions and calculations can support ACOs in improving their quality of care. A few commenters suggested that CMS provide prospective information on both the quality score that would qualify an ACO for savings and the methodology used to calculate the benchmarks.

Response: We thank the commenters for their feedback. We plan to provide updates to the APP Toolkit available at *https://qpp.cms.gov/resource-library* and other educational documents for ACOs to include Medicare CQM guidance and specifications and associated policies as close to the start of the performance as possible.

For information on how shared savings and shared losses are calculated, please refer to the Medicare Shared Savings Program Shared Savings and Losses and Assignment Methodology and Quality Performance Standard Specifications, available on the Shared Savings Program website under Program Guidance & Specifications (for example, in Version 11 (PDF, 1.9MB), refer to Section 4.3 Performance Year Financial Reconciliation Calculations). Version 11 is available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2.*

Comment: Several commenters requested that CMS publish MIPS Quality performance category scores in the Public Use Files (PUF) to bring greater transparency to the calculation of the 40th percentile MIPS Quality performance category score calculation.

Response: We appreciate the commenters' feedback. In the Medicare Shared Savings Program Performance Year Financial and Quality Results PUF, we provided several ACO-specific variables related to quality performance results including the ACO's quality score, an indicator whether the ACO met the quality performance standard, indicators for each of the three measure reporting options (that is, Web Interface, eCQM, MIPS CQM), and an indicator whether the ACO did not completely report quality for any of the reporting options. We may consider adding additional ACO-specific variables in future years. ACOs can review their measure-specific performance used to calculate their MIPS Quality performance category score along with their final MIPS Quality performance category score in their MIPS performance feedback report. ACOs are also required to publicly report their quality measure scores on their websites per § 425.308(b)(5). We also provide quality measure benchmarks for the current performance year on the Shared Savings Program website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.*

Comment: One commenter requested that CMS publish the percentile performance thresholds for the individual quality measures prior to the performance year.

Response: For measures that have historical benchmarks, we generally publish them around the start of each performance year at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations.* Measures with performance period benchmarks—which include the administrative claims measures: Measure# 479 Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Groups and Measure# 484 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions—are published after the submission period for the applicable performance year. Benchmark resources are published in the Quality Payment Program resource library and are updated for each performance year at *https://qpp.cms.gov/resources/resource-library.*

Comment: One commenter stated that if Medicare CQMs are established as proposed, there will not be any historical data for these measures. Therefore, the commenter requested that CMS clarify how the proposal to use a rolling 3-performance year average with a lag of 1 performance year will incorporate Medicare CQMs to calculate the 40th percentile MIPS Quality performance category score.

Response: We acknowledge that Medicare CQM data will not be part of the performance year 2024 and 2025 historic reference periods, but the 2026 historic reference period will be inclusive of MIPS Quality performance category scores that are based on Medicare CQMs reported in performance year 2024. As finalized in section III.G.2.b of this final rule, performance year 2024 will be the first year that Medicare CQMs will be available for Shared Savings Program ACOs under the APP. As a result, historical Medicare CQM data will not

be available at the time the 40th percentile MIPS Quality performance category score is calculated for performance years 2024 and 2025; however, the historical data will be available at the time the 40th percentile MIPS Quality performance category score is calculated for performance year 2026 (based on the average of the 40th percentile MIPS Quality performance category score from performance years 2022 through 2024). With the sunsetting of the CMS Web Interface at the end of performance year 2024 and as more ACOs transition to reporting eCQMs/MIPS CQMs/Medicare CQMs, the historic 3-year performance average of the MIPS Quality Performance Category Score will gradually incorporate additional Medicare CQM data in each subsequent performance year.

After consideration of the public comments, we are finalizing our proposal to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score for performance year 2024 and subsequent performance years. Specifically, we will use a rolling 3-performance year average with a lag of 1-performance year (for example, the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 will be based on averaging the 40th percentile MIPS Quality performance category scores from performance years 2020 through 2022). We will provide ACOs with the performance score that equates to the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior to the start of the performance year (for example, the 40th percentile MIPS Quality performance category score based on historical data and applicable for performance year 2024 would be released on the Shared Savings Program website in December 2023).

Table 30 shows the 40th percentile MIPS Quality performance category scores for performance years 2018 through 2021 based on the current methodology as published in the CY 2023 PFS final rule (87 FR 69868). The methodology we are finalizing in this final rule will be effective for performance year 2024 and subsequent performance years. We added the projected 40th percentile MIPS Quality performance category scores for performance year 2022 based on the methodology we are finalizing for illustrative purposes to Table 30. We note that Table 30 is same as Table 29 that was included in the CY 2024 PFS proposed rule (88 FR 52432). Based on the actual 40th percentile MIPS Quality performance category score values in Table 30, we can provide, for illustrative purposes, the 40th percentile MIPS Quality performance category score value for the quality performance standard for performance year 2024. We calculate the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 by first summing the 2020 (75.59), 2021 (77.83), and 2022 (77.73) 40th percentile Quality performance category score values to arrive at a value of 231.15 [75.59 + 77.83 + 77.73 = 231.15]. Note that performance year 2023 is skipped for the one-year lag. We then divide the value of 231.15 by three (the number of years included in the historical reference period) to arrive at a 40th percentile MIPS Quality performance category score value of 77.05 for performance year 2024 [231.15 ÷ 3 = 77.05].

TABLE 30: 40th Percentile MIPS Quality Performance Category Scores Using Current and Finalized Methodology

Performance Year		Actual 40th percentile MIPS Quality performance category score*	40th percentile MIPS Quality performance category score using historical methodology
2018		70.80*	--
2019		70.82*	--
2020		75.59*	--
2021		77.83*	--
2022	77.73^	72.40 (estimated for illustrative purposes) **	

* As published in Table 64 of the CY 2023 PFS final rule (87 FR 69868). The 40th percentile MIPS Quality performance category score was calculated by taking the 40th percentile of all submission-level MIPS Quality performance category scores (the unweighted distribution of scores), excluding entities/providers eligible for facility-based scoring.

^ As published in the Medicare Shared Savings Program: Performance Scores that Equate to the 30th and 40th Percentile MIPS Quality Performance Category Scores for Performance Years 2018 to 2022 document found at *https://www.cms.gov/files/document/medicare-shared-savings-program-performance-scores-equate-30th-and-40th-percentile-mips-quality.pdf*.

** As estimated for illustrative purposes based on the finalized methodology (as discussed in III.G.2.e. of this final rule). The performance year 2022 projected 40th percentile MIPS Quality performance category score for the quality performance standard is based on the average of the 2018, 2019, and 2020 40th percentile MIPS Quality performance category scores.

f. Apply a Shared Savings Program Scoring Policy for Excluded APP Measures and APP Measures That Lack a Benchmark

(1) Background

In the CY 2021 PFS final rule (85 FR 84720 through 84734), we finalized an approach that aligns the Shared Savings Program quality performance scoring methodology with the MIPS scoring methodology. We also stated that for each quality measure that an ACO submits that has significant changes, the total available measure achievement points are reduced by 10 points under the APP under current MIPS scoring policy (§ 414.1380(b)(1)(vii)(A)) (85 FR 84725)). In the CY 2021 PFS final rule (85 FR 84901), we finalized policies at § 414.1380(b)(1)(vii)(A) to provide that for each measure under MIPS that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. We stated that ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. As described at § 414.1380(b)(1)(vii)(A), measures that are excluded due to significant changes are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points.

In performance year 2022, two of the eCQMs/MIPS CQMs that are part of the APP measure set were excluded from MIPS measure achievement points and total available measure achievement points for the MIPS Quality performance category under § 414.1380(b)(1)(vii)(A). Specifically, the eCQM version of the Preventive Care and Screening: Screening for Depression and Follow-up Plan measure (Quality ID #134) and the Controlling High Blood Pressure measure (Quality ID #236) were excluded. Thus, under MIPS scoring policies, ACOs reporting one or both of these measures had their total measure achievement points and total available measure achievement points reduced by 10 (for reporting one measure) or 20 (for reporting both measures) points, respectively. Under the APP, these ACOs were still required to report all 6 measures; however, their performance year 2022 MIPS Quality performance category score was based on the 4 or 5 non-excluded measures (depending on whether the ACO reported one or both excluded measures) in the APP measure set. Consequently, the resulting MIPS Quality performance category score for an ACO that would have performed well on the excluded quality measures would be lower than it otherwise would have been if those measures were not excluded. Alternatively, if an ACO would have performed poorly on the excluded quality measures, then the resulting MIPS Quality performance category score would be higher than it otherwise would have been if those measures were not excluded. In either scenario, an ACO is required to report quality performance for all measures under the APP and has no control over whether and which measures are excluded.

(2) Revisions

Given that the Shared Savings Program does not determine which quality measures are excluded and that ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the ACOs' control, such as in the event a measure is excluded. Therefore, in the CY 2024 PFS proposed rule (88 FR 52432 and 52433), we proposed that, for performance year 2024 and subsequent performance years, if (1) an ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1), and (2) the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion under § 414.1380(b)(1)(vii)(A), then we would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), for the relevant performance year. This policy aims to alleviate the potential adverse impacts to shared savings determinations that may arise in the event that one or more of the quality measures required under the APP is excluded. We also proposed to make conforming changes to the regulation text § 425.512 by revising paragraph (a)(5)(i) and adding paragraph (a)(7).

We finalized in the CY 2023 PFS final rule (87 FR 69845) that unscored measures are removed from the calculation of an ACO's health equity adjustment, effectively receiving a performance scaler of 0 for those measures. However, we inadvertently did not codify this policy in the Code of Federal Regulations. Therefore, in the CY 2024 PFS proposed rule (88 FR 52433), we proposed to codify this policy by revising § 425.512(b)(3)(ii)(B) to state that CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. We proposed that the regulation text changes would be effective for performance year 2023 and subsequent performance years as the policy was finalized in the CY 2023 PFS final rule to calculate the health equity adjustment for performance year 2023 and subsequent performance years.

We also proposed that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1).

We proposed a change to the MIPS policy to remove the 10 percent threshold for changes to codes, clinical guidelines, or measure specifications for all measure types and are finalizing this policy as proposed (88 FR 52592 and 52593). We believe that our proposal to apply a floor to an ACO's Quality performance category score in determining the ACO's quality performance standard in the event that the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced under § 414.1380(b)(1)(vii)(A) functions in concert with our proposal being finalized in section IV.A.1.b.(2)(d) of this final rule. We refer readers to section IV.A.1.b.(2)(d) of this final rule for further discussion of the finalized changes to the MIPS scoring policy.

The following is a summary of the comments we received on the proposal

to establish a Shared Savings Program scoring policy for excluded APP measures and our response.

Comment: All comments we received were in support of the proposal to apply a Shared Savings Program scoring policy for excluded APP measures. Several commenters stated that these changes will ensure that ACOs are not negatively impacted by measure changes or benchmark issues that occur mid-year and are outside the ACO's control.

Response: Although several commenters stated that the proposed changes will ensure that ACOs are not negatively impacted by benchmark issues, we did not consider applying the proposed scoring policy to measures with benchmark issues as we were developing the proposals for the CY 2024 PFS proposed rule.

Under § 414.1380(b)(1)(i)(A), beginning with the CY 2023 performance period/2025 MIPS payment year, for eCQMs and MIPS CQMs, that meet the MIPS data completeness requirement but do not have a benchmark (for example, a historical or performance period benchmark) will receive zero achievement points (or 3 points for small practices). The scoring policies applicable to eCQMs and MIPS CQMs would also be applicable to Medicare CQMs beginning in performance year 2024. Given that the Shared Savings Program does not determine which quality measures do not have a benchmark and that ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the ACOs' control, such as in the event a measure does not have a benchmark. Therefore, we are finalizing at § 425.512(a)(7) the proposed policy with modification to include eCQMs, MIPS CQMs, and Medicare CQMs within the APP measure set that do not have a benchmark as described at § 414.1380(b)(1)(i)(A). We are also clarifying that this policy will not apply if an ACO's MIPS Quality performance category score is not impacted by measure exclusion or the lack of a benchmark.

We also sought public comment on our proposal to revise § 425.512(b)(3)(ii)(B) to state that, for the purposes of calculating the health equity adjustment to an ACO's quality score, CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. We proposed that the regulation text changes would be effective for performance year 2023 and subsequent performance years as the policy to calculate the health equity adjustment for performance year 2023 and subsequent performance years was finalized in the CY 2023 PFS final rule. Additionally, we proposed that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1). We note that our summary of comment and response for this proposal is not sequential to the policy's placement in our proposed rule. The placement here is not consequential to the finalization of the policy.

We did not receive public comments on these proposals; and therefore, we are finalizing these policies as proposed.

After consideration of the public comments, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), we are finalizing at § 425.512(a)(7) that for performance year 2024 and subsequent performance years, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP measure set and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when the ACO meets either of the following:

(i) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(ii) At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

We are also finalizing conforming changes to § 425.512 by revising paragraph (a)(5)(i) and adding paragraph (a)(7).

In proposing to bifurcate our scoring policies for the performance year 2024 and subsequent performance years we inadvertently failed to update § 425.512(b)(3)(i) to properly refer to the new § 425.512(a)(7). Among other things, § 425.512(b)(3)(i) applies the health equity adjustment calculated pursuant to § 425.512(b) to performance year 2024 and subsequent performance years.[210] We are finalizing a modification to add the determination of quality performance score for an ACO affected by this Shared Savings Program Scoring Policy to the list of uses of the ACO's health equity adjusted quality performance score. Specifically, we are revising redesignated paragraph (b)(4)(i) to read as follows: In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(1), (a)(5)(i)(B), and (a)(7) of this section.

g. Require Spanish Language Administration of the CAHPS for MIPS Survey

(1) Background

We have created official translations of the CAHPS for MIPS survey in seven languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese (81 FR 77386), in addition to the required administration of English survey. However, use of these translations is mostly voluntary, with the exception of a requirement to administer the Spanish translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Organizations (groups, virtual groups, subgroups, and APM entities) that elect CAHPS for MIPS must contract with a CMS-approved survey vendor to administer the survey and must request survey translations for the vendor to administer the survey in an optional language. Generally, the use of survey translations adds additional survey administration cost to the organization.

(2) Revisions

As discussed in section IV.A.4.f.(1)(c)(ii) of this final rule, we proposed to require Spanish language administration of the CAHPS for MIPS survey for organizations that elect CAHPS for MIPS. Specifically, we proposed to require organizations to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed

[210] Except in the case of an ACO that meets the quality performance standard pursuant to § 425.512(a)(5)(i)(B).

in the CAHPS for MIPS Quality Assurance Guidelines beginning with 2024 survey administration. This proposal is part of our efforts to advance health equity. We refer readers to section IV.A.4.f.(1)(c)(ii) of this final rule for further discussion of our proposal related to the CAHPS for MIPS survey.

The Quality Payment Program proposed Spanish language survey administration requirement for the CAHPS for MIPS Survey can be found in section IV.A.4.f.(1)(c)(ii) of this final rule. Comments received for the Spanish language requirement for the Shared Savings Program are included in section IV.A.4.f.(1)(c)(ii) with comments received by the Quality Payment Program. We refer readers to section IV.A.4.f.(1)(c)(ii) of this final rule, where we finalize this policy as proposed.

h. Align CEHRT Requirements for Shared Savings Program ACOs With MIPS

(1) Background

Many of our programs require the use of certified electronic health record (EHR) technology (CEHRT), including the Quality Payment Program, Shared Savings Program, and other value-based payment initiatives. For the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. In addition, section 1899(b)(3)(D) of the Act authorizes the Secretary to incorporate reporting requirements and incentive payments from section 1848 of the Act into the Shared Savings Program, such as requirements and payments related to electronic prescribing and electronic health records, including using alternative criteria for determining whether to make such incentive payments. Under these authorities, we have incorporated reporting requirements related to the adoption and use of CEHRT in our regulations, including specifically cross-referencing the Quality Payment Program's definition of CEHRT (§ 414.1305) in our regulatory definition of CEHRT at § 425.20. For the Shared Savings Program and Quality Payment Program, CEHRT currently is defined at § 414.1305 as EHR technology (which could include multiple technologies) certified by the Office of the National Coordinator for Health Information Technology (ONC) under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, set forth at 45 CFR 170.102, and a designated set of the 2015 Edition health information technology (IT) certification criteria as further provided therein.

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), sections 13001 through 13424 of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, February 17, 2009), established ONC under the Department of Health and Human Services, authorizing ONC to adopt standards for certifying health IT. ONC has codified its standards, implementation specifications, certification criteria, and certification program for health IT under 45 CFR part 170. Specifically, ONC has codified its certification criteria for health IT, including EHRs, at 45 CFR 170.315, which are currently referred to as the ''2015 Edition health IT certification criteria.'' For more information regarding ONC's current policies, standards, and certification requirements for health IT, please refer to 45 CFR part 170, particularly § 170.315, and the ONC Certification of Health IT website at *https://www.healthit.gov/topic/certification-ehrs/certification-health-it.*

In the CY 2019 PFS final rule (83 FR 59982 through 59988), we adopted three key requirements related to ACOs' use of CEHRT, beginning with the performance years starting on January 1, 2019.

First, ACOs must certify annually, at the end of each performance year, that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year. The ACO's eligible clinicians must use CEHRT that meets the definition in our regulation at § 425.20, which provides that CEHRT has the same meaning as under the Quality Payment Program at § 414.1305. Specifically, we updated our regulations at § 425.506(f) to reflect that, beginning with the performance years starting on January 1, 2019:

- ACOs in a track that does not meet the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Levels A through D, must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers.
- ACOs in a track that meets the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Level E or the ENCHANCED track, must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at § 414.1415(a)(1)(i). Under this requirement, for performance years beginning in 2019, 75 percent of eligible clinicians must use CEHRT to document and communicate clinical care to their patients or health care providers.

Second, we also revised the Shared Savings Program requirements for data submission and certifications at § 425.302(a)(3)(iii) to require the ACO to certify at the end of each performance year, that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

Finally, we updated our regulations at § 425.20 to incorporate the definition of CEHRT at § 414.1305 that applies under the Quality Payment Program. The Quality Payment Program's regulation at § 414.1305 defines CEHRT as EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition at § 170.102 and has been certified as meeting certain other criteria set forth in ONC's 2015 Edition health IT certification criteria at § 170.315 as further described in § 414.1305. Applying the Shared Savings Program's definition at § 425.20, ACOs under the Shared Savings Program must use EHR technology meeting the Quality Payment Program's definition of CEHRT at § 414.1305 to meet the requirements set forth in our regulation at § 425.506(f). In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23746 through 23917), which appeared in the April 18, 2023, **Federal Register**, ONC has proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC has proposed to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology

(IT) development timelines (88 FR 23757 through 23762).) As further discussed in section IV.A.4.f.(4)(c) of this final rule, we are finalizing our proposal to modify the Quality Payment Program's definition of CEHRT at § 414.1305 to flexibly incorporate any changes by ONC to its definition of Base EHR and its certification criteria for Health IT.

(2) Removing CEHRT Use Threshold Requirements and Requiring Reporting of the MIPS Promoting Interoperability Performance Category

To streamline CEHRT threshold requirements for ACOs and align with the Quality Reporting Program's Merit-Based Incentive Payment System (MIPS), we proposed to sunset the Shared Savings Program CEHRT threshold requirements and modify our regulations at § 425.506(f) to indicate that they will be applicable only through performance year 2023 (88 FR 52433). We further proposed, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this subchapter) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We proposed to codify this new requirement at § 425.507.

Specifically, we proposed that any requirements applicable to MIPS eligible clinicians reporting on objectives and measures specified by CMS for the MIPS Promoting Interoperability performance category would apply to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO at § 425.507(a). We further proposed that if any of these requirements for a MIPS eligible clinician reporting for the MIPS Promoting Interoperability performance category, including objectives and measures, are amended through rulemaking (such as adoption, modification, or removal of an objective or measure), then the new or modified requirements will also be applicable to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO under § 425.507. For instance, in section IV.A.4.f.(4) of this final rule, we proposed several modifications to the MIPS Promoting Interoperability performance category's requirements, including modifying the performance period at § 414.1320, as well as specific measures such as the High Priority Safety Assurance Factors for EHR Resilience (SAFER) Guides measure. To the extent these or other policies are finalized through rulemaking, then these requirements would also be applicable to ACO participants as provided by our proposal here.

To further align with applicable requirements for the MIPS Promoting Interoperability performance category, we proposed that MIPS eligible clinicians, QPs, Partial QPs, and ACOs as APM entities may be exempt from our proposed regulation at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity: (1) does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii); (2) is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or (3) has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS Promoting Interoperability performance category as an individual, group, or virtual group or the ACO reports MIPS Promoting Interoperability performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QP the exemption would not apply for purposes of satisfying our proposed regulation at § 425.507 (88 FR 52433).

Exclusions to MIPS eligible clinicians described at § 414.1310(b)(1)(iii) include eligible clinicians who do not exceed the MIPS low volume threshold. Eligible clinicians who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS as described at § 414.1310(b)(2). Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC) who provide services that are billed exclusively under the FQHC or RHC payment methodologies may voluntarily report the MIPS Promoting Interoperability performance category as a group, virtual group, or APM entity. MIPS eligible clinicians, QPs, and Partial QPs practicing in FQHCs or RHCs who provide services that are billed exclusively under FQHC or RHC payment methodologies may voluntarily report the MIPS Promoting Interoperability performance category as an individual, group, virtual group, or APM entity. It is important to note that exclusions to MIPS eligible clinicians as described at § 414.1310(b)(1)(i) and (ii) are not applicable to our proposal at § 425.507 because QPs and Partial QPs are required to report MIPS Promoting Interoperability performance category for purposes of satisfying the Shared Savings Program proposal at § 425.507. Examples of applicable exclusions under § 414.1380(c)(2) for reweighting of the MIPS Promoting Interoperability performance category include, but are not limited to, the following:

- MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO who are granted a hardship exception under § 414.1380(c)(2)(i)(C) at the individual, group, virtual group, or APM entity level.
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as described at § 414.1380(c)(2)(i)(A)(4).
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the Promoting Interoperability performance category as described at § 414.1380(c)(2)(i)(A)(*4*).[211]

[211] In the CY 2024 PFS proposed rule (88 FR 52435), we referenced the exclusion for MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the Promoting Interoperability performance category as described

Continued

Incorporating MIPS Promoting Interoperability performance category's requirements into the Shared Savings Program will alleviate the burden that the current policy creates for ACOs. Because the Shared Savings Program CEHRT attestation requirement and the MIPS Promoting Interoperability category requirements are not the same, ACOs have the burden of managing compliance with two different CEHRT program requirements. In finalizing the Shared Savings Program CEHRT attestation in the CY 2019 PFS final rule, we stated our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center (83 FR 59983). Given our unified goal and vision for the use of CEHRT, our proposal at § 425.507 will allow ACOs to focus on a unified set of program requirements for the use of CEHRT and reduce the administrative burden of managing compliance with a different set of program requirements with the same aim.

While ACOs would be able to report the MIPS Promoting Interoperability category at the individual, group, virtual group, or APM entity level for purposes of satisfying our proposed policy at § 425.507, we encourage ACOs to evaluate reporting the MIPS Promoting Interoperability performance category at the APM entity level for purposes of satisfying the Shared Savings Program regulation proposed at § 425.507. In the CY 2023 PFS final rule, we finalized a policy to introduce a voluntary reporting option for APM entities to report the MIPS Promoting Interoperability performance category at the APM entity level beginning with the CY 2023 performance period (87 FR 70033). For purposes of MIPS scoring and payment adjustments, if the ACO reports the MIPS Promoting Interoperability performance category at the APM entity level, the APM entity's score for the MIPS Promoting Interoperability performance category would be the first score identified to generate the APM entity level score. If the ACO does not report the MIPS Promoting Interoperability performance category at the APM entity level, the ACO's individual and group scores would be calculated as a weighted average up to the APM entity level to generate the APM entity level score for purposes of scoring the MIPS Promoting Interoperability performance category. If an eligible clinician reports the MIPS Promoting Interoperability performance category at the individual or group level under traditional MIPS or the APM Performance Pathway (APP) in addition to reporting the MIPS Promoting Interoperability performance at the APM entity level via the APP, for purposes of MIPS scoring and payment adjustments, that eligible clinician would receive the higher of their individual, group, or APM entity Promoting Interoperability performance category score. For more information about reporting the MIPS Promoting Interoperability performance category at the APM entity level, we direct readers to the MIPS Promoting Interoperability User Guide, which is updated each performance year, in the QPP Resource library at *https://qpp.cms.gov/resources/resource-library.* We anticipate releasing subregulatory guidance for ACOs that participate in the Shared Savings Program about voluntarily reporting the MIPS Promoting Interoperability performance category at the APM entity level in future performance years.

We solicited comments on our proposal that, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);

- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or

- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We proposed to codify this new requirement at § 425.507.

We also solicited comments on an alternative proposal to narrow the proposal to require ACOs to report the measures and requirements under the MIPS Promoting Interoperability performance category, in accordance with our regulations at 42 CFR part 414 subpart O, at the APM entity level. This alternative proposal would remove the option for MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO to report the MIPS Promoting Interoperability performance category at the individual, group, or virtual group level for purposes of satisfying our proposal at § 425.507.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments in support of the proposal to align CEHRT requirements with MIPS, citing the importance of meaningful CEHRT use and of expanding provider participation in Promoting Interoperability. One commenter also stated that the proposal will support CMS' goal of advancing eCQM capabilities among ACO participants, since use of CEHRT includes the ability to standardize the capture and reporting of data relevant for quality reporting. Another commenter supported aligning CEHRT requirements because it would lead to comprehensive reporting requirements across ACOs and facilitate better care coordination.

Response: We thank commenters for their support.

Comment: Several commenters were opposed to the proposal citing concerns that the proposal would increase administrative burden, especially for small practices, and discourage participation in the Shared Savings Program.

Response: We are finalizing with modifications our proposal to align the Shared Savings Program CEHRT requirement with MIPS Promoting Interoperability to clarify the requirement that an ACO participant, ACO provider/supplier, and ACO

at § 414.1380(c)(2)(i)(A)(*4*) twice in error. This error has been addressed in this final rule.

professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305 of this chapter) satisfy all of the requirements detailed at § 425.507(a). In response to the commenters' concerns that our proposal would increase administrative burden and discourage participation in the Shared Savings Program, our intent is to allow the ACO to exclude an ACO participant, ACO provider/supplier, or ACO professional from reporting MIPS Promoting Interoperability performance category in accordance with applicable policies that exclude or otherwise exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414 subpart O, provided however, that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified in § 425.507(a) solely on the basis of being a QP or Partial QP. We are finalizing our proposal with modifications to make clear the examples of exclusions that would be applicable to the requirements specified at § 425.507(a). Applicable exclusions to paragraph (a) may include the following:

- Low volume threshold as set forth at § 414.1310(b)(1)(iii),
- Eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician as set forth in § 414.1310(b)(2),
- Reweighting of the MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2).

These modifications are consistent with our original proposal that the Shared Savings Program's CEHRT requirements fully align with MIPS Promoting Interoperability performance category's requirements (88 FR 52434).

For example, if an ACO has 40 ACO participants that are MIPS eligible clinicians and 10 of the ACO participants do not earn a MIPS Promoting Interoperability performance category score because the ACO participants did not exceed the low volume threshold as set forth at § 414.1310(b)(1)(iii), then the ACO does not count in its public reporting the 10 ACO participants that did not earn a MIPS Promoting Interoperability performance category score because the ACO participants did not exceed the low volume threshold.

In another example, if in the ACO in the example above, 5 of the 10 ACO participants that did not exceed the low volume threshold as set forth at § 414.1310(b)(1)(iii), voluntarily report under the MIPS Promoting Interoperability performance category, those 5 ACO participants must be included in the in the number of ACO participants, ACO providers/suppliers, or ACO professionals that the ACO publicly reports. In this example, the ACO must publicly report the 35 ACO participants [(30 ACO participants without an exclusion) + (5 ACO participants that voluntarily reported) = 35 ACO participants] that earned a MIPS Promoting Interoperability performance category score. The ACO in this example does not count in its public reporting the 5 ACO participants that did not earn a MIPS Promoting Interoperability performance category score because the ACO participants did not exceed the low volume threshold.

In response to the comment regarding burden to small practices, we are assessing the appropriateness of exemptions to the requirements at § 425.507(a) based on Special status as defined at § 414.1305 and may address this in future rulemaking. We also note that the new reporting option to report MIPS Promoting Interoperability performance category at the ACO level, in addition to group reporting options, will help alleviate individual clinician reporting burden.

ACOs will have access to the MIPS eligibility status of the eligible clinicians that participate in the ACO at our website at *https://qpp.cms.gov*. ACOs are encouraged to check their participant's MIPS eligibility before and during the performance year to ensure that they have the most up to date eligibility information.

Comment: Several commenters stated that they believe that this reporting requirement would create a disincentive for ACOs to participate in an Advanced APM and obtain QP status. Many commenters believed that the proposal is at odds with MIPS policies that exclude QPs and Partial QPs from reporting MIPS. One commenter stated that QP determinations at the National Provider Identifier (NPI) level, instead of the ACO entity level, will initiate significant reporting challenges for ACOs that have to report for both QP and non-QP providers. One commenter was concerned that the Advanced APM must require all participating eligible clinicians to use CEHRT, citing that this could have the unintended consequence of limiting non-physician qualified health care professional participation in APMs due to financial constraints.

A few commenters had concerns that this requirement negates the benefit of APM participation for providers that alleviated some of the administrative reporting burden under MIPS. These commenters noted that they believe that aligning ACO reporting to the MIPS Promoting Interoperability requirements undercuts a primary benefit of APM participation for individual providers, thus weakening the incentive to participate in the program.

Response: In response to commenters' concerns about additional burden for QPs and Partial QPs, the new reporting option to report the MIPS Promoting Interoperability performance category at the ACO level, in addition to group reporting options, will help alleviate individual clinician's reporting burden.

Regarding commenters' statements that they believe that this reporting requirement would create a disincentive for ACOs to participate in an Advanced APM and obtain QP status, we wish to clarify that QP and Partial QP status are dependent, in part, on the APM being compliant with the Advanced APM criteria set forth at § 414.1415. Our proposal to align the Shared Savings Program's CEHRT requirement with MIPS Promoting Interoperability is compliant with the policy we are finalizing in section IV.A.4.n. of this final rule regarding Advanced APMs' requirement to use CEHRT for PY 2025 and subsequent performance years. This policy will sunset the current 75 percent CEHRT use requirement for Advanced APMs and replace it with a requirement that to be an Advanced APM, the APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use CEHRT. This policy is consistent with section 1833(z)(3)(D)(i)(I) of the Act, which generally requires that Advanced APMs require their participants to use CEHRT as defined in section 1848(o)(4) of the Act (88 FR 52627). As such, for Level E of the BASIC Track and the ENHANCED track of the Shared Savings Program to be eligible to be considered Advanced APMs in PY 2025 and subsequent performance years, the Shared Savings Program needs to update our CEHRT requirement to align with our proposal for CEHRT use for Advanced APMs, as well as maintain compliance with the other Advanced APM criteria detailed at § 414.1415.

Comment: Several commenters were concerned about the timeline for the implementation of this requirement given that ACOs must remove practices from their ACO participation list before the final rule is published. Commenters also had concerns that the proposed timeline does not allow ACOs time to bring small practices into compliance with CEHRT requirements. Many

commenters urged CMS to delay the implementation of these proposals.

Response: We recognize the concerns raised by commenters that finalizing this requirement for the PY 2024 would limit ACO's ability to work with their new ACO participants, ACO providers/suppliers, and ACO professionals to meet the CEHRT and MIPS Promoting Interoperability performance category reporting requirement. Therefore, after consideration of the public comments we received on this proposal, we have decided to delay implementation of this requirement to performance years beginning on or after January 1, 2025. The proposal would promote consistent CEHRT use across all Shared Savings Program ACOs, advance digital quality measurement, promote interoperability among clinicians through greater availability of digital data, and further align the Shared Savings Program with MIPS.

Comment: A few commenters opposed the proposal to align the Shared Savings Program's CEHRT requirements with MIPS, citing the different goals and functions of MIPS, the Shared Savings Program, and APMs. One commenter stated that that MIPS measures quality within point-in-time encounters by clinicians, whereas ACOs coordinate care across the continuum.

Response: The MIPS Promoting Interoperability performance category's reporting requirements are more comprehensive than the Advanced APM requirements and address key functions that can facilitate better care coordination and quality measurement and improvement. For example, the MIPS Promoting Interoperability performance category requires clinicians to demonstrate use of CEHRT and attest that they engage in activities to support CEHRT use and health information exchange, as well as activities to prevent information blocking or actions that limit interoperability. In contrast, the Shared Savings Program attestation requirement provides limited insight into CEHRT capabilities and use by ACOs.

MIPS and more advanced value-based arrangements, like the Shared Savings Program, operate on a continuum, with clinicians making decisions annually about whether to continue in MIPS or join more advanced payment models.[212] As we advance towards our goal to have all people with Traditional Medicare in an accountable care relationship with a health care provider by 2030, as outlined in our Innovation Strategy Refresh which can be accessed at *https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper,* alignment between MIPS and advanced value-based arrangements, like the Shared Savings Program, will ease the transition to accountable care. When value-based models are aligned, it becomes easier for health care providers to understand how they can succeed and provide high quality care, which lowers barriers to participation and accelerates adoption of value-based arrangements.

Comment: One commenter sought clarification on the impact on the ACO if individual clinicians within the ACO do not meet the MIPS Promoting Interoperability performance category's reporting requirements.

Response: We thank commenters for their comments. We are making an additional modification to paragraph (b) to specify exclusions that may be applicable for purposes of satisfying the Shared Savings Program requirements at § 425.507(a). Specifically, we are clarifying in § 425.507(b) our intention that any applicable policies that exclude or otherwise exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414, subpart O also apply to exclude ACO participants, ACO providers/suppliers, and ACO professionals from meeting the reporting requirement set forth in § 425.507(a). However, we are also clarifying in § 425.507(b), an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified in § 425.507(a) solely on the basis of being a QP or Partial QP; we expect QPs and Partial QPs in an ACO to report MIPS Promoting Interoperability performance category unless they are excluded or exempt from doing so under another applicable MIPS policy. This is consistent with our original proposal that the Shared Savings Program's CEHRT requirements fully align with MIPS Promoting Interoperability performance category's requirements (88 FR 52435). Together, these modifications more clearly delineate the obligations of ACO participants, ACO providers/suppliers, and ACO professionals under this policy.

We refer readers to Table 31 of this final rule for a non-exhaustive list of exclusions for that may be applicable to reporting the MIPS Promoting Interoperability performance category for purposes of satisfying the Shared Savings Program CEHRT policy for performance years beginning on or after January 1, 2025.

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[212] ''The Medicare Value-Based Care Strategy: Alignment, Growth, And Equity'', Health Affairs Forefront, July 21, 2022. *DOI: 10.1377/forefront.20220719.558038.*

TABLE 31: Examples of exclusions for reporting the MIPS Promoting Interoperability performance category for purpose of satisfying the Shared Savings Program CEHRT Alignment policy for performance years beginning on or after January 1, 2025

Example	Description	MIPS PI reporting for purposes of satisfying the Shared Savings Program CEHRT Alignment policy[a]	ACO Public Reporting^
Exclusion to MIPS eligible clinician	An ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that meets one or more of the following* exclusions to MIPS eligible clinician: (herein referred to as "certain exclusions to MIPS eligible clinician"): ● Does not exceed the low volume threshold (LVT) ● Eligible clinicians who are not MIPS eligible clinicians	An ACO participant, ACO provider/supplier, or ACO professional that meets one or more of the certain exclusions to MIPS eligible clinician for the applicable performance year is **not required** to report and/or earn a MIPS Promoting Interoperability performance category score for purposes of satisfying the Shared Savings Program CEHRT Alignment policy for that performance year.	The ACO **does not count** in the number of ACO participants, ACO providers/suppliers, and ACO professionals that the ACO publicly reports, an ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that meets certain exclusions to MIPS eligible clinician unless the ACO participant, ACO provider/supplier, or ACO professional voluntarily reports under the MIPS Promoting Interoperability performance category.
Eligible for reweighting of the MIPS Promoting Interoperability performance category	An ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that does not earn a MIPS Promoting Interoperability performance category score because the MIPS Promoting	An ACO participant, ACO provider/supplier, or ACO professional that does not earn a MIPS Promoting Interoperability performance category score for the applicable performance year because the MIPS Promoting Interoperability performance category was	The ACO **does not count** in the number of ACO participants, ACO providers/suppliers, and ACO professionals that the ACO publicly reports, an ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that does not earn a

Example	Description	MIPS PI reporting for purposes of satisfying the Shared Savings Program CEHRT Alignment policy[a]	ACO Public Reporting[^]
	Interoperability performance category was reweighted to zero percent of the final score.**	reweighted to zero percent of the final score is **not required** to report and/or earn a MIPS Promoting Interoperability performance category score for purposes of satisfying the Shared Savings Program CEHRT Alignment policy for that performance year.	MIPS Promoting Interoperability performance category score because the MIPS Promoting Interoperability performance category was reweighted to zero percent of the final score unless the ACO participant, ACO provider/supplier, or ACO professional voluntarily reports under the MIPS Promoting Interoperability performance category.
QPs or Partial QPs with an exclusion	An ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that is a QP or Partial QP for the applicable performance year and **meets** any of the following (herein referred to as "exclusions as described at § 425.507(b)" and as described elsewhere in Table 31 of this final rule): • Certain exclusions to MIPS eligible clinician, or • Eligible for reweighting of MIPS Promoting Interoperability performance category to zero percent of the final score	An ACO participant, ACO provider/supplier, or ACO professional that is a QP or Partial QP for the applicable performance year and meets an exclusion as described at § 425.507(b) are **not required** to report and/or earn a score in the MIPS Promoting Interoperability performance category for purposes of satisfying the Shared Savings Program CEHRT Alignment policy for that performance year.	The ACO **does not count** in the number of ACO participants, ACO providers/suppliers, and ACO professionals that the ACO publicly reports, an ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that is a QP or Partial QP for the applicable performance year that meets an exclusion as described at § 425.507(b) unless the ACO participant, ACO provider/supplier, or ACO professional voluntarily reports under the MIPS Promoting Interoperability performance category.
QPs or Partial QPs without an exclusion	An ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that is a QP or Partial QP for the applicable performance year and **does not meet** any of the exclusions as described at § 425.507(b) and as described in Table 31 of this final rule.	An ACO participant, ACO provider/supplier, or ACO professional that is a QP or Partial QP for the applicable performance year and does not meet an exclusion as described at § 425.507(b) **must** report and/or earn a score in the MIPS Promoting Interoperability performance category for purposes of satisfying the Shared Savings Program CEHRT Alignment policy for that performance year.	The ACO **must count** in the number of ACO participants, ACO providers/suppliers, and ACO professionals that the ACO publicly reports, an ACO participant, ACO provider/supplier, or ACO professional participating in the ACO that is a QP or Partial QP for the applicable performance year that does not meet an exclusion as described at § 425.507(b).

[a] MIPS PI Reporting for purposes of satisfying the Shared Savings Program CEHRT Alignment policy is described at § 425.507(a).

[^] ACO Public Reporting is described at § 425.308(b)(9).

* Certain exclusions to MIPS eligible clinician are described at § 425.507(b)(1) and (b)(2).

** Reweighting of the MIPS Promoting Interoperability performance category are described at § 425.507(b)(3).

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It may be helpful to note that an FQHC or RHC that bills exclusively under the FQHC or RHC payment methodologies and that meets one or more of the exclusions described at § 425.507(b) and in Table 31 of this final rule for the applicable performance year are not required to report and/or earn a score in the MIPS Promoting Interoperability performance category for purposes of satisfying the Shared Savings Program CEHRT Alignment policy for that performance year. Similarly, the ACO does not count in the number of ACO participants, ACO providers/suppliers, and ACO professionals that the ACO publicly reports an FQHC or RHC that bills exclusively under the FQHC or RHC payment methodologies and meets one or more of the exclusions described at § 425.507(b) and in Table 31 of this final rule for the applicable performance year, unless that FQHC or RHC voluntarily reports under the MIPS Promoting Interoperability performance category.

Beginning in PY 2025 and subsequent performance years, if an ACO fails to meet the requirements at § 425.507 and § 425.308(b)(9), CMS may take remedial action before termination for noncompliance as described at § 425.216, which includes providing a warning notice, requesting a corrective action plan (CAP) from the ACO, or placing the ACO on a special monitoring plan.

ACOs are required to manage their ACO participant and ACO provider/supplier lists. Additionally, to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS, participant agreements must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement as detailed at § 425.116(a)(7).

Comment: One commenter suggested that the goal of this proposal could better be achieved by requesting that EHR developers pull data automatically from CEHRT systems and report this data to provide CMS with data regarding adoption, use, and interoperability of CEHRT with less burden to ACOs.

Response: We note that the commenter's suggested approach could lead to under-reporting of the use of CEHRT, which would not support our goal of ensuring that ACO participants have robust CEHRT capabilities, nor would it provide a complete and accurate picture of ACO capabilities and could lead to compliance actions as previously noted. Our proposal to align the Shared Savings Program CEHRT requirement with MIPS Promoting Interoperability is the best way to allow ACOs to focus on a unified set of program requirements for the use of CEHRT. Additionally, the new reporting option to report MIPS Promoting Interoperability performance category at the ACO level, in addition to group reporting options, will help alleviate individual clinician reporting burden.

After consideration of public comments, we are finalizing, with modification and minor technical corrections, our proposal to align the Shared Savings Program's CEHRT requirements with MIPS, to delay the implementation of these amended policies until PY 2025. The modification to delay implementation of this proposal by 1-year is responsive to public feedback raising concerns that finalizing this requirement for the PY 2024 would limit ACO's ability to work with new ACO participants on their CEHRT readiness. This delay will allow ACOs ample time to consider the readiness of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants (QPs), or Partial Qualifying APM Participants (Partial QPs) to meet the requirements of the MIPS Promoting Interoperability performance category.

We are finalizing our proposal with modification to our new CEHRT reporting policy at § 425.507(a) for performance years beginning on or after January 1, 2025, unless otherwise excluded, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305), regardless of track, must satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414, subpart Oat the individual, group, virtual group, or APM entity level.
- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

We are finalizing at § 425.507(b) that an ACO participant, ACO provider/supplier, or ACO professional is excluded from the requirements specified in § 425.507(a) in accordance with applicable policies that exclude or otherwise exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414, subpart O, provided however, that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified at § 425.507(a) solely on the basis of being a QP or Partial QP. Applicable exclusions may include:

- Low volume threshold as set forth at § 414.1310(b)(1)(iii) of this chapter.
- Eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician as set forth in § 414.1310(b)(2) of this chapter.
- Reweighting of the MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2) of this chapter.

We are finalizing our proposal with modifications to codify this new requirement at § 425.507.

(3) Updating Public Reporting Requirements

As described in the CY 2019 final rule (80 FR 32813 through 32815), we believe that one important aspect of patient-centered care is patient engagement and transparency, which can be achieved by the public reporting of ACO quality and cost performance. Public reporting helps to hold ACOs accountable and may improve a beneficiary's ability to make informed health care choices, as well as facilitate an ACO's ability to improve the quality and efficiency of its care. To ensure our public reporting requirements reflect our proposal to require reporting of objectives, measures, and activities under the MIPS Promoting Interoperability performance category as discussed above, in CY 2024 final rule (85 FR 52436) we also proposed to require ACOs to publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as proposed at § 425.507. We proposed to codify this requirement at § 425.308(b)(9).

We proposed that MIPS eligible clinicians, QPs, and Partial QPs who would be excluded from reporting under the proposed regulation at § 425.507(b) as discussed previously may be excluded from the number of MIPS eligible clinicians, QPs, or Partial

QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS Promoting Interoperability performance category as an individual, group, or virtual group, or the ACO reports the MIPS Promoting Interoperability performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QPs should be included in the number of MIPS eligible clinicians, QPs, and Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal to publicly report the number of MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level. This commenter supported the public reporting requirement as a way to hold ACOs more accountable.

Response: We thank commenters for their support.

Comment: One commenter did not support the public reporting requirement, citing that this information could fluctuate often and would be confusing to Medicare beneficiaries instead of being informative.

Response: Public reporting may improve a beneficiary's ability to make informed health care choices, as well as facilitate an ACO's ability to improve the quality and efficiency of its care. As such, this requirement will ensure that our public reporting requirements reflect our proposal to require reporting of objectives, measures, and activities under the MIPS Promoting Interoperability performance category and promote robust CEHRT use and capabilities by ACOs.

After consideration of public comments, we are finalizing with modifications our proposal to update the Shared Savings Program public reporting requirements to delay the implementation of these revisions until PY 2025. The modification to delay implementation of this proposal by 1-year aligns with our modification to delay the implementation of our proposal to align the Shared Savings Program CEHRT requirement with MIPS. We are also finalizing modifications to our proposal at § 425.308(b)(9) to conform with our language finalized at § 425.507.

Lastly, as we discussed in our proposal if MIPS eligible clinicians, QPs, and Partial QPs that are excluded under § 425.507(b) report the MIPS PI performance category, the MIPS eligible clinicians, QPs, or Partial QPs should be included in the number of MIPS eligible clinicians, QPs, or Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9) (88 FR 52436). We are finalizing modifications to our proposal at § 425.308(b)(9) to make clear in our regulation text that ACOs must include in the public reporting the number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under § 425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable performance year.

We are finalizing that for performance year 2025 and subsequent performance years, the total number of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants (QPs), or Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category as set forth in § 425.507, that is comprised of the following—

- The number of ACO participants, ACO providers/suppliers, and ACO professionals that meet the requirements of § 425.507(a) and are not excluded under § 425.507(b) for the applicable performance year; and
- The number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under § 425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable performance year.

(4) Updating Annual Certification Requirements

We find that the MIPS Promoting Interoperability performance category's reporting requirements are more comprehensive and better address the key functions that facilitate better care coordination and quality measurement for ACOs. Our proposal to align the Shared Savings Program CEHRT requirements with MIPS would allow for greater insight into CEHRT use among ACO clinicians.

Currently, under § 425.302(a)(3)(iii), at the end of each performance year, ACOs must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable CEHRT threshold percentage specified at § 425.506(f). As discussed in section III.G.2.h.(2) of this final rule, we proposed to sunset the Shared Savings Program CEHRT threshold requirements and modify § 425.506(f) to indicate that they will end with performance year 2023.

To ensure our certification requirements align with our proposal in section III.G.2.h.(2) of this final rule, we also proposed to revise our regulation at § 425.302(a)(3)(iii) to make the current Shared Savings Program Annual Certification requirement applicable for only performance years 2019 through 2023. That is, we proposed to sunset the CEHRT certification requirement in the Shared Savings Program by amending regulations to no longer require ACO clinicians to report the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified at § 425.506(f).

We solicited comments on our proposal to sunset the CEHRT certification requirement in the Shared Savings Program at §§ 425.302(a)(3)(iii) and 425.506(f) and to add new requirements at § 425.507, as previously discussed. We also solicited comments on our proposal to add a new requirement for public reporting in § 425.308(b)(9), as previously discussed.

We did not receive public comments on our proposal to modify our annual certification requirement at § 425.302(a)(3)(iii). We are finalizing our proposal with modification to delay the alignment of the Shared Savings Program CEHRT requirement with MIPS Promoting Interoperability until PY 2025. Specifically, we are finalizing revisions to our regulation at § 425.302(a)(3)(iii) to make the current Shared Savings Program Annual Certification requirement applicable for only performance years 2019 through 2024.

i. MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs—Request for Information (RFI)

In the CY 2021 PFS proposed rule (85 FR 50232 and 50233), we proposed that for performance year 2021 and subsequent performance years, ACOs would be assessed on a measure set under the APP for Shared Savings Program ACOs. As part of finalizing the APP measure set (85 FR 34727), we stated that the transition to the APP

measure set was intended to reduce reporting burden and eliminate differences in the way ACOs are scored compared to their MIPS eligible clinicians, while also moving toward a more outcome-based, primary care focused measure set. Additionally, we stated that we selected the measures to be included because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program.

We received public comments raising concerns about the challenges and applicability of these measures to specialists that are part of their ACOs (85 FR 34727). Commenters provided feedback that: reducing the number of ACO quality measures would make specialists less likely to participate in the Shared Savings Program; the proposed measures are not relevant to ophthalmology specialty practices and suggested that the same measure sets used in MIPS be permitted for reporting through the APP or a protocol be put in place to determine if the measures are relevant to the clinicians reporting under the APP; CMS should work with interested parties to refine the current set of measures to make it more appropriate for ACOs, which are responsible for total cost of care for the populations they serve; CMS should clarify if the outcome measures selected are representative of all of the different types of populations that ACOs treat and recommended that CMS take patient compliance and case mix into consideration when selecting measures because some patients may take longer to achieve health goals and ACOs may not have the same relative volume of patients with diagnoses such as diabetes and hypertension.

In the CY 2022 PFS proposed rule (86 FR 39270), we solicited comments on reporting options for specialist providers within an ACO. Specifically, we stated that we have heard from interested parties that the population health/primary care focused measures in the APP are not applicable for specialist providers within an ACO. We noted in the final rule that we may consider feedback we received to inform future rulemaking (86 FR 65264).

In the CY 2022 PFS final rule (86 FR 65376), MVPs were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will be implemented through notice and comment rulemaking over the next few years to offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. Building upon our commitment to align quality measures across CMS,[213] we refer readers to Appendix 3: MVP Inventory, where we finalize the maintenance changes to the Value in Primary Care MVP. We noted that the primary care MVP would create continuity between the primary care measures assessed under MIPS and the measures providers would be accountable for in the Medicare Shared Savings Program.

In the CY 2024 PFS proposed rule (88 FR 52437), we noted that in light of the public comments described above and the finalization and continued development of the MVPs, we believe we need incentives for specialists in Shared Savings Program ACOs to report clinically relevant quality measures and to allow patients, referring clinicians, and ACOs to have more information regarding specialists involved in patient care. We believe that encouraging specialists to report on MVPs will lead to increased specialty engagement in the Shared Savings Program, thereby holding specialists accountable for quality improvement.

Beginning in CY 2023, specialists that report under MIPS, including specialists that participate in Shared Savings Program ACOs, have the option to register to report MVPs for the applicable CY performance period as described at § 414.1365(b) as a group, subgroup, or individual and to report on relevant MVP quality measures as described at § 414.1365(c). In the proposed rule, we solicited comments on scoring incentives that would be applied to an ACO's health equity adjusted quality performance score beginning in performance year 2025 when specialists who participate in the ACO report quality MVPs as described at § 414.1365(c)(1) (88 FR 52437).

We described in the proposed rule that, similar to the health equity adjustment finalized in the CY 2023 PFS final rule (87 FR 69838), we are considering bonus points for ACOs with specialists reporting quality MVPs as described at § 414.1365(c)(1) that would be applied after MIPS scoring is complete (88 FR 52437). ACOs may receive up to a maximum of 10 additional points added to their ACO's health equity adjusted quality performance score if they meet the data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), in addition to administering the CAHPS for MIPS survey. In addition to specialists that participate in the ACO reporting quality MVPs described at § 414.1365(c)(1), an ACO would be required to report all measures in the APP measure set, meet the data completeness requirement at § 414.1340 and receive a MIPS Quality performance category score under § 414.1380(b)(1) to be eligible for bonus points.

As stated in our proposed rule, our overarching intent is to have specialists participate in ACOs in a meaningful way and to collect quality data that is comparable to data reported by other specialty providers in quality MVPs (88 FR 52437). We solicited comments on our overall approach to align quality measures in the Adult Universal Foundation with measures used for evaluation in the Medicare Shared Savings Program. We also solicited comments on the following aspects of MVP reporting for specialists in Shared Savings Program ACOs:

- In order to highlight specialty clinical practice within ACOs, how should we encourage specialist reporting of MVPs?
- How should we encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and to address clinician concerns over measure appropriateness?
- How should we consider encouraging specialists to report the MVP that is most relevant to their clinical practice?
- How should we distinguish bonus points for ACOs that report on a larger volume of patients through MVPs?
- How should we provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs?
- What concerns and considerations should we be aware of when assessing ACOs for quality performance based on reporting quality measures within MVPs?
- Would incentivizing specialty MVPs create a disincentive for ACOs to report primary care focused APP and/or MVP measures?
- In the event that MIPS quality measures in MVPs are excluded under § 414.1380(b)(1)(vii)(A), should we apply the proposed Shared Savings Program scoring policy for excluded APP measures as described in section III.G.2.f. of this final rule?

As previously noted, providing ACOs with bonus points to their health equity adjusted quality performance score

[213] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

when ACOs' specialty clinicians report MVPs serves to encourage reporting of MVPs. Therefore, we do not intend to establish bonus points as a permanent policy. We solicited comments on how long we should have bonus points in place in order to incentivize MVP reporting. Once specialists are reporting MVPs, overall aggregate specialty performance within an ACO could be assessed. We solicited comments on if and how CMS should consider assessing overall specialty performance as part of the APP in the future.

We noted that in section IV.A.1.b. of this final rule, we included an RFI on how we can leverage MIPS policies to enable more Medicare beneficiaries to benefit from accountable care relationships within APMs and provide rigorous performance standards for those clinicians who report MVPs and remain in MIPS. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

j. Revisions to the Requirement To Meet the Case Minimum Requirement for Quality Performance Standard Determinations

(1) Background

For the eCQM/MIPS CQM reporting incentive for performance year 2024 and for the extreme and uncontrollable circumstances policy (§ 425.512(a)(2), (a)(5)(i)(A)(*2*), (c)(3)), we require ACOs to meet the case minimum requirement at § 414.1380 to determine the quality performance standard for ACOs in the first performance year of their first agreement period.

Section 414.1380 includes policies related to all of MIPS scoring and is not specific to the Quality performance category. Further, the phrase ''case minimum'' is mentioned in multiple paragraphs at § 414.1380. The broad reference to § 414.1380 under § 425.512(a)(2), (a)(5)(i)(A)(*2*), and (c)(3) does not specify which paragraph at § 414.1380 is applicable when applying case minimum for purposes of determining an ACO's quality performance standard. We believe that the references to meeting the case minimum requirement at § 414.1380 in the context of determining an ACO's quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(*2*), and (c)(3) is not sufficient in describing our policy's intent, which is to apply the MIPS Quality performance category scoring policies as described at § 414.1380(b)(1) in determining the ACO quality performance standard.

(2) Revisions

To alleviate confusion regarding the reference to case minimum in determining the ACO quality performance standard for performance year 2024 and subsequent performance years, we proposed to replace the references to meeting the case minimum requirement at § 414.1380 from § 425.512(a)(2), (a)(5)(i)(A)(*2*), and (c)(3) with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) in order to meet the quality performance standard (88 FR 52438). As described in our proposed rule, this revision would correct the purpose of our reference to case minimums by incorporating all of the applications of case minimums in the MIPS Quality performance category scoring policies in our policies to determine an ACO's quality performance standard under the Shared Savings Program (88 FR 52438). For example, under current policy at § 414.1380(b)(1)(i)(A)(*2*)(*ii*) in performance year 2024, if an ACO does not meet the case minimum requirement on an administrative claims-based measure, that measure would be excluded from the ACO's MIPS Quality performance category measure achievement points (numerator) and total available measure achievement points (denominator). If the ACO in this example meets the data completeness requirement at § 414.1340 for the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey, the ACO would receive a MIPS Quality performance category score. The resulting MIPS Quality performance category score in this example would be used to determine the ACO's quality performance standard under the Shared Savings Program.

All ACOs that participated in the Shared Savings Program were affected by an extreme and uncontrollable circumstance as described at § 425.512(c)(1) for performance years 2021, 2022, and 2023 due to the COVID–19 public health emergency. As stated in our proposal, we believe that any unintended impact of meeting the case minimum requirement at § 414.1380 in evaluating an ACO's quality performance standard for performance years 2021, 2022, and 2023 was mitigated by the application of the extreme and uncontrollable circumstance policy (88 FR 52438). Specifically, we stated that it is not our intent to exclude an ACO who received a MIPS Quality performance category score, but reported less than 20 cases on any measure(s) in the APP measure set from achieving the quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(*2*), and (c)(3), if that ACO is otherwise eligible to meet the quality performance standard (88 FR 52438).

Separately, we proposed to address a gap in the current rule regarding the ''minimum beneficiary sampling requirement'' at § 414.1380(b)(1)(vii)(B) (88 FR 52439). This policy provides for a 10-point reduction in the total available measure achievement points for MIPS eligible clinicians that submit five measures or fewer and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirement. As we stated in our proposal, the case minimum is not applicable to the CAHPS for MIPS survey, we did not intend to preclude ACOs that do not meet the minimum beneficiary sampling requirement to field a CAHPS for MIPS survey from meeting the Shared Savings Program quality performance standard or the alternative quality performance standard (88 FR 52439). We proposed revisions to the following regulation text sections:

- At § 425.512(a)(2)(ii) and (iii), we proposed to replace the phrase ''case minimum requirement at § 414.1380 of this subchapter'' with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.''

Additionally, we proposed to replace the phrase ''CAHPS for MIPS survey'' with the phrase ''CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter)'' (88 FR 52439). To read as follows: For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO would meet the quality performance standard under the Shared Savings Program, if:

++ For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

++ For performance year 2025 and subsequent performance years. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs and the CAHPS for MIPS survey

(except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

• At § 425.512(a)(5)(i)(A)(*2*), we proposed to remove the phrase ''and the case minimum requirement at § 414.1380 of this subchapter.'' As follows: If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

++ We are not including a requirement under § 425.512(a)(5)(i)(A)(*2*) for the ACO to receive a MIPS Quality performance category score under § 414.1380(b)(1). As described at § 414.1380(b)(1)(vii), the MIPS Quality performance category score is the sum of all the measure achievement points divided by the sum of total available measure achievement points for the quality performance category. As stated in our proposal, it would not be appropriate to require an ACO to receive a MIPS Quality performance category score in determining whether the ACO met the Shared Savings Program quality performance standard based on measure-level performance (such as in the case of the eCQM/MIPS CQM reporting incentive) (88 FR 52439).

• At § 425.512(c)(3)(iii), we proposed to remove the phrase ''case minimum'' for performance 2024 and subsequent performance years and replace with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.'' To read as follows: For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

We proposed to revise § 425.512(a)(5)(iii)(A) and (B) to read as follows:

• For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

• For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

Additionally, we proposed to add clarifying language to the proposed redesignated paragraph (b)(2) of § 425.512 on calculating an ACO's health equity adjusted quality performance score as follows:

• For performance year 2024 and subsequent performance years, CMS would calculate the ACO's health equity adjusted quality performance score as the sum of: the ACO's MIPS Quality performance category score for all measures in the APP measure set, and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section, to which the sum of these values may not exceed 100 percent, if the following requirements are met: (1) The ACO reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set; (2) meets the data completeness requirement at § 414.1340 for the three eCQMs/MIPS CQMs/Medicare CQMs; and (3) administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).

The following is a summary of the comments we received on these proposals and our responses.

Comment: Two commenters supported our proposal to revise the requirement to meet the case minimum requirement for quality performance standard determinations. One commenter stated that they believe that this proposal will better incorporate all case minimums in the MIPS Quality performance category scoring policy to determine an ACO's quality performance standard under the Shared Savings Program.

Response: We appreciate the commenters' support.

After consideration of public comments, we are finalizing the policies as proposed. For performance year 2024 and subsequent performance years, we are finalizing our proposal to replace the references to meeting the case minimum requirement at § 414.1380 from § 425.512(a)(2), (a)(5)(i)(A)(*2*), and (c)(3) with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) in order to meet the quality performance standard. We are also finalizing our proposal to address a gap in the current rule regarding the ''minimum beneficiary sampling requirement'' at § 414.1380(b)(1)(vii)(B) (88 FR 52439). We are also finalizing revisions to the following regulation text sections as proposed:

• At § 425.512(a)(2)(ii) and (iii), replace the phrase ''case minimum requirement at § 414.1380 of this subchapter'' with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.''

• To replace the phrase ''CAHPS for MIPS survey'' with the phrase ''CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).'' To read as follows: For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO will meet the quality performance standard if it meets the requirements under this paragraph (a)(2).

++ For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

++ For performance year 2025 and subsequent performance years. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

• At § 425.512(a)(5)(i)(A)(*2*), to remove the phrase ''and the case minimum requirement at § 414.1380 of this subchapter.'' To read as follows: If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting

the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

- At § 425.512(c)(3)(iii), to remove the phrase ''case minimum'' for performance 2024 and subsequent performance years and replace with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.'' To read as follows: For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

We are finalizing our proposal to revise § 425.512(a)(5)(iii)(A) and (B) to read as follows:

- For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.
- For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

Additionally, we are finalizing the addition of clarifying language to the redesignated paragraph (b)(2) of § 425.512 on calculating an ACO's health equity adjusted quality performance score as follows:

- For performance year 2024 and subsequent performance years. For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

3. Determining Beneficiary Assignment Under the Shared Savings Program

a. Modifications to the Step-Wise Assignment Methodology and Approach To Identifying the Assignable Beneficiary Population

(1) Background

(a) Background on Assignment Methodology

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. As we have explained in earlier rulemaking, the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services. In the context of the Shared Savings Program, ''assignment'' refers to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of certain primary care services from physicians and other health care practitioners associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.[214]

The regulations governing the assignment methodology under the Shared Savings Program are in 42 CFR part 425, subpart E. Under claims-based assignment, we determine a Medicare FFS beneficiary is assigned to an ACO if the beneficiary meets the criteria in § 425.401(a) to be eligible for assignment to an ACO, and the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology specified in §§ 425.402 and 425.404. Section 425.402 specifies a step-wise assignment methodology for determining an ACO's assigned beneficiary population based on beneficiaries' use of primary care services. In accordance with § 425.402(b)(1), as a ''pre-step'' in the two-step claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service furnished by a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This pre-step is designed to satisfy the statutory requirement under section 1899(c)(1) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO. Beneficiaries who meet the pre-step requirement are then assigned to an ACO through either one of two steps specified in § 425.402(b)(3) and (b)(4).

Under the first step of the assignment process, a beneficiary who is eligible for assignment and meets the pre-step requirement is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by primary care physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) who are ACO professionals in the ACO are greater than the allowed charges for primary care services furnished during the assignment window by primary care physicians, NPs, PAs, or CNSs who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. The second step of the assignment methodology applies to the remainder of the beneficiaries who are eligible for assignment and meet the pre-step requirement, who have not had a primary care service rendered during the assignment window by any primary care physician, NP, PA, or CNS, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by physicians who are ACO professionals with specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such

[214] See for example, 76 FR 67851, and 83 FR 67863.

specialty designations who are ACO professionals in any other ACO, or who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

The Shared Savings Program step-wise assignment process is offered in two similar, but distinct, claims-based assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. Consistent with the requirements of section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019. We use the same step-wise assignment methodology under § 425.402 to assign beneficiaries to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

In the June 2015 final rule (80 FR 32699), we finalized the definition of ''assignment window'' under § 425.20 to mean the 12-month period used to assign beneficiaries to an ACO. As described in the December 2018 final rule (83 FR 67861), the assignment window for ACOs under prospective assignment is a 12-month period offset from the calendar year (for example, October through September preceding the calendar year), while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year. Operationally, in determining beneficiary assignment for each performance year and benchmark year, we identify allowed charges for services billed under the HCPCS and CPT codes included in the applicable definition of primary care services under § 425.400(c), and according to the step-wise assignment methodology specified in subpart E of the Shared Savings Program's regulations, during all months of the 12-month period of the assignment window.

The step-wise assignment methodology was initially established with the November 2011 final rule and was modified through subsequent rulemaking. For instance, with the June 2015 final rule, we modified the approach to include claims for primary care services furnished by non-physician practitioners (NPs, PAs, and CNSs) in step 1 of the assignment methodology rather than in step 2, and to exclude services provided by certain physician specialties from step 2 of the assignment process. We refer readers to the November 2011 final rule (76 FR 67853 through 67858) and the June 2015 final rule (80 FR 32748 through 32755) for a discussion of the relevant background and related considerations. Generally, as we have previously explained in rulemaking (see, for example, 76 FR 67853 through 67855; see also 80 FR 32748 and 32754), the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services, such as in areas with primary care physician shortages. Further, including services furnished by NPs, PAs, and CNSs in determining where a beneficiary has received the plurality of primary care services in step 1 of the assignment methodology helps ensure that a beneficiary is assigned to the ACO whose ACO participants are actually providing the plurality of primary care for that beneficiary, and thus, should be responsible for managing the patient's overall care, or is not assigned to any ACO if the plurality of the beneficiary's primary care is furnished by practitioners in a non-ACO entity (see, for example, 80 FR 32748).

Various Shared Savings Program operations are based on the ACO's assigned population, or consider the size of the ACO's assigned population, which are summarized as follows:

- Within the Shared Savings Program's financial methodology:

++ CMS determines benchmark and performance year expenditures based on the ACO's assigned population as specified under subpart G of the regulations.

++ CMS determines the counties to include in the ACO's regional service area based on the ACO's assigned population (refer to definition of ACO's regional service area in § 425.20), and uses the ACO's assigned population in determining the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)) which is applied in calculating the two-way blend of national and regional growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(iv) and 425.652(a)(5)(iv) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2). CMS also uses the ACO's regional service area to determine the regional adjustment to the ACO's historical benchmark according to § 425.656.

++ CMS considers the proportion of the ACO's assigned beneficiary population that is dually eligible for Medicare and Medicaid and the difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and when calculating the offset factor applied to negative regional adjustments (see § 425.656(c)(4)).

++ CMS considers the size of the ACO's assigned population in calculating the proration factor when determining the ACO's eligibility for the prior savings adjustment (see § 425.658(b)(3)), as well as in determining the minimum savings rate (MSR)/minimum loss rate (MLR) for ACOs that select the option to have their MSR/MLR calculated based on the number of beneficiaries assigned to the ACO (refer to § 425.605(b)(2)(i)(C) (BASIC track) and § 425.610(b)(1)(iii) (ENHANCED track)).

++ CMS determines average prospective HCC risk scores for assigned beneficiaries for purposes of adjusting assigned beneficiary expenditures for severity and case mix (refer to §§ 425.601(a)(3) and (10), 425.605(a)(1), and 425.610(a)(2), (3) and (10)), adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

- In determinations related to an ACO's eligibility for participation for the Shared Savings Program:

++ CMS determines expenditures based on the ACO's assigned population when identifying if the ACO is a high revenue or low revenue ACO (as defined under § 425.20).

++ CMS considers whether an ACO meets the requirement to have at least 5,000 Medicare FFS assigned beneficiaries (see § 425.110).

++ CMS uses the ACO's number of assigned beneficiaries in calculating and recalculating the amount of the repayment mechanism required for ACOs participating under a two-sided model (see § 425.204(f)).

- For ACOs eligible to receive AIPs (see § 425.630(b)), CMS considers the size of the ACO's assigned population and the risk factors-based score of those beneficiaries in determining the quarterly payment amount (see § 425.630(f)).

• For ACOs that meet the reporting requirements for receiving a health equity adjusted quality performance score (see § 425.512(b)), CMS considers the proportion of the ACO's assigned beneficiary population that is underserved in determining the ACO's health equity adjustment bonus points (see § 425.512(b)(2)(iv)).

• For ACOs affected by an extreme and uncontrollable circumstance, CMS considers the proportion of the ACO's assigned beneficiaries residing in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance in determining the ACO's quality score (see § 425.512(c)(1)(i)). CMS considers the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance in determining the amount of shared losses owed by ACOs under a two-sided model (refer to §§ 425.605(f)(1) and 425.610(i)(1)).

• For ACOs that have established a beneficiary incentive program, beneficiaries assigned to an ACO who receive a qualifying service are eligible to receive an incentive payment (see § 425.304(c)(3)(ii) through (iv)).

• In accordance with the Shared Savings Program regulations under subpart H, CMS provides ACOs with certain aggregate reports and beneficiary-identifiable claims data on the ACO's assigned beneficiary population.

Further, a non-claims-based process for voluntary alignment applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment. Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. In the November 2018 final rule (83 FR 59959 through 59964), we finalized changes to the beneficiary voluntary alignment policies CMS previously established to implement the requirements under section 1899(c)(2)(B) of the Act (refer to § 425.402(e), as revised). In the November 2018 final rule (83 FR 59964), we revised the requirements related to primary care services and practitioner specialties previously established for the voluntary alignment process. As a result of this change, a voluntarily aligned beneficiary is no longer required to receive a primary care service from an ACO professional to be assigned to the ACO in which the beneficiary's designated primary care clinician is participating. Additionally, the revision established that a beneficiary can be voluntarily aligned to an ACO based on their selection of any ACO professional as their primary clinician, regardless of the ACO professional's specialty and including NPs, PAs, and CNSs. As specified in § 425.402(e)(1), and subject to § 425.402(e)(2), assignment under voluntary alignment supersedes any assignment that otherwise may have occurred under claims-based assignment.

(b) Background on Identification and Uses of the Assignable Beneficiary Population Under the Shared Savings Program

To identify the assignable beneficiary population, which is used in program financial calculations, we apply a similar logic as is used to identify the Medicare beneficiaries who can be assigned to an ACO in the pre-step to the claims-based assignment methodology (see, for example, 81 FR 5843, and 81 FR 37985). In the June 2016 final rule (81 FR 37950), we finalized policies to use the assignable beneficiary population (a subset of the larger population of Medicare FFS beneficiaries) as the basis of certain calculations that had previously been based on the overall Medicare FFS population, including expenditures used to trend and update ACOs' historical benchmarks and to establish the truncation thresholds used in expenditure calculations. In the June 2016 final rule (see 81 FR 37985 through 37988), we finalized the definition of ''assignable beneficiary'' under § 425.20 to mean a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). We specified that the assignable population used to calculate national and regional benchmarking factors was to be identified using the 12-month calendar year assignment window corresponding to the benchmark or performance year for all ACOs, regardless of assignment methodology which applied to the ACO, which at that time was determined by an ACO's track. We explained our belief that using assignable beneficiaries across all program calculations based on national and regional FFS expenditures would result in factors that are generally more comparable to ACO expenditures than factors based on the overall Medicare FFS population, which can include non-utilizers of health care services and other beneficiaries not eligible for assignment (see, for example, 81 FR 5843 and 5844).

In the CY 2023 PFS final rule (87 FR 69929 through 69932), we finalized a modification to this policy, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, to calculate risk-adjusted regional expenditures and the share of assignable beneficiaries assigned to an ACO using county-level values based on the assignable population identified using an assignment window that is consistent with the ACO's assignment methodology selection for the applicable performance year. (Refer to §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), and 425.654(a)(1)(i).) Under this approach, for ACOs selecting prospective assignment, we will use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we will use an assignable population of beneficiaries identified based on the calendar year assignment window (87 FR 69930). We also specified in the CY 2023 PFS final rule (87 FR 69931) that we would continue to compute all factors used in calculations that are based on the national assignable FFS population using an assignable population identified based on the calendar year assignment window. For ACOs participating under agreement periods beginning on or after July 1, 2019, and before January 1, 2024, we will continue to identify the assignable population that is the basis for calculating national and regional factors using the 12-month period based on a calendar year, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, regardless of the ACO's assignment methodology. (See § 425.601. See also 87 FR 69929, for a description of relevant background.)

The assignable beneficiary population is used in various calculations under the Shared Savings Program, including the following:

• CMS determines the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of truncating beneficiary expenditures in order to minimize variation from catastrophically large claims (see §§ 425.601(a)(4) and (c)(3), 425.605(a)(3), 425.610(a)(4)(ii), 425.652(a)(4), and 425.654(a)(3)).

• CMS determines average county FFS expenditures based on expenditures for the assignable

population of beneficiaries in each county of an ACO's regional service area (see §§ 425.601(c) and 425.654(a)) for purposes of calculating the ACO's regional FFS expenditures (see §§ 425.601(d) and 425.654(b)). CMS also determines the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)). The ACO's regional FFS expenditures and the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO are used in the following calculations:

++ Trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5) and 425.652(a)(5).

++ Determine the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2).

++ Determine the adjustment to the ACO's benchmark according to §§ 425.601(a)(8) and 425.652(a)(8).

• CMS determines national per capita FFS expenditures for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.652(a)(8)(iv), and determining a flat dollar amount ACPT according to § 425.660(b)(3).

• CMS determines national growth rates for assignable beneficiaries that are used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and to determine the blended growth rates used update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

• CMS determines average prospective HCC risk scores for assignable beneficiaries for purposes of adjusting county FFS expenditures for severity and case mix of assignable beneficiaries in the county according to §§ 425.601(c)(4) and 425.654(a)(4), calculating the regional adjustment to the historical benchmark by adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

(c) Concerns About Beneficiaries Excluded From the Current Assignment Methodology Based on the Pre-Step Requirement and Definition of an Assignable Beneficiary

We have established a goal that 100 percent of beneficiaries enrolled in Original Medicare be involved in a care relationship with accountability for quality and total cost of care by 2030.[215] We have also established health equity as a top priority through our CMS Framework for Health Equity (2022–2032).[216] However, we believe that the assignment pre-step and definition of assignable beneficiary may create barriers for some beneficiaries otherwise eligible for assignment to be assigned to ACOs. Revising the pre-step and definition of assignable beneficiary thus represents an opportunity to expand the assigned and assignable populations.

ACOs and other interested parties have also raised concerns that the current pre-step and definition of assignable beneficiary create barriers for some beneficiaries to be assigned to ACOs. For example, in previous proposed rules, we have received input from commenters that the pre-step requirement, as implemented in the current assignment methodology, systematically excludes from assignment beneficiaries who only received primary care from NPs, PAs, and CNSs. In response to the CY 2023 PFS proposed rule, a commenter noted that the current claims-based assignment methodology creates a barrier for NPs and their patients to participate in ACOs.[217]

Additional analysis by CMS has found that expanding the assignment methodology to allow more opportunities for beneficiaries to be assignable based on their receipt of primary care services provided by NPs, PAs, or CNSs would reduce the barriers for underserved beneficiaries to be assigned to ACOs. As described elsewhere in this section of this final rule, we have modeled the impact of revising the step-wise assignment methodology and expanding the definition of an assignable beneficiary. We observed that such an approach could add to the ACO-assigned population[218] and the national assignable population[219] identified under current Shared Savings Program policies a population of beneficiaries that are more likely to be disabled, be enrolled in the Medicare Part D low-income subsidy (LIS) and reside in areas with higher ADI scores. The newly added beneficiaries to the ACO-assigned and national assignable populations also had a lower average prospective HCC risk score, lower total per capita-year spending, higher hospice utilization rate, and higher mortality rate than the ACO-assigned and national assignable populations under current Shared Savings Program policies. Therefore, we believe that adjusting the assignment methodology within the flexibility available under the statute so that additional beneficiaries can be included in the population of beneficiaries assigned to ACOs participating in the Shared Savings Program, and modifying the definition of assignable beneficiary to include a broader population, would make meaningful steps toward greater health equity and align with priorities recently emphasized in our CMS Framework for Health Equity (2022–2032).[220]

(2) Revisions

(a) Overview of Revisions To Incorporate Use of an Expanded Window for Assignment

Section 1899(c)(1)(A) of the Act requires that claims-based assignment to ACOs be based on beneficiaries' utilization of primary care services furnished by ACO professionals who are physicians. In the CY 2024 PFS proposed rule (88 FR 52440 through 52449), we proposed to use an expanded window for assignment in a new step 3 to the claims-based assignment process to identify additional beneficiaries for ACO assignment (described in section III.G.3.a.(2)(b). of the proposed rule, 88 FR 52444 through 52446), and we

[215] Seshamani M., Fowler E., Brooks-LaSure C., Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

[216] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

[217] See comment letter from American Association of Nurse Practitioners, to Chiquita Brooks-LaSure, Administrator, CMS (September 6, 2022), available at *https://www.regulations.gov/comment/CMS-2022-0113-21927.*

[218] By ''ACO-assigned population,'' we refer to the population of beneficiaries assigned to ACOs pursuant to the Shared Savings Program assignment methodology specified under 42 CFR part 425, subpart E.

[219] By ''national assignable population'' we refer to the population of beneficiaries that meet the definition of assignable beneficiary under § 425.20, across the national population of Medicare FFS enrollees. We use this term for clarity, in certain contexts, to underscore a reference to the assignable population determined at the national level, across the Medicare FFS population.

[220] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

proposed to modify the definition of ''assignable beneficiary'' to be consistent with this use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population after application of the existing methodology (described in section III.G.3.a.(2)(c). of the proposed rule, 88 FR 52446 and 52447). We proposed to add a new definition of ''Expanded window for assignment'' in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window (as defined under § 425.20) and the preceding 12 months (described in section III.G.3.a.(2)(a). of the proposed rule, 88 FR 52443 through 52444).

The following is a brief summary of the proposed uses of the expanded window for assignment, described in greater detail elsewhere within section III.G.3.a of the proposed rule. First, we proposed that beneficiaries would be assigned to ACOs pursuant to the proposed step 3 to the beneficiary assignment methodology only after the current steps 1 and 2 have been carried out, and step 3 would apply only to beneficiaries who do not meet the pre-step requirement but who received at least one primary care service during the proposed expanded window for assignment with an ACO professional who is a primary care physician or a physician who has one of the specialty designations included in § 425.402(c). Beneficiaries qualifying for step 3 would be assigned based on the plurality of allowed charges for primary care services during this expanded window for assignment. Second, the proposed revision to the definition of an assignable beneficiary would similarly include beneficiaries who received at least one primary care service during the proposed expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). In combination with using the expanded window for assignment for identifying beneficiaries who received at least one primary care service from a primary care physician or a physician whose specialty designation is used in assignment, under both the proposed step 3 for assignment and proposed revised definition of an assignable beneficiary, we would continue to consider whether beneficiaries received at least one primary care service during the 12-month assignment window. We proposed that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

As we explained in the CY 2024 PFS proposed rule (see 88 FR 52443 through 52444), a number of factors informed our consideration of the duration of the expanded window for assignment. We stated our belief that a 24-month expanded window for assignment, as opposed to a longer period, would prioritize primary care services that were provided more recently. Through the proposed modifications to the assignment methodology and the definition of assignable beneficiary, we sought to better account for beneficiaries who may be receiving their primary care predominantly from non-physician practitioners during the 12-month assignment window, but who received care from a physician in the preceding 12 months, in recognition of the statutory requirement in section 1899(c) of the Act that claims-based assignment be based on receipt of primary care services from physicians who are ACO professionals. We stated our belief that primary care services furnished by NPs, PAs, and CNSs during the 12-month assignment window could reflect their work in clinical teams in collaboration with and under the supervision of physicians, and thereby represent a continuation of the beneficiary's primary care relationship with a physician from the previous year. Furthermore, use of a 24-month expanded window for assignment would build on experience we have gained and lessons learned from testing Medicare ACO initiatives by the Center for Medicare and Medicaid Innovation (Innovation Center), specifically from the use of a 2-year beneficiary alignment period in the ACO Realizing Equity, Access, and Community Health (REACH) Model and the Next Generation ACO (NGACO) Model.[221]

We also explained our belief that it would be timely to propose modifications to the definition of ''assignment window'' under § 425.20 for improved clarity and consistency with the programmatic applications of the assignment window. Under the existing definition, assignment window means the 12-month period used to assign beneficiaries to an ACO. However, under existing Shared Savings Program policies and under the proposed changes described in section III.G.3.a of the proposed rule, we use the term assignment window in referencing our identification of assignable beneficiaries. Therefore, we proposed to modify the definition of assignment window to mean the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both (88 FR 52443).

We solicited comments on proposed modifications to § 425.20, to revise the definition of ''assignable beneficiary,'' ''assignment window,'' and add a new definition of ''expanded window for assignment''.

We summarize and respond to public comments we received on these proposals elsewhere in this section of this final rule.

(b) Revisions To Add a Step 3 to the Beneficiary Assignment Methodology

For the performance year beginning on January 1, 2025, and subsequent performance years, we proposed to revise the step-wise beneficiary assignment methodology, as described in § 425.402, to include a step 3, which we proposed would utilize the proposed expanded window for assignment to identify additional beneficiaries for assignment among Medicare FFS beneficiaries who were not identified under the existing pre-step. (Refer to 88 FR 52444 through 52446.) Specifically, step 3 would identify all such beneficiaries not identified by the pre-step criterion specified in § 425.402(b)(1), who also meet the following criteria:

(1) Received at least one primary care service with a non-physician ACO professional (NP, PA, or CNS) in the ACO during the applicable 12-month assignment window.

(2) Received at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c) during the applicable 24-month expanded window for assignment.

A beneficiary meeting the aforementioned criteria would then be assigned to the ACO if the allowed charges for primary care services

[221] See, for example, CMS, Center for Medicare & Medicaid Innovation, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Operating Guide: Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-financial-op-guide* (refer to Appendix B, Beneficiary Alignment Procedures). See also, CMS, Center for Medicare & Medicaid Innovation, Next Generation ACO Model Benchmarking Methods (December 15, 2015), available at *https://innovation.cms.gov/files/x/nextgenaco-methodology.pdf* (refer to Appendix A, Next Generation ACO Model Alignment Procedures). In summary, under the ACO REACH Model and NGACO Model the alignment period consists of two alignment years. The first alignment year is the 12- month period ending 18 months prior to the start of the relevant performance year or base year. The second alignment year is the 12-month period ending 6 months prior to the start of the relevant performance year or base year.

furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, non-physician ACO professionals, or physicians with specialty designations included in § 425.402(c) during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations included in § 425.402(c), NPs (as defined at § 410.75(b)), PAs (as defined at § 410.74(a)(2)), and CNSs (as defined at § 410.76(b)) who are ACO professionals in any other ACO or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Further, in order to be assigned to an ACO through the step-wise assignment methodology, we proposed that a Medicare FFS beneficiary would continue to need to meet the eligibility criteria in § 425.401(a) for the 12-month assignment window, regardless of whether the beneficiary is assigned to an ACO in step 1 or 2, or proposed step 3. Under the proposed approach, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from claims-based assignment as they are under the current assignment methodology. Beneficiaries who meet the pre-step based on a 12-month assignment window (as specified in § 425.402(b)(1)) but are not assigned to an ACO in steps 1 or 2 would also continue to not be assigned to an ACO as these beneficiaries would not be considered for assignment in step 3. The proposed changes also would not change beneficiary voluntary alignment, which would continue to supersede claims-based assignment, as specified in § 425.402(e).

As specified in § 425.400(a)(3)(ii), beneficiaries who are prospectively assigned to an ACO will remain assigned to the ACO at the end of the benchmark or performance year, unless they meet any of the exclusion criteria under § 425.401(b). As a result, under claims-based assignment, a beneficiary prospectively assigned to an ACO is not eligible for assignment to a different ACO for the same benchmark or performance year.[222] We proposed to continue to apply this approach for beneficiaries prospectively assigned at step 1, step 2, or proposed step 3. In other words, a beneficiary who is assigned to an ACO based on prospective assignment through step 1 or 2 or proposed step 3 would remain assigned to that ACO for the benchmark or performance year (unless they meet any of the exclusion criteria under § 425.401(b)). Under this approach, a beneficiary prospectively assigned to an ACO for a benchmark or performance year would not be assigned to another ACO under prospective assignment or to an ACO under preliminary prospective assignment with retrospective reconciliation, even if the other ACO provides the plurality of the beneficiary's primary care services during the relevant benchmark or performance year.

We explained that the use of a 24-month expanded window for assignment would also require changes to the timeframe for which we recognize additional primary care service codes related to the COVID–19 Public Health Emergency (PHE), as outlined in § 425.400(c)(2). Under § 425.400(c)(2), we use certain additional primary care service codes in determining beneficiary assignment under § 425.400(c)(1) when the assignment window for a benchmark or performance year includes any month(s) during the COVID–19 PHE (as defined in § 400.200). In accordance with § 425.400(c)(2)(ii), the additional primary care service codes are applicable to all months of the assignment window, when the assignment window includes any month(s) during the COVID–19 PHE, with the exception of certain additional CPT codes (99441, 99442, and 99443) which we use in determining assignment until they are longer payable under Medicare FFS payment policies (as specified under § 425.400(c)(2)(i)(A)(*2*)). We refer readers to discussions in earlier rulemaking for the development of this policy, including 85 FR 84748 through 84755, 85 FR 84791 through 84793, and 86 FR 65276. We proposed to modify the regulations at § 425.400(c)(2)(i) and (ii) to incorporate references to the expanded window for assignment, such that we would apply the additional primary care service codes to all months of the assignment window or applicable expanded window for assignment when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 PHE (88 FR 52445). We explained that these proposed changes would be necessary to capture the additional codes related to the COVID–19 PHE when using the expanded window for assignment in determining assignment for a benchmark or performance year.[223]

The proposed use of an expanded window for assignment in an enhanced step-wise assignment methodology would result in a greater overall number of beneficiaries assigned to ACOs. All beneficiaries who are assigned to an ACO under the current methodology would continue to be assigned to an ACO under the proposed methodology. Under the proposed methodology, a beneficiary who does not meet the current pre-step requirement would also be eligible to be assigned to an ACO if they (a) received at least one primary care service from a NP, PA, or CNS who is an ACO professional in the ACO during the applicable assignment window and (b) received at least one primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the applicable expanded window for assignment.

Under proposed changes, the 12-month assignment window would continue to represent the period used to identify allowed charges for primary care services received from ACO professionals and analogous practitioners not participating in an ACO, for purposes of claims-based beneficiary assignment during steps 1 and 2. Thus, most beneficiaries currently assigned to an ACO under the existing assignment methodology would continue to be assigned to the same ACO under the proposed changes. We anticipated that only a very small share of beneficiaries would be assigned to a different ACO under the proposed assignment methodology, and any change in ACO assignment would be due to the operational order in which assignment is run and the precedence of prospective assignment over preliminary prospective assignment with retrospective reconciliation. Specifically, there may be a small share of beneficiaries who would be prospectively assigned to an ACO under the proposed step 3 for prospective assignment that differs from the retrospective ACO the beneficiary is

[222] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 2.3.2.2, ''Prospective Assignment'').

[223] See, for example, HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency (May 11, 2023), available at *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.* See also Letter to U.S. Governors from HHS Secretary Xavier Becerra on renewing COVID–19 Public Health Emergency (PHE) (February 9, 2023), available at *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html* (specifying the U.S. Department of Health and Human Services was planning for the COVID–19 PHE to end on May 11, 2023).

currently assigned to under steps 1 or 2 for preliminary prospective assignment with retrospective reconciliation. This precedence of prospective assignment follows the current assignment methodology, which currently assigns beneficiaries via steps 1 and 2 of prospective assignment to an ACO that may be different than the ACO to which the beneficiary would have been assigned via steps 1 or 2 if assigned to an ACO under preliminary prospective assignment with retrospective reconciliation. For the average retrospective ACO, the share of assigned beneficiaries affected by this precedence of prospective assignment has historically been very small, approximately 1.3 percent from 2018 through 2021.

The proposed addition of step 3 would add a population of otherwise omitted beneficiaries by using the expanded window for assignment to identify the required physician visit with an ACO professional and to determine the plurality of allowed charges for primary care services. Functionally, the beneficiaries who would be newly assigned are beneficiaries who received a primary care service from an ACO professional who is a primary care physician (as defined under § 425.20) or who has one of the specialty designations included in § 425.402(c) in the 12-month period prior to the assignment window and received a primary care service from a NP (as defined at § 410.75(b)), a PA (as defined at § 410.74(a)(2)), or a CNS (as defined at § 410.76(b)) during the assignment window. Notably, the proposed step 3 would continue to be consistent with section 1899(c)(1)(A) of the Act, because a beneficiary would have to have received a primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the expanded window for assignment to be eligible for assignment to the ACO.

Similar to any other change that affects beneficiary assignment, the proposed use of an expanded window for assignment in a step 3 could impact downstream aspects of the Shared Savings Program that rely on the assigned population, including the following potential effects:

- Larger populations of assigned beneficiaries could contribute to more ACOs meeting minimum size requirements to participate in the program.
- A larger assigned population would result in lower minimum savings rates for ACOs subject to a variable minimum savings rate (that is, ACOs in a one-sided risk model on the BASIC track's glide path or ACOs in a two-sided risk model that elected a variable minimum savings rate). Lower minimum savings rates reflect a lower threshold for ACOs to meet in order to share in savings. Similarly, a larger assigned population would result in a lower minimum loss rate for ACOs participating in a two-sided risk model with a variable minimum loss rate, which reflects a lower threshold for ACOs participating in a two-sided risk model to meet before they must share in losses.
- A larger assigned population would enable higher performance payment limits, which are based on a percentage of an ACO's total benchmark expenditures. As an ACO's assigned beneficiary population increases, so too do the ACO's total benchmark expenditures. Because the maximum shared savings an ACO can earn is determined as a percentage of total benchmark expenditures, a larger assigned population would result in a higher performance payment limit. Similarly, a larger assigned population would result in larger loss sharing limits for ACOs in two-sided risk models because loss sharing limits are also determined as a percentage of aggregate benchmarks.
- A larger assigned population could affect an ACO's revenue status as the ACO's ACO participants' total Medicare Parts A and B FFS revenue would not change but the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures would increase. In other words, revenue-to-expenditure ratios would decrease for ACOs that receive a larger assigned beneficiary population. Compared to the current assignment methodology, the proposed assignment methodology change could result in some ACOs being identified as low revenue instead of high revenue. As a result, other program elements tied to revenue status could then be affected by the proposed changes, specifically an ACO's eligibility for AIPs.
- Changes in the assigned population could directly affect ACOs' average risk scores, mix of beneficiaries across enrollment types, regional service area, and total expenditures during benchmark and performance years.

Expected impacts on several other program elements would depend on differences in the changes observed for beneficiaries added to the assignable population versus beneficiaries added to the ACO's assigned beneficiaries. For example, the impact of the proposed change to the assignment methodology on ACO performance would depend in part on the difference in spending levels and trends between those beneficiaries added to the assignable population, nationally and within an ACO's regional service area, versus those beneficiaries added to the ACO's assigned beneficiary population. The data shared with ACOs on their assignable and assigned beneficiaries would change under the proposed policy as the population of assignable and assigned beneficiaries changes.

We proposed modifications to subpart E of the Shared Savings Program regulations to specify the revised beneficiary assignment methodology. We proposed to specify the new step 3 in a new provision at § 425.402(b)(5). We also proposed technical and conforming changes to incorporate the revised methodology. We proposed to amend § 425.402(b)(1), describing the existing pre-step of the assignment methodology that would remain applicable for step 1 and step 2, to refer to the identification of all beneficiaries who had ''at least one primary care service *during the applicable assignment window* with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in [§ 425.402(c)]'' (emphasis added to reflect revised text). In § 425.402(c), which indicates the primary specialty designations used in assignment, we proposed to specify that the listed specialties would be considered for ACO professionals in step 2 (as described in § 425.402(b)(4)) and the proposed step 3 (which would become a new provision at § 425.402(b)(5)) of the assignment methodology. In § 425.400(a)(2)(ii), which generally describes quarterly updates to preliminary prospective assignment with retrospective reconciliation, we proposed to specify that assignment would be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404. Lastly, in § 425.400(a)(3)(i), which generally describes prospective assignment of beneficiaries to ACOs at the beginning of each benchmark or performance year, we proposed to amend the reference that specifies that we base prospective assignment on the beneficiary's use of primary care services in the most recent 12 months for which data are available, to specify instead the beneficiary's use of primary care services in the most recent 12 months or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

We summarize and respond to public comments we received on these proposals elsewhere in this section of this final rule.

(c) Revisions to the Definition of an Assignable Beneficiary

As described in the CY 2024 PFS proposed rule (88 FR 52446 through 52447), consistent with the previously described proposal to use an expanded window for assignment in an enhanced step-wise assignment methodology, we proposed to revise the definition of Assignable beneficiary in § 425.20 to include additional beneficiaries who would be identified using the expanded window for assignment. Under the proposal, we would continue to utilize the criterion in the existing definition, under which assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). Further, for the performance year beginning January 1, 2025 and subsequent performance years, we proposed that a Medicare FFS beneficiary who does not meet this requirement but who meets both of the following criteria would also be considered an assignable beneficiary:

- Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is a NP (as defined at § 410.75(b)), PA (as defined at § 410.74(a)(2)), or a CNS (as defined at § 410.76(b)).

We explained that the proposed use of an expanded window for assignment would result in a greater number of beneficiaries included in the assignable population (88 FR 52446). All beneficiaries who are currently assignable would continue to be assignable under the proposed revisions to the definition of an assignable beneficiary. Under the proposed definition, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from the population of assignable beneficiaries, just as they are excluded in the current definition of an assignable beneficiary. In other words, the 12-month assignment window would continue to represent the timeframe within which beneficiaries must receive at least one primary care service to be identified as an assignable beneficiary. Moreover, to identify a broader assignable population under this proposed approach, we specified it would be important to consider the criterion for the beneficiary to have received a primary care service during the 12-month assignment window to be met through a service furnished from a non-physician practitioner (NP, PA, and CNS), or from a primary care physician or a physician who has one of the specialty designations included in § 425.402(c) (as is required under the current definition).

The proposed approach to expanding the assignable beneficiary population could impact downstream aspects of the Shared Savings Program that rely on the assignable population, including the following effects:

- Changes in the distribution of expenditures among the national assignable population could affect the thresholds used to truncate expenditures.
- Changes in average per capita expenditures and risk scores among assignable beneficiaries in a given benchmark year could affect the average risk-adjusted spending within ACOs' regional service areas, which could affect regional adjustments.
- Differential changes in average per capita expenditures and risk scores over time could affect trend and update factors that are based on changes in expenditures for the national assignable population and in the risk-adjusted expenditures for the population of assignable beneficiaries in an ACO's regional service area.
- Changes in average prospective HCC risk scores for the national assignable population could affect the factors used to renormalize risk scores each benchmark and performance year and to risk-adjust the flat-dollar ACPT amounts.
- Changes in the number of assignable beneficiaries across ACO regional service areas could affect ACOs' market shares, which determine the weights used for blending the national and regional benchmark trend and update factors.
- Changes in the level of national FFS expenditures for the assignable population could affect the caps applied to the regional adjustment and prior savings adjustment to the historical benchmark and the calculation of the flat-dollar ACPT amount.

Under the current regulations, the time period we use to identify the assignable population that will be used to calculate different factors used in program financial calculations depends on whether it is a national or regional factor, the start date of an ACO's agreement period and, in some cases, an ACO's selected assignment methodology. Under the proposed revised definition of assignable beneficiary, for all ACOs (regardless of agreement period start date), for the performance year beginning on January 1, 2025, and subsequent performance years, for benchmark year and performance year factors based on the national assignable population, we would identify the assignable population using the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, and the preceding 12 months. We noted that under the proposal we would also use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months when identifying the assignable population for regional factors for performance year 2025 and subsequent performance years for use in calculations for ACOs that are continuing in agreement periods that began before January 1, 2024 (88 FR 52447).

For ACOs participating in agreement periods beginning on January 1, 2024, and in subsequent years, for performance year 2025 and in subsequent years for regional factors, we would identify the assignable population using the 24-month expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). That is, for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we would use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months. For ACOs selecting prospective assignment, the 24-month expanded window for assignment would be comprised of the 12-month, offset assignment window plus the preceding 12 months. For example, we would use October 1, 2022, to September 30, 2024, as the 24-month expanded window for assignment to identify the assignable population for performance year 2025 for ACOs under prospective assignment.

We proposed technical and conforming changes to provisions in subpart G of the Shared Savings

Program regulations that refer to the assignment window used to identify the assignable beneficiary population to incorporate references to the proposed approach to using an expanded window for assignment in identifying the assignable population for performance year 2025 and in subsequent performance years (88 FR 52447). We explained that the regulations establishing the benchmarking methodology for ACOs with agreement periods beginning before January 1, 2024, do not directly reference the assignment window, and thus would not require conforming changes. However, there are benchmarking methodology provisions for ACOs with agreement periods beginning on January 1, 2024, and in subsequent years that directly refer to the assignment window. Thus, we proposed to amend these provisions to specify that the assignable population would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii):

- In §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), provisions on calculating the county-level share of assignable beneficiaries who are assigned to the ACO for each county in the ACO's regional service area for purposes of calculating the blended national-regional growth rates used in trending and updating the benchmark (respectively).
- In the provision on redetermination of the regional adjustment for the second or each subsequent performance year during the term of the agreement period in § 425.652(a)(9)(ii).
- In the provision on the calculation of average county FFS expenditures for assignable beneficiaries in each county in the ACO's regional service area in § 425.654(a)(1)(i).
- In the provision on adjusting for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable beneficiary population for the ACO's regional service area for BY3, in calculating average per capita expenditures for the ACO's regional service area, in § 425.656(b)(3).

Similarly, we also proposed to specify in the new provision at § 425.655(b)(1) that the assignable population that would be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the proposed regional risk score growth cap adjustment factor (refer to section III.G.4.b. of this final rule) would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii) (88 FR 52447).

We solicited comments on our proposed modifications to the definition of assignable beneficiary in § 425.20. We also solicited comments on our proposed technical and conforming changes to references to the identification of assignable beneficiaries in subpart G of the Shared Savings Program regulations, as well as in the proposed new regulation at § 425.655 (on calculating the regional risk score growth cap adjustment factor), to incorporate the use of the assignment window or expanded window for assignment in identification of the assignable beneficiary population.

We summarize and respond to public comments we received on these proposals elsewhere in this section of this final rule.

(d) Simulations To Understand the Potential Effect of Proposed Changes

To understand the potential impact of using an expanded window for assignment to identify assignable beneficiaries, we simulated the impact of using the proposed definition of an assignable beneficiary using data for performance year (PY) 2021.[224] To simplify the analysis, this simulation used CY 2021 as the assignment window. Thus, the expanded window for assignment spanned from January 1, 2020, through December 31, 2021. We used a calendar year basis because we do not expect the impact of the proposed changes to meaningfully differ between retrospective and prospective assignment windows, the latter of which uses an offset window. In this analysis, the national assignable population included a total of 26.2 million beneficiaries based on the current methodology. The simulation applying the proposed policies then added 762,156 newly assignable beneficiaries, growing the national assignable population by about 2.9 percent. Additional analysis on estimated impacts of the proposed changes was included in the Regulatory Impact Analysis in section VI.E. of the proposed rule (see 88 FR 52706 through 52710, and 88 FR 52731). We solicited comments on the proposed approach and the potential effects of the proposed approach, including its effects modeled in the aforementioned simulation and its effects in other scenarios that commenters might have considered. We anticipated continuing additional simulations on the effect of the proposed changes to the assignment methodology to further inform our understanding of the potential impacts of the proposal and indicated that we planned to publish results from such additional simulations in the final rule.

As described in the CY 2024 PFS proposed rule, the original simulation results suggest that an expanded window for assignment may increase access to accountable care for underserved beneficiaries. Relative to the national assignable population as determined under the current assignment methodology, the group of added beneficiaries from the expanded window for assignment simulation were more likely to be disabled Medicare enrollees, resided in areas with slightly higher average Area Deprivation Index (ADI) national percentile rank (a measure of neighborhood socioeconomic disadvantage), and had a larger share with at least one month of Medicare Part D LIS enrollment (refer to Table 32).

[224] In the CY 2024 PFS proposed rule (88 FR 52448), we incorrectly stated that the simulation used the proposed definition for an assignable beneficiary and proposed step 3, using the set of ACOs and data for performance year 2021. This language inadvertently indicated that we simulated the potential impact of using an expanded window for assignment on both the assignable and ACO-assigned populations. The original simulation only simulated the impact of using an expanded window for assignment on the assignable population.

TABLE 32: Selected Characteristics of Beneficiaries Added to the National Assignable Population for PY 2021 through the Expanded Window for Assignment Simulation

	National Assignable Population Under Current Assignment Methods	Added to the National Assignable Population in the Simulation	National Assignable Population Under the Simulation
Total Beneficiaries	26,169,153	762,156	26,931,309
Total Person Years[1]	24,900,013	694,132	25,594,145
Share of Person Years by Medicare Enrollment Type			
End-Stage Renal Disease (ESRD)	0.9%	1.0%	0.9%
Disabled	11.1%	15.2%	11.2%
Aged/Dual	8.5%	7.6%	8.5%
Aged/Non-Dual	79.5%	76.3%	79.4%
Mean ADI National Percentile Rank[2]	43.2	46.5	43.3
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	20.4%	24.0%	20.5%

[1] This approach is consistent with calculation of ACO-assigned beneficiary person years as described in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version # 11, January 2023) available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*. Note that calculations of person years exclude months associated with episodes of care for treatment of COVID-19. Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications of Policies to Address the Public Health Emergency for COVID-19 (December 2020) available at https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf.

[2] Mean ADI National Percentile Rank was calculated as a weighted mean, weighted by person years, among beneficiaries with non-missing ADI percentile.

Note: Percentages in the table may not sum to 100% due to rounding. Similarly, total person years assigned to an ACO under current assignment methods and the total person years added to the ACO-assigned population in the simulation may not sum to the total person years assigned to an ACO under the simulation due to rounding.

These simulation results also suggest that using a 24-month expanded window for assignment in proposed step 3 of the claims-based assignment methodology would increase access to accountable care among beneficiaries with Medicare coverage for part of a year (such as beneficiaries who die during the performance year). The group of added assignable beneficiaries in the simulation previously described had a lower average prospective HCC risk score, lower total per capita spending in CY 2021, higher hospice utilization, and a higher mortality rate when compared to assignable beneficiaries identified using the current definition of assignable beneficiary. These results suggest that beneficiaries who would be added to the assignable population under the proposed changes may benefit from greater care coordination through ACOs.

We summarize and respond to public comments we received on these considerations elsewhere in this section of this final rule.

(e) Implementation of Revisions

In the CY 2024 PFS proposed rule (88 FR 52449), we proposed that the expanded window for assignment and revised step-wise assignment methodology would be applicable to all ACOs for the performance year beginning on January 1, 2025, and in subsequent performance years. For example, for a calendar year assignment window that runs from January 1, 2025, through December 31, 2025, the expanded window for assignment would run from January 1, 2024, through December 31, 2025. For an offset assignment window that runs from October 1, 2023, through September 30, 2024, the expanded window for assignment would run from October 1, 2022, through September 30, 2024. Consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the new methodology each time assignment is determined for a given benchmark or performance year and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. For example, applicant eligibility for PY 2024 will be determined during CY 2023. We explained that we would not be able to review public comments and decide whether to finalize the proposed changes in sufficient time to apply the expanded window for assignment and revised methodology for PY 2024 applications. Additionally, we anticipated that the proposed revised approach, if finalized, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. For these reasons, we would not be able to apply the expanded window for assignment and revised step-wise beneficiary assignment methodology for the performance year starting on January 1, 2024, and we proposed to apply this change beginning with the performance year starting on January 1, 2025.

We proposed that we would apply the proposed revised approach to determining beneficiary assignment and the revised definition of assignable beneficiary in establishing, adjusting, updating, and resetting historical benchmarks for ACOs entering new agreement periods beginning on January 1, 2025, and subsequent years. Also consistent with how we have implemented previous changes to the assignment methodology, we proposed that we would adjust benchmarks for all ACOs in agreement periods for which performance year 2025 is a second or subsequent performance year at the start of performance year 2025, so that the ACO benchmarks reflect the use of the same assignment rules and definition of assignable beneficiary as would apply in the performance year (refer to §§ 425.601(a)(9) and 425.652(a)(9)). We noted our belief that the expanded window for assignment and proposed step 3 represent a valuable change that would fill an important gap in the current assignment methodology. We stated that we have outlined a renewed vision and strategy for driving health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries.[225] In a January 2022 article, we stated our goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[226] Many Medicare FFS beneficiaries are currently excluded from the assignable and Shared Savings Program assigned populations despite receiving primary care from ACO professional NPs, PAs, and CNSs during the existing 12-month assignment window, and these excluded beneficiaries tend to come from populations characterized by greater social risk factors. We explained more specifically that beneficiaries likely to be added to the assignable population are more likely to be disabled, be enrolled in the Medicare Part D LIS, and reside in areas with higher ADI scores. We explained our belief that the proposed change to the assignment methodology represents an opportunity to not only grow the share of Medicare beneficiaries involved in accountable care relationships but to also support efforts to improve health equity in the Medicare program.

We solicited comments on the proposed changes to establish a new defined term in § 425.20, expanded window for assignment, for use in a proposed additional step 3 in the beneficiary assignment methodology and in identifying the assignable beneficiary population, revisions to the definition of assignable beneficiary, as well as proposed technical and conforming changes to provisions of the Shared Savings Program regulations, including the definition of assignment window under § 425.20, and provisions within subpart E and subpart G. We explained that the proposed changes, if finalized, would be applicable for the performance year beginning on January 1, 2025, and subsequent performance years. We welcomed comments on all aspects of the proposed changes, including the length of the expanded window for assignment. We also solicited comments on additional policies that CMS should consider for potential future rulemaking on our assignment methodology, with the goal of increasing the number of Original Medicare FFS beneficiaries assigned to an ACO, particularly in underserved communities.

We received public comments on the proposals and considerations described in section III.G.3.a of the CY 2024 PFS proposed rule. The following is a summary of the comments we received and our responses.

Comment: A large majority of commenters addressing our proposed modifications to the assignment methodology and to the definition of an assignable beneficiary were broadly supportive of an approach that would better account for beneficiaries' primary care relationships with non-physician practitioners. Some commenters expressed support for the overall goal of expanding access to accountable care, particularly for beneficiaries in rural and other areas experiencing primary care physician shortages.

Among these commenters, approximately half supported finalizing modifications as proposed. These commenters agreed that proposed changes would better account for beneficiaries' primary care relationships with non-physician practitioners and help bring a greater number of underserved beneficiaries into the Shared Savings Program.

Although generally supporting the proposals, many commenters shared various concerns about the proposed approach to include additional beneficiaries in the assigned and assignable populations based on primary care services provided by non-physician practitioners, and suggested changes to the proposed approach to address these concerns, including changes that may require modifications to other Medicare policies.

Response: We summarize and respond to commenters' specific concerns and suggestions throughout the rest of this section of this final rule. Following consideration of all public comments received, we are finalizing these proposals without modification. We believe these proposals represent important strides toward including additional beneficiaries in the ACO-assigned and the national assignable populations, improving beneficiary access to accountable care (particularly among underserved beneficiaries), and moving toward greater health equity, in alignment with priorities emphasized in our CMS Framework for Health Equity (2022–2032).[227] These changes are also aligned with HHS' Initiative to Strengthen Primary Care [228] because, by better recognizing and considering the variety of clinician types who participate in delivering high-quality primary care, these changes advance coordinated, integrated primary care and promote health equity.

Comment: Many commenters requested additional analysis and information on the potential impact on ACOs of the proposed modifications to the assignment methodology and definition of an assignable beneficiary, asking for more information on either one or a combination of the proposals. One commenter requested that CMS make such additional information available with sufficient time for ACOs to review it prior to entering agreement periods beginning on January 1, 2025. Other commenters, including both those that expressed general support for and others that opposed the proposed changes, asked for further analysis by CMS before finalizing the proposed changes.

Many commenters specifically requested analysis on more years of data than the one year of data used for the simulation analysis described in the CY 2024 PFS proposed rule. Some commenters pointed to the simulation of changes to the national assignable population provided in Table 30 of the

[225] See, for example, CMS Innovation Center ''Strategic Direction'' web page, at *https://innovation.cms.gov/strategic-direction.* See also, CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper.*

[226] Seshamani M., Fowler E., Brooks-LaSure C., Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

[227] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), *16–22,* available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

[228] U.S. Department of Health and Human Services, Request for Information (RFI): *HHS Initiative to Strengthen Primary Health Care,* 87 FR 38168 through 38170 (June 27, 2022).

CY 2024 PFS proposed rule (see 88 FR 52448), which relied on PY 2021 data, which they noted was impacted by anomalies related to the COVID–19 pandemic. These commenters suggested that CMS expand this simulation to include data from additional years, such as 2019, 2020, 2021, and 2022.

Several commenters expressed concern that revising the definition of an assignable beneficiary will have varying effects on ACOs' financial performance due to the definition's effect on the national and regional assignable populations, which are used to calculate an ACO's benchmark. In particular, these commenters explained that while CMS estimated that the overall growth in the national assignable population will be small, CMS did not examine changes to regional assignable populations, which are used in certain calculations to adjust and update ACOs' financial benchmarks. As a result, some commenters were concerned that rural ACOs might be disproportionately affected, in part due to their smaller size.

Given these concerns, commenters urged CMS to provide additional analysis of the impact of the revisions to the definition of assignable beneficiary and proposed step 3 to assess financial and performance-related factors, including the following:

- Impacts to ACO benchmarks.
- Potential changes to regional factors based on regional FFS expenditures calculated with the new definition of an assignable beneficiary to ensure that any implementation of these proposals does not result in unintended consequences for rural ACOs and ACOs in underserved communities.
- Changes to ACO per beneficiary per year expenditures and average risk scores under the new definition of assignable beneficiary.
- Differential impact ''based on geography, ACO size and composition,'' ACOs participating under preliminary prospective assignment with retrospective reconciliation versus ACOs under prospective assignment, and ACOs with large beneficiary populations receiving care from safety net providers.
- The impact of the proposed changes on various Shared Savings Program calculations, including minimum savings rates, performance payment limits, risk adjustment, and the determination of an ACO's status as high revenue or low revenue.

Several commenters urged CMS to provide additional analysis to assess the impact of the proposed changes at the individual ACO level, and with specificity for sub-populations of beneficiaries by demographic factors. In particular, these commenters urged CMS to provide this analysis to ensure the proposals would not have disparate impacts on ACO financial performance, and as several commenters put it, result in ''artificial winners and losers.'' However, the commenters did not provide specific suggestions on how to conduct this analysis.

Response: In the CY 2024 PFS proposed rule (88 FR 52448 through 52449), we described results from our analysis simulating the impact of our proposed modifications to the definition of an assignable beneficiary on the assignable population, and these results are restated in section III.G.3.a.(2)(d) of this final rule. Following publication of that proposed rule, we further simulated our proposed changes on both the assignable and ACO-assigned populations using multiple years of data. While the original analysis focused on simulating the impact of our proposed changes on the assignable population for PY 2021, in these later analyses, we simulated changes for both the assignable and ACO-assigned populations for PYs 2019 and 2021 using the set of 364 ACOs that participated in the Shared Savings Program in both of those PYs. The additional simulation also allowed us to further examine how these proposals would impact ACOs, including the expected impact of these proposals on ACO financial performance measured in terms of gross savings. Furthermore, the additional analysis using two years of data allowed us to confirm that findings from PY 2021—a year affected by the PHE for COVID–19—were not anomalous. As with the initial analysis, we simplified this additional analysis by using CYs 2019 and 2021 as the respective assignment windows for each of these PYs, which would align with the assignment window for preliminary prospective assignment with retrospective reconciliation. Thus, the expanded window for assignment spanned from January 1, 2020, through December 31, 2021 for CY 2021, and from January 1, 2018, through December 31, 2019 for CY 2019.

We agree with commenters that providing findings of additional analysis of the impact of the revisions to the definition of assignable beneficiary and proposed step 3 to assess financial and performance-related factors is important to illustrate the policy changes, and we remain committed to ensuring program transparency. The additional analysis we summarize in this section addresses commenters' requests for more information on the impact of the proposed changes on assignment of beneficiaries, ACO benchmarks, ACO gross savings, and ACO per capita savings and average risk scores in both a year affected by the PHE for COVID–19 and a year not affected by the PHE for COVID–19. The simulation of the impact of the proposed changes on ACO benchmarks and gross savings accounts for changes to regional adjustments and regional risk ratios as a result of the proposed step 3 and the proposed changes to the definition of an assignable beneficiary, thereby addressing the requests from commenters for additional analysis on the impact of the proposed changes on ''regional factors.''

We note that commenters did not include detailed recommended specifications for analyzing differential impacts on a number of metrics or factors relevant to the Shared Savings Program. We believe our analysis based on the following factors (described in greater detail in this response) corresponds to the general categories of analysis requested by commenters: distinguishing ACOs based on their number of assigned beneficiaries as an indicator of ACO size; distinguishing ACOs based on their market share in their regional service areas; [229] distinguishing ACOs located in urban versus ACOs in rural areas based a classification system for identifying the urbanicity of the counties in which the ACO's assigned beneficiaries reside; [230] and distinguishing ACOs according to what commenters referred to as ''ACO composition'' (to mean the demographic factors of the ACOs' assigned beneficiaries) or share of underserved populations, according to the ACO's proportion of assigned beneficiary person years by Medicare enrollment type, share of beneficiaries with an ADI national percentile rank of 85 or greater, and share of beneficiaries with at least

[229] An ACO's aggregate market share is calculated as the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the performance year for each Medicare enrollment type. In calculating this weighted average, the weight applied to the share for each Medicare enrollment type is equal to the ACO's performance year assigned beneficiary person years for that enrollment type.

[230] For this analysis, we classified ACOs into urbanicity categories (for example, ''Large Central Metropolitan,'' or ''Noncore'') as defined by the U.S. Census Bureau Delineation files, available at *https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html,* and using the National Center for Health Statistics (NCHS) Urban-Rural Classification Scheme for Counties, available at *https://www.cdc.gov/nchs/data_access/urban_rural.htm,* based on the urbanicity of the counties in which their assigned beneficiaries reside. We classified ACOs into the urbanicity category representing the plurality of their assigned beneficiaries.

one month of Medicare Part D LIS enrollment. Our additional analysis examined the differential financial impact on, and possible unintended consequences for, different groups of ACOs based on their proportion of assigned beneficiaries dually eligible for Medicare and Medicaid.

A comparison of the simulated impact on the assignable population for PY 2019 and PY 2021 revealed similar patterns between the two years, suggesting that the PHE for COVID–19 likely did not meaningfully affect the PY 2021 simulation results shared in the CY 2024 PFS proposed rule. As with PY 2021, in PY 2019 the group of added beneficiaries from the expanded window for assignment simulation were more likely to be disabled Medicare enrollees and have an ADI national percentile rank of 85 or greater, and a larger share of these beneficiaries had at least one month of Medicare Part D LIS enrollment (refer to Table 33). Additionally, for both PY 2019 and PY 2021, the group of added assignable beneficiaries in the simulation had a lower average prospective HCC risk score, lower total per capita spending in CY 2021, and higher hospice utilization when compared to the population identified using the current definition of assignable beneficiary.

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TABLE 33: Selected Characteristics of Beneficiaries Added to the National Assignable Population for PY 2019 and PY 2021 through the Expanded Window for Assignment Simulation

	National Assignable Population Under Current Assignment Methods	Added to the National Assignable Population in the Simulation	National Assignable Population Under the Simulation
PY 2019			
Total Beneficiaries	28,599,089	711,107	29,310,196
Total Person Years[1]	27,209,440	651,700	27,861,140
Share of Person Years by Medicare Enrollment Type			
End-Stage Renal Disease (ESRD)	1.1%	1.0%	1.1%
Disabled	13.2%	18.4%	13.4%
Aged/Dual	8.9%	8.4%	8.9%
Aged/Non-Dual	76.8%	72.2%	76.7%
Share of beneficiaries with ADI National Percentile Rank of 85 or greater	11.3%	12.8%	11.3%
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	23.2%	28.1%	23.3%
PY 2021			
Total Beneficiaries	26,169,153	762,156	26,931,309
Total Person Years[1]	24,900,013	694,132	25,594,145
Share of Person Years by Medicare Enrollment Type			
End-Stage Renal Disease (ESRD)	0.9%	1.0%	0.9%
Disabled	11.1%	15.2%	11.2%
Aged/Dual	8.5%	7.6%	8.5%
Aged/Non-Dual	79.5%	76.3%	79.4%
Share of beneficiaries with ADI National Percentile Rank of 85 or greater	9.8%	10.9%	9.9%
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	20.4%	24.0%	20.5%

[1] This approach is consistent with calculation of ACO-assigned beneficiary person years as described in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version # 11, January 2023) available *at https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*. Note that calculations of person years exclude months associated with episodes of care for treatment of COVID-19. Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications of Policies to Address the Public Health Emergency for COVID-19 (December 2020) available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf*.

Note: Percentages in the table may not sum to 100% due to rounding. Similarly, total person years assigned to an ACO under current assignment methods and the total person years added to the ACO-assigned population in the simulation may not sum to the total person years assigned to an ACO under the simulation due to rounding.

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We present similar results in Table 34 for the simulations of the proposed addition of step 3 to the beneficiary assignment methodology. The simulations increased the total number of beneficiaries assigned to ACOs by 2.1 percent in PY 2019 and by 2.3 percent in PY 2021. Across both PY 2019 and PY 2021, the vast majority of ACOs (95.4 percent in PY 2019 and 93.9 percent in PY 2021) observed an increase between 0 and 5 percent in their number of assigned beneficiaries. Under these simulations, no ACOs observed a decrease in size of their assigned beneficiary population. Characteristics of beneficiaries newly added to the ACO-assigned populations for PY 2019 and PY 2021 resembled those of beneficiaries newly added to the national assignable population in the analysis described in the CY 2024 PFS proposed rule (88 FR 52448 through 52449). Compared to the ACO-assigned population under the current assignment methodology, beneficiaries newly added pursuant to proposed step 3 were more likely to be disabled Medicare enrollees and have an ADI national percentile rank of 85 or greater and a larger share of these beneficiaries had at least one month of Medicare Part D LIS enrollment. This group of

beneficiaries newly added to the ACO-assigned population also had a lower average prospective HCC risk score, lower total per capita spending, and higher hospice utilization rate in PY 2019 and PY 2021 when compared to the ACO-assigned population under the current assignment methodology.

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TABLE 34: Selected Characteristics of Beneficiaries Added to the ACO-Assigned Population for PY 2019 and PY 2021 through the Step 3 Assignment Simulation

	ACO-Assigned Population Under Current Assignment Methods	Added to the ACO-Assigned Population in the Simulation	ACO-Assigned Population Under the Simulation
PY 2019			
Total Beneficiaries	10,284,764	213,544	10,498,308
Total Person Years[1]	10,020,314	205,610	10,225,924
Share of Person Years by Medicare Enrollment Type			
End-Stage Renal Disease (ESRD)	0.7%	0.8%	0.7%
Disabled	11.2%	14.9%	11.3%
Aged/Dual	6.4%	6.4%	6.4%
Aged/Non-Dual	81.7%	77.9%	81.6%
Share of beneficiaries with ADI National Percentile Rank of 85 or greater	10.8%	11.6%	10.8%
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	17.4%	20.9%	17.4%
PY 2021			
Total Beneficiaries	10,446,047	239,498	10,685,545
Total Person Years[1]	10,194,779	230,442	10,425,222
Share of Person Years by Medicare Enrollment Type			
End-Stage Renal Disease (ESRD)	0.6%	0.7%	0.6%
Disabled	9.2%	12.1%	9.3%
Aged/Dual	6.0%	6.1%	6.0%
Aged/Non-Dual	84.2%	81.2%	84.1%
Share of beneficiaries with ADI National Percentile Rank of 85 or greater	9.0%	9.8%	9.0%
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	15.0%	17.5%	15.0%

[1] This approach is consistent with calculation of ACO-assigned beneficiary person years as described in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version # 11, January 2023) available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*. Note that calculations of person years exclude months associated with episodes of care for treatment of COVID-19. Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications of Policies to Address the Public Health Emergency for COVID-19 (December 2020) available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf*.

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Note: Percentages in the table may not sum to 100% due to rounding. Similarly, total person years assigned to an ACO under current assignment methods and the total

person years added to the ACO-assigned population in the simulation may not sum to the total person years assigned to an ACO under the simulation due to rounding.

We also simulated the impact of the proposed modifications to the assignment methodology and the definition of an assignable beneficiary on ACOs' financial performance, measured in terms of gross savings (that is, benchmarks minus expenditures). To conduct this financial impact simulation, we made additional simplifying assumptions. We assumed that CY 2019 represented Benchmark Year 3 (BY3) and that CY 2021 represented PY2. We then calculated key benchmarking components to simulate ACOs' updated benchmarks and compared these updated benchmarks to ACOs' simulated PY 2021 expenditures to estimate gross savings. We then made gross savings estimates using the current assignment methodology and definition of assignable beneficiary and compared those estimates to gross savings estimates made using the proposed modifications to the beneficiary assignment methodology and definition of an assignable beneficiary.

As summarized in Table 35, on average, the simulated financial impact of the proposed modifications to the beneficiary assignment methodology and to the definition of an assignable beneficiary was relatively small. We observed slight average decreases in ACOs' per capita benchmarks that we attribute primarily to a slight decrease (1.7 percent) in the average regional adjustment. When analyzing combined impacts on ACO's benchmarks and performance year spending, we observed that average ACO per capita gross savings decreased by $4.30, or 1.3 percent, but total gross savings increased by an average $66,618, or 0.9 percent. In other words, in these illustrative analyses based on 2019 and 2021 data although the average ACO generated lower gross savings on a per capita basis, the average ACO generated greater total dollar savings due to an increase in the total number of assigned beneficiaries. Actual financial impacts from the proposed modifications to the beneficiary assignment methodology and to the definition of an assignable beneficiary, may vary based on how ACOs increase care coordination and multiple other factors. Impacts on actual gross savings calculations starting in PY2024 might be even more limited than the relatively modest impacts estimated from the simulation because the simulation compared a 2019 base year to a 2021 performance year (and corresponding lookback period) that included unusual effects of COVID–19 on utilization of primary care services.

TABLE 35: Average Estimated Impact of the Step 3 Assignment Simulation on ACOs' Gross Savings for PY 2021 assuming CY 2019 as BY3 (Benchmarks Minus Expenditures)

	Average Under Current Methodology	Average Under Step 3 Simulation	Average Change from Current Methodology (relative % change)
Per capita gross savings	$334.53	$330.22	-$4.30 (-1.3%)
Total gross savings	$7,496,707	$7,563,325	$66,618 (0.9%)

Note: The difference between the average under current methodology and the average under the step 3 simulation may not exactly equal the average change from current methodology due to rounding.

The impacts on individual ACOs were also relatively small for a majority of ACOs. Approximately half of ACOs (49.5 percent) observed greater total gross savings under the simulation using an assignment methodology that included the proposed step 3 and revised definition of an assignable beneficiary, and the magnitude of these changes was relatively small. Approximately two-thirds of ACOs (66.8 percent) saw changes in their total gross savings that were within plus or minus 10 percent of what they observed under the current methodology; nearly half (47.3 percent) were within plus or minus 5 percent. We also found that for very few ACOs, the direction of their performance changed, from generating gross savings to observing gross losses, and vice versa. Only 3 ACOs switched from generating total gross savings to observing total gross losses, while 6 ACOs switched from generating total gross losses to observing total gross savings. The changes in performance that we observed for these ACOs was somewhat expected given that ACOs with total gross savings or losses closer to zero are especially likely to switch from generating savings to observing losses, or vice versa, because the threshold for them to do so is very low.

We also examined whether the simulated financial impact of the proposed addition of step 3 and the revised definition of assignable beneficiary differed by ACOs with different characteristics, but we did not observe any meaningful differences. For example, ACOs located in the most urban areas (classified as ''Large Central Metropolitan'') observed a median impact on their total gross savings that was similar to the impact on ACOs located in the most rural areas (classified as ''Noncore''). We similarly found no meaningful differences in financial impact between ACOs with different market shares in their regional service area, between ACOs with different levels of penetration across all Shared Savings Program ACOs in their regional service area,[231] between ACOs of different sizes (that is, ACOs with relatively large assigned beneficiary populations versus ACOs with relatively small populations), between ACOs with higher versus lower shares of beneficiaries dually eligible for Medicare and Medicaid, or between ACOs under prospective assignment versus preliminary prospective assignment with retrospective reconciliation.

Comparing the simulation results for low revenue ACOs and high revenue ACOs (as defined according to § 425.20), we found that high revenue ACOs observed a more positive average impact from the simulated addition of step 3 to the assignment methodology on their per capita and total gross savings (−$8.61 versus −$0.14 for per capita savings impact, and −$15,255 versus $145,835 for total savings impact for low revenue and high revenue ACOs, respectively). However, the mean difference in these impacts was small relative to the large variation in impact within both subgroups.

In summary, we found that proposed modifications to add step 3 to the beneficiary assignment methodology

[231] The penetration level across all Shared Savings Program ACOs is calculated as the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to any Shared Savings Program ACO for the performance year for each Medicare enrollment type.

added a meaningful number of beneficiaries to the ACO-assigned population, and when combined with proposed revisions to the definition of an assignable beneficiary, had a relatively small impact on gross savings performance for a majority of ACOs. Furthermore, the simulated impact of these proposals did not appear to differ meaningfully between ACOs with different characteristics, as explained previously in this section, including for ACOs located in rural areas and for ACOs with higher versus lower shares of beneficiaries dually eligible for Medicare and Medicaid.

With respect to the request from one commenter that CMS further assess the impact of the proposed changes on various Shared Savings Program calculations, including minimum savings rates, performance payment limits, risk adjustment, and the determination of an ACO's status as high revenue or low revenue, our analysis did not directly examine all of these calculations. However, we note that our findings on the impact of the proposed changes on ACOs' assigned beneficiary populations imply mostly small decreases in minimum savings rates (due to small increases in the size of ACOs' assigned populations) and slightly higher performance payment limits (due to increases in ACOs' total benchmarks related to their larger assigned beneficiary populations). While ACO participant revenue would not be affected by the proposed changes, we anticipate small increases in total assigned beneficiary expenditures (due to larger assigned beneficiary populations), which could lead to fewer ACOs being identified as high revenue ACOs. We also note that our analysis did incorporate risk adjustment when estimating the updated benchmarks used to calculate simulated gross savings under both the current and proposed assignment methodologies and definitions of assignable beneficiary. The relatively small estimated impacts on gross savings imply that the proposed changes to the assignment methodology and definition of assignable beneficiaries will have a limited impact on risk adjustment calculations.

We considered the findings from this additional analysis in our decision of whether to finalize these proposals. Because the additional analysis did not show meaningful differential impacts on ACOs among the different groups of ACOs we described previously, we did not see reason to modify or delay the proposed changes. The findings suggest it is unlikely that the proposed changes will have significant negative consequences on ACOs, and we continue to anticipate that the benefits of the proposed changes such as recognizing the clinicians that are providing high-quality primary care, expanding access to accountable care, particularly for beneficiaries in rural and other areas experiencing primary care physician shortages, and reducing the barriers for underserved beneficiaries to be assigned to ACOs, will outweigh any risk of potential negative effects.

Comment: Many commenters, including those supportive of and those opposed to the proposals to revise the definition of assignable beneficiary and add step 3 to the step-wise assignment methodology, raised concerns about CMS's ability to distinguish between non-physician practitioners who practice primary care and those who practice specialty care, resulting in the assignment of beneficiaries that is driven by specialty care provided by ACO professionals (such as after an acute event requiring specialty care), rather than being reflective of the beneficiaries' primary care relationships with the ACO. A few commenters indicated that the concerns about the lack of specialty code designations for non-physician practitioners has been an ongoing issue, and commenters worried that the proposed new step 3 would exacerbate this problem in the context of beneficiary assignment. Commenters tended to explain that these circumstances result from an increase in non-physician practitioners working in specialty practices, and the lack of specialty designations in the Medicare health care provider taxonomy code classification for these practitioners by which to identify and remove such providers from use in assignment.

Commenters further described their concerns about this dynamic. Some commenters stated that beneficiaries receiving care from non-physician practitioners working in specialty practices tend to be those beneficiaries receiving a high-cost procedure or care for an acute condition in that performance year and are not assigned to the same ACO again in future performance years, affecting the ACO's ability to coordinate the beneficiaries' care and in turn the ACO's ability to reduce expenditures below its benchmark and improve the quality of care furnished to those beneficiaries. According to one commenter, such circumstances, where an ACO is held accountable for the care furnished to a beneficiary whose care is not being coordinated by the ACO, makes it harder for participating ACOs to succeed and thus creates disincentives for new ACOs to participate in the Shared Savings Program. A few commenters suggested that the impact of this concern would be dependent on an ACO's composition and that ACOs containing large multispecialty practices or academic medical centers would experience higher rates of specialist-driven assignment related to care delivered by non-physician practitioners in these settings. One commenter, shared concerns that the proposed approach would lead to beneficiaries being assigned to their ACO due to a visit with a non-physician practitioner who is ''not participating in nor understand[s] the population health objectives'' crucial to the ACO's success. One commenter expressed concern about assignment of beneficiaries residing in long-term nursing facility settings. This commenter noted that non-physician practitioners provide a significant amount of wound care and behavioral health care, which affects the determination of where a beneficiary receives the plurality of their primary care services and results in beneficiaries failing to be assigned to an ACO with which they have a ''primary care relationship.''

Response: After further considering existing evidence and our analysis of the population that would be newly assigned under the proposed step 3 of the assignment methodology, we do not share the commenters' concerns regarding the potential impact on assignment resulting from a lack of secondary specialty code designations for non-physician practitioners. We agree and recognize that non-physician practitioners may practice as specialty providers. However, in the June 2015 final rule (80 FR 32749 through 32750) when we finalized changes to step 1 of the assignment methodology to include claims for primary care services furnished by NPs, PAs, and CNSs under step 1 of the step-wise assignment methodology, commenters noted, and we agreed, that most non-physician practitioners have been trained in primary care or in providing services in primary care settings, or both. Recent research and analysis also support this point. A 2022 survey by the American Association of Nurse Practitioners found that 88.0 percent of NPs are certified in an area of primary care and that 70.3 percent deliver primary care.[232] In addition, we performed an analysis of 2022 Medicare claims data and found that only 7 percent of primary care

[232] Refer to American Association of Nurse Practitioners, NP Fact Sheet (Updated November 2022), available at *https://www.aanp.org/about/all-about-nps/np-fact-sheet.*

services identified under § 425.400(c) billed by NPs, PAs, and CNSs participating in ACOs were billed through medical groups comprised mostly (greater than 50 percent) of physicians with specialties that are not used in assigning beneficiaries to ACOs. In contrast, 93 percent were billed through either medical groups comprised mostly of primary care physicians or multi-specialty practices comprised mostly of clinicians with primary care or other specialty designations used in beneficiary assignment under § 425.402(c). Furthermore, claims-based beneficiary assignment currently is and will continue to be based on allowed charges for primary care services identified under § 425.400(c); therefore, to the extent NPs, PAs, and CNSs furnish specialty care services not included in the definition of primary care services used in assignment, such services would not be considered in assigning beneficiaries.

Additionally, under the current assignment methodology, only a very small share of claims-based assigned beneficiaries (approximately 2.2 percent of beneficiaries assigned under preliminary prospective assignment with retrospective reconciliation and approximately 3.3 percent of beneficiaries assigned under prospective assignment in PY 2022) are assigned in step 2 based on the plurality of primary care services provided by specialty physicians. Because only 7 percent of primary care services billed by NPs, PAs, and CNSs were billed through medical groups comprised mostly of physicians with specialties that are not used in assigning beneficiaries to ACOs, and because specialty services that might be billed by such specialist non-physician practitioners are not included in the primary care services identified for purposes of assigning beneficiaries (under § 425.400(c), we believe it is unlikely that a significantly high proportion of beneficiaries assigned to ACOs based on the revised step-wise methodology would be assigned to ACOs based on their receipt of primary care services provided by specialist non-physician practitioners.

Many beneficiaries have an established relationship with a physician and maintain their primary care relationship with the physician's practice through subsequent visits with NPs, PAs, and CNSs. The new step 3 is designed and expected to capture beneficiaries who receive their primary care from ACOs that rely on advanced practice provider care models—that is, ACOs in which NPs, PAs, and CNSs collaborate with primary care physicians and other physicians with specialties used in assignment to manage their patients' primary care. We believe that assignment of these beneficiaries to ACOs under step 3 reflects assignment of these beneficiaries to the ACOs that primarily managed their primary care during the expanded window for assignment.

Elsewhere in our response to comments in this section of this final rule we describe our additional analysis of the proposed changes to both the assignment methodology and to the definition of an assignable beneficiary. Our analysis shows that approximately 83 percent of beneficiaries newly added to the ACO-assigned population under step 3 for PY 2019 received at least one primary care service (as defined at § 425.400(c)) from a primary care physician (as defined at § 425.20), as opposed to a physician who has one of the specialty designations included in § 425.402(c), at the same ACO in 2018 that they were assigned to for PY 2019.[233] On average, we found that those primary care physician visits accounted for a majority of allowed charges for all primary care services received by those beneficiaries in 2018. This finding further supported the notion that the NPs, PAs, and CNSs seen by new step 3-assigned beneficiaries in the assignment window at the ACO were an extension of a primary care relationship between the beneficiaries and primary care physicians in the ACO in the prior year, suggesting further that these NPs, PAs, and CNSs are serving a primary care rather than specialty function. In other words, the ACO that was assigned a beneficiary in step 3 for PY 2019 was the ACO which included the primary care physicians who most often provided the beneficiary's primary care in the 12-months preceding the assignment window, and, during the assignment window, the beneficiary continued to receive primary care services from non-physician practitioners participating in the ACO.

We also note that beneficiaries assigned in step 3 must have received a primary care service from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c) during the expanded window for assignment. As we noted in the June 2015 final rule (80 FR 32750), we expect that specialist physicians often take the role of primary care physicians in the overall treatment of beneficiaries with certain chronic conditions, and such patterns are captured in step 2 in the current assignment methodology. As explained previously in this section, our analysis suggests that non-physician practitioners functioning as specialists represent a minority of non-physician practitioners. However, consistent with that analysis and similar to primary care services furnished by specialist physicians that are captured by step 2, to the extent that primary care services are furnished by specialist non-physician practitioners, we believe that those non-physician specialists would likely be acting as primary care providers and considering the primary care they provide as part of our assignment methodology would be appropriate for identifying the ACO professionals most responsible for a beneficiary's primary care. As a result, we believe that the proposed step 3 reflects an improved approach for capturing existing primary care relationships that include non-physician practitioners.

We acknowledge commenters' concern that some ACOs with large multispecialty practices may have higher likelihood of having a beneficiary assigned based on services furnished by specialty-focused non-physician practitioners. However, we do not believe this concern outweighs the benefits of our proposal. As our analysis of 2022 Medicare claims data suggests and we explain elsewhere in this section of this final rule, we do not believe that a significant percentage of beneficiaries will be assigned to ACOs pursuant to step 3 based on their receipt of primary care services provided by specialist non-physician practitioners. Step 3 will apply to a very limited, specific population of beneficiaries, namely beneficiaries who, during the assignment window, did not have a visit with a primary care physician or a physician with one of the specialty designations included in § 425.402(c) who is an ACO professional in the ACO. Furthermore, as explained previously in this section, our analysis of the expected impact of the new step 3 indicates that, during the expanded window for assignment, the vast majority of beneficiaries newly added to the ACO-assigned population under step 3 will likely have received one or more primary care services from a primary

[233] We conducted this additional sub-analysis on one of the PYs in the simulation by examining the specific types of practitioners seen by beneficiaries newly added to the ACO assigned population with the step 3 simulation. For this sub-analysis, we selected PY 2019 to avoid any possible confounding effects of the PHE for COVID–19. The remaining 17 percent received at least one primary care service, as defined at § 425.400(c), from a physician who has one of the specialty designations included in § 425.402(c) and no primary care services from a primary care physician.

care physician (as defined at § 425.20), as opposed to a physician who has one of the specialty designations included in § 425.402(c), who is participating in the ACO to which the beneficiary is assigned. In addition, our analysis suggests a high likelihood that those primary care physician visits will account for most of the beneficiaries' primary care services furnished in the 12 months preceding the assignment window and that those beneficiaries will receive primary care services from non-physician practitioners participating in the ACO during the assignment window.

We are limited in the extent to which we can address the commenter's concern about assignment of beneficiaries residing in long-term nursing facilities as a result of services for wound care or behavioral health care because the commenter did not provide sufficient information that we can use to identify the services about which they are concerned (such as the related HCPCS and CPT codes included in the definition of primary care services). Generally, we believe Medicare FFS beneficiaries residing in long-term care facilities, among other beneficiaries added to ACOs' assigned populations in step 3, would benefit from better care coordination through ACOs. In addition, as explained previously in this section, we do not believe that a significant percentage of beneficiaries will be assigned to ACOs pursuant to step 3 based on their receipt of primary care services provided by specialist non-physician practitioners, and we continue to anticipate that the benefits of the proposed changes will outweigh any risk of potential negative effects.

Comment: Among comments raising concerns about distinguishing between non-physician practitioners working as specialists from those working in primary care, most asked for a more refined approach and offered various suggestions for distinguishing between these different types of providers. As explained by some commenters, these suggestions were oriented towards ensuring that non-physician practitioners who deliver primary care, as opposed to specialty care, play a prominent role in ACO assignment. One commenter specifically noted that changes accounting for the specialty of non-physician practitioners used in assignment should apply to both step 1 and the proposed new step 3 of the assignment process.

One suggestion common across multiple comments was for CMS to consider developing a new taxonomy to identify primary care or specialty care focused non-physician practitioners and to update the Provider Enrollment, Chain, and Ownership System (PECOS) to incorporate this new taxonomy. A few commenters suggested that to start this process, CMS could collect this information as an optional field in the Medicare provider enrollment application. One commenter stated an alternative option could be to expand the current specialty codes utilized in determining assignment, such as through rulemaking or guidance, because the current codes are too generic to differentiate between NPs, PAs, and CNSs that primarily practice primary care versus specialty care. Another commenter urged CMS to consider using patient relationship codes established under MACRA.[234]

Several commenters suggested revising Shared Savings Program policies to permit participation by ACOs comprised of ACO participants identified by a combination of NPIs and Medicare-enrolled billing TINs through which one or more ACO providers/suppliers bill Medicare. One commenter stated that such a change would enable the integration of specialists into the Shared Savings Program because it would allow ACOs to ''segment primary care providers and specialist providers,'' but did not provide additional details on what they meant by segmenting providers and how it would enable that integration. Similarly, some commenters requested that, without means to distinguish non-physician practitioners who practice primary care from those who practice specialty care, ACOs be permitted to identify specialty-focused practitioners so that CMS could ensure that services furnished by those practitioners to beneficiaries would not be considered as part of beneficiary assignment.

One commenter asked CMS to provide clarification on guardrails CMS intends to implement to ensure that a beneficiary with a complex condition being managed by a specialist outside the ACO and for whom that specialty care comprises the bulk of the beneficiary's care is not assigned to an ACO based on the services by NPs or PAs who are ACO professionals in that ACO.

More generally, some commenters noted that ACOs struggle to maintain assignment year-to-year for beneficiaries assigned ''through specialists,'' and some suggested that CMS should explore strategies to support ACOs in ''leveraging specialty-driven assignment'' to develop longitudinal primary care relationships with these beneficiaries, but these commenters did not clarify whether the specialists they are concerned about include non-physician practitioners and did not provide specific suggestions on what these strategies could be.

Other commenters stated that CMS needs to conduct in-depth analysis to ensure more patients are not assigned to ACOs as a result of care provided by ''specialists'' under the proposed changes. Some commenters recommended this analysis include differences in risk scores and costs for beneficiaries assigned to ACOs as a result of care provided by specialists to inform future policy development, but commenters did not specify whether specialists in this analysis would include non-physician practitioners.

Response: At this time, we will not establish additional procedures to distinguish between non-physician practitioners working as specialists from those working in primary care for purposes of step 3, or as some commenters requested, for step 1 of the assignment process. In the June 2015 final rule (80 FR 32749 through 32750) when we finalized changes to step 1 of the assignment methodology to include claims for primary care services furnished by NPs, PAs, and CNSs under step 1 of the assignment process, some commenters suggested that CMS take additional steps to assure that the NPs, PAs and CNSs considered under step 1 are truly primary care providers in order to better assure accurate assignment of beneficiaries to ACOs based on beneficiaries' receipt of primary care services. In our response to these commenters in the June 2015 final rule, we stated that at that time we would not establish special procedures to determine whether NPs, PAs, and CNSs are performing primary care and not specialty care. We continue to believe that most non-physician practitioners have been trained in primary care or provide services in primary care settings or both. In addition, as explained previously in this section, our analysis suggests that non-physician practitioners functioning as specialists represent a minority of non-physician practitioners and we do not believe that a significant percentage of beneficiaries will be assigned to ACOs pursuant to step 3 based on their receipt of primary care services provided by specialist non-physician practitioners. Furthermore, similar special procedures to distinguish between practitioners working as specialists from those working in primary care have posed

[234] For more information on MACRA patient relationship codes, refer to *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes-webinar-FAQ.PDF*.

significant challenges in the past when applied in the context of RHC and FQHC services. As we explained in the CY 2018 PFS final rule that removed the attestation requirement for RHC and FQHC participants (82 FR 53210), the procedure that relied on ACOs to report and identify all individual physicians that directly provide primary care services within ACO participant RHCs and FQHCs for purposes of beneficiary assignment is prone to error and can create significant operational burdens.

We decline to adopt the suggestions by commenters to further differentiate use of claims billed as a primary care service by non-physician practitioners in assignment through changes to the Medicare provider specialty code taxonomy. Currently, Medicare claims do not contain the necessary information to distinguish services by non-physician practitioners provided in a primary care versus specialty capacity. Creating new codes or modifying the Medicare provider specialty code taxonomy would require review and approval through rulemaking, and include consideration of several factors such as: whether the specialty has the authority to bill Medicare and if the specialty treats a significant volume of the Medicare population; evidence that the practice pattern of the specialty is markedly different from that of other specialties; evidence of any specialized training and/or certification required by the providers; credentialing or other recognition by another organization, such as the American Board of Medical Specialties; and the availability of a corresponding Healthcare Provider Taxonomy Code.

We also decline to change the Shared Savings Program policies to permit participation by ACOs comprised of ACO participants identified by a combination of NPIs and Medicare-enrolled billing TINs through which one or more ACO providers/suppliers bill Medicare, instead of requiring that all ACO participants that comprise an ACO be identified by a Medicare-enrolled TIN through which one or more ACO providers/suppliers bill Medicare. Commenters requesting we make such a change go beyond the scope of our proposals described in the CY 2024 PFS proposed rule. However, we noted that as we stated in previous rulemaking (80 FR 67874), we believe that defining ACO participants to include all NPIs that have reassigned their billing rights to the ACO participant TIN is a means to allow the ACO's redesigned care processes to more broadly reach all Medicare FFS beneficiaries that may receive care from ACO participants and provides incentives for lower-performing providers within an ACO participant TIN to improve. We also continue to have concerns about ACOs selecting only the highest-performing providers within a practice to be part of the ACO while less efficient and less effective providers are not part of the ACO, because this structure could have negative implications for patients seen by the ACO participant and for the Medicare Trust Funds. Therefore, we continue to believe that maintaining the definition of ACO participant at the TIN level continues to be an effective approach in achieving the program's goals of improved care and reduced expenditures, for Medicare FFS beneficiaries more broadly.

We also decline to incorporate patient relationship categories and codes established under MACRA into our assignment methodology at this time. These HCPCS Level II modifier codes are currently being tested for their potential use in the attribution methodology for the cost measures being used under MACRA. Reporting is currently voluntary to help collect data for testing and educate clinicians and stakeholders about the proper use of these code modifiers. In addition, given that the codes are based on categories of patient relationships, it is not clear how they could be incorporated into the claims-based assignment process. Use of patient relationship codes might require structural changes to the assignment process that were not contemplated in the CY 2024 PFS proposed rule. Absent data on how they may impact beneficiary assignment in the Shared Savings Program, it is not clear how we might use the patient relationship codes in beneficiary assignment or what the effect of that use may be. Possible use of these patient relationship codes in beneficiary ACO assignment would require additional investigation and request for comments.

Finally, we decline to adopt a policy to ensure that beneficiaries are not assigned to an ACO due to services provided by NPs, PAs, and CNSs if the majority of the beneficiary's care is provided by a specialist physician outside the ACO. We note that under step 3, a beneficiary who received primary care from an NP, PA, or CNS participating in an ACO but received the plurality of their primary care during the expanded window for assignment from a specialist physician outside of a given ACO would not be assigned to that ACO.

Comment: Several commenters expressed support for the proposed definition of the expanded window for assignment, that is, the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months. Some commenters explained their belief that the proposed approach would appropriately align the expanded window for assignment with the different 12-month assignment windows for ACOs under prospective assignment versus preliminary prospective assignment with retrospective reconciliation. Another commenter explained that the proposed definition of the expanded window for assignment would better account for beneficiaries who receive primary care from NPs, PAs, and CNSs.

One commenter encouraged CMS to consider revising the expanded window for assignment to 36 months, to align the window with the CMS definition of an established patient relationship.[235] The commenter explained that this is an already-defined timeframe and that using such an approach could assist with increasing beneficiary participation in an ACO.

Response: We appreciate the commenters' support for the proposed definition of the expanded window for assignment, which we are finalizing as proposed. We agree with the commenter's sentiment that a 24-month expanded window for assignment will better account for beneficiaries who receive primary care from NPs, PAs and CNSs.

We are unsure how to interpret the statements from some commenters that the proposed approach would appropriately align the expanded window for assignment with the different 12-month assignment windows for ACOs under prospective assignment versus preliminary prospective assignment with retrospective reconciliation. As we explained in the proposed rule (88 FR 52443), the expanded window for assignment for prospective assignment will differ from the expanded window for assignment for preliminary prospective assignment with retrospective reconciliation. The expanded window for assignment to be defined at § 425.20 will mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both, that includes the applicable 12-month

[235] CMS defines an established patient as a person who receives professional services from the physician, non-physician practitioner, or another physician of the same specialty who belongs to the same group practice within the previous 3 years. Refer to CMS, Evaluation and Management Services Guide, MLN Booklet (MLN006764 August 2023), pg. 17, available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/eval-mgmt-serv-guide-icn006764.pdf.*

assignment window (as defined under § 425.20) and the preceding 12 months. For example, for a calendar year assignment window that runs from January 1, 2025, through December 31, 2025, the expanded window for assignment would run from January 1, 2024, through December 31, 2025. For an offset assignment window that runs from October 1, 2023, through September 30, 2024, the expanded window for assignment would run from October 1, 2022, through September 30, 2024.

At this time, we decline to adopt the commenter's suggestion to use a 36-month expanded window for assignment, but will continue to monitor beneficiary assignment to ACOs in the future and consider proposing additional changes, as appropriate. As we described in section III.G.3.a.(2)(a) of this final rule, we believe that a 24-month expanded window for assignment, as opposed to a longer period, would prioritize primary care services that were provided more recently. We believe that primary care services furnished by nurse practitioners, physician assistants, and clinical nurse specialists during the 12-month assignment window could reflect their work in clinical teams in collaboration with and under the supervision of physicians, and thereby represent a continuation of the beneficiary's primary care relationship with a physician from the previous year. Furthermore, use of a 24-month expanded window for assignment builds on experience we have gained and lessons learned from testing Medicare ACO initiatives by the Innovation Center, specifically from the use of a two-year beneficiary alignment period in the ACO REACH Model and the NGACO Model.

Comment: Some commenters expressed concerns that the expanded window for assignment might inappropriately assign beneficiaries based on their receipt of services from practitioners who no longer serve as their primary care provider. One commenter urged CMS not to finalize the expanded window over concerns about beneficiaries who might reside in multiple states for different parts of the year.

Response: As with the existing step-wise methodology, the revised approach would determine assignment based on the plurality of allowed charges for primary care services furnished to the beneficiary during the assignment window or expanded window for assignment, regardless of whether the beneficiary may live in different geographic areas at different points in time in the assignment window or expanded window for assignment. In the June 2015 final rule (80 FR 32745), we reported results of an analysis we conducted that indicated that beneficiary relocation out of an ACO's service area impacted only a very small number of beneficiaries within an ACO's assigned population, and these beneficiaries did not represent a significant portion of the ACO's assigned population. We do not expect that expanding the window for assignment to 24 months would meaningfully change this outcome. In addition, we believe that beneficiaries who generally live in multiple geographic areas over the course of a year may be likely to follow a similar pattern each calendar year of changing locations and obtaining primary care services. We do not expect a 12-month change in the length of the assignment window to significantly change how those beneficiaries are assigned because we believe they generally would maintain that same pattern across a 24-month window. We reiterate our belief, explained in the June 2015 final rule, that continuing to include those beneficiaries who have not permanently moved, but who otherwise live in two or more geographic locations during the year, provides an excellent opportunity for ACOs to make sure the care for such beneficiaries is coordinated.

Comment: A few commenters, addressing our statement in the proposed rule that, as with the current step-wise methodology, under the proposed step 3 a beneficiary prospectively assigned to an ACO for a benchmark or performance year would not be assigned to another ACO under prospective assignment or preliminary prospective assignment with retrospective reconciliation, even if the other ACO provides the plurality of the beneficiary's primary care services during the relevant benchmark or performance year, asked that CMS monitor for any effects that the precedence of prospective assignment may have on smaller ACOs subject to preliminary prospective assignment with retrospective reconciliation, to which beneficiaries prospectively assigned to another ACO through step-wise assignment, including the proposed step 3, could not be assigned.

One commenter described concerns that the expanded window for assignment would increase the number of beneficiaries assigned to ACOs based on a timeframe that ''is not most reflective of the primary care physician relationship,'' with a disproportionately negative impact on ACOs operating under prospective assignment. The commenter explained that under prospective assignment, beneficiaries who have not seen a physician who is an ACO professional in the applicable 12-month assignment window but are assigned to an ACO based on the expanded window for assignment will be ''locked in'' to that ACO for the performance year; however, under preliminary prospective assignment with retrospective reconciliation many of these beneficiaries would ''drop'' from the assignment list over the course of the performance year as new claims and services are considered in assignment. The commenter further cited concerns that preliminary prospective assignment with retrospective reconciliation serves as a means for ACOs to ''game'' assignment by encouraging higher-cost beneficiaries to receive care from providers that do not bill under an ACO participant TIN in the ACO, and focusing on ensuring lower-cost beneficiaries remain assigned to the ACO. The commenter suggested that CMS make assignment using the expanded window for assignment an annual option for ACOs to elect along with the choice of preliminary prospective assignment with retrospective reconciliation or prospective assignment. In the alternative, if the expanded window for assignment is used in our methodology for assigning beneficiaries to all ACOs, the commenter suggested that CMS remove the option for ACOs to select preliminary prospective assignment with retrospective reconciliation and require all ACOs to participate under prospective assignment.

Response: In the CY 2024 PFS proposed rule (88 FR 52445), we acknowledged that there may be a small share of beneficiaries who would be prospectively assigned to an ACO under the proposed step 3 for prospective assignment that differs from the ACO the beneficiary is currently assigned to under steps 1 or 2 under preliminary prospective assignment with retrospective reconciliation. We noted that this precedence of prospective assignment follows the current assignment methodology, which currently assigns beneficiaries via steps 1 and 2 of prospective assignment to an ACO that may be different than the ACO to which the beneficiary would have been assigned via steps 1 or 2 if assigned to an ACO under preliminary prospective assignment with retrospective reconciliation. For the average ACO under preliminary prospective assignment with retrospective reconciliation, the share of assigned beneficiaries affected by this

precedence of prospective assignment has historically been very small, approximately 1.3 percent from 2018 through 2021. We anticipate monitoring the impact of the use of step 3 on the size of ACOs' assigned populations, including for differences in impact based on an ACO's selection of assignment methodology, and on smaller ACOs, including with respect to ACOs' ability to meet the requirement to have at least 5,000 assigned beneficiaries under § 425.110(a).

We also believe that the benefits of the proposed changes to the step-wise methodology outweigh the risk of prospectively assigning a beneficiary in step 3 to an ACO based on a physician visit and the beneficiary's use of primary care services during the expanded window for assignment instead of to another ACO to which the beneficiary would have been assigned under preliminary prospective assignment with retrospective reconciliation based on the plurality of allowed charges for primary care services furnished to the beneficiary during the benchmark or performance year. Overall, we expect that a very small proportion of beneficiaries assigned in step 3 will fall into this category, while the vast majority of beneficiaries assigned in step 3 will be beneficiaries who would not have otherwise been brought into an accountable care relationship.

Additionally, we do not share the concerns of the commenter who stated that the expanded window for assignment would increase the number of beneficiaries assigned to ACOs based on a timeframe that ''is not most reflective of the primary care physician relationship,'' with a disproportionately negative impact on ACOs operating under prospective assignment. We refer the commenter to the additional analysis that we describe elsewhere in this section of this final rule, indicating that, during the expanded window for assignment, a large majority of beneficiaries assigned to ACOs pursuant to step 3 will have received one or more primary care services from a primary care physicians (as defined at § 425.20), as opposed to a physician who has one of the specialty designations included in § 425.402(c), who is participating in the ACO to which the beneficiary is assigned. Further, we note that ACOs have the option to elect prospective assignment or preliminary prospective assignment with retrospective reconciliation on an annual basis. ACOs that share the concern of the commenter could elect the methodology they find most appropriate for their ACO. With respect to the concern over gaming beneficiary assignment by encouraging higher-cost beneficiaries to receive care from providers and suppliers that do not bill under an ACO participant TIN in the ACO, we do not expect step 3 to incentivize or enable an ACO to engage in this type of behavior to a greater degree than the current step-wise methodology does, and we remind the commenter that we monitor ACO avoidance of at-risk beneficiaries pursuant to the regulations at § 425.316(b).

We decline to adopt the commenter's suggestion to allow ACOs the option to elect whether to use the expanded window for assignment for purposes of assignment each year. The proposed expanded window for assignment would apply to both the step 3 in the assignment methodology and to the definition of an assignable beneficiary. We believe it is necessary to maintain symmetry between the step-wise assignment methodology and the definition of an assignable beneficiary. Applying the expanded window for assignment in the step-wise beneficiary assignment methodology but not to the definition of an assignable beneficiary, or vice-versa, could create programmatic inconsistencies and may result in differential changes in average per capita expenditures and risk scores, resulting in inaccurate benchmarks due to distortions to benchmark trend and update factors that are based on changes in expenditures for the national assignable population and in the risk-adjusted expenditures for the population of assignable beneficiaries in an ACO's regional service area. Elsewhere in this section of this final rule, we explain that numerous aspects of the Shared Savings Program rely on the ACO-assigned population and the assignable population (see sections III.G.3.a.(2)(b) and (c) of this final rule). That is, various aspects of the program's benchmarking and financial methodology applicable to all ACOs, such as in the calculation of the regional adjustment and in the calculation of regional service area expenditures, will be determined in part by the national and regional populations of assignable beneficiaries identified through use of an expanded window for assignment. We also decline to adopt an alternative that would allow ACOs the option to elect whether to use the expanded window for assignment for both assignment and establishing the assignable population. It would be operationally complex and unduly burdensome for CMS to create multiple assignable beneficiary populations for different ACOs using different definitions of an assignable beneficiary. It would also be operationally complex and unduly burdensome to perform beneficiary assignment using step 3 for some ACOs but not for others. Among other operational concerns, with each distinct beneficiary assignment methodology, we would need to apply precedence rules for handling cases when a given beneficiary is assigned to different ACOs under different methodologies. Doing so would create excessive complexity in administering the program and excessive complexity for ACOs participating in the program to review and track.

We decline to adopt the suggestion by the commenter to require ACOs to participate under prospective assignment. Section 1899(c)(2)(A) of the Act, as amended by the Bipartisan Budget Act of 2018, provides that the Secretary shall permit ACOs to choose to have Medicare FFS beneficiaries assigned prospectively, rather than retrospectively. Consistent with section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs in agreement periods beginning on July 1, 2019, and in subsequent years the opportunity to select their beneficiary assignment methodology annually.

Comment: One commenter, who supported the proposed approach, requested CMS clarify in the final rule that an eligible beneficiary who received at least one primary care service with an NP, PA, or CNS participating in the ACO during the applicable 12-month assignment window would be considered an assignable beneficiary in certain cases. Specifically, the commenter described the following cases:

- The primary care physician, who used to be an ACO professional in the ACO and provided the primary care service to the beneficiary in the 12 months preceding the assignment window, is no longer billing under the TIN of an ACO participant during the applicable 12-month assignment window;
- The ACO participant, which was the entity whose TIN the primary care physician was billing under when they provided the primary care service to the beneficiary in the 12-month period preceding the assignment window, is no longer participating in the Shared Savings Program ACO during the applicable 12-month assignment window; and
- The physician, an ACO professional in the ACO who had one of the primary specialty designations identified in § 425.402(c) and provided the primary care service to the beneficiary in the 12 months preceding the assignment

window, changed specialty designation in the PECOS and no longer had one of the primary specialty designations identified in § 425.402(c) during the applicable 12-month assignment window.

Response: We interpret this commenter's question as requesting clarification of whether a beneficiary would be considered assignable to the ACO. We note that to actually be assigned, the beneficiary would have to have received the plurality of their primary care services from ACO professionals participating in the ACO during the applicable 12-month assignment window for steps 1 and 2 or during the expanded window for assignment for step 3. In the first case, the beneficiary would be considered assignable because the Shared Savings Program recognizes primary care services at the ACO–TIN level, and not at the ACO–TIN–NPI (that is, practitioner) level. In the second case, if the TIN was removed from the ACO's ACO participant list for the performance year that beneficiary assignment is being conducted for, then the beneficiary would not be assignable to the ACO on the basis of primary care services billed under that TIN. In the third case, the beneficiary would be assignable if the physician's specialty on the claim indicates a primary care physician or one of the specialty designations included in § 425.402(c). Note that CMS does not use PECOS to determine physician specialty, but rather uses the physician's specialty listed on the claim record.

Comment: One commenter, which supported the inclusion of step 3, explained that it had conducted an analysis and found that expanding the window for assignment and adding step 3 had the desired effect of expanding the number of beneficiaries assigned to ACOs. Additionally, the commenter stated that they found that the proposed step 3 ''led to assignment in approximately 90 percent of the cases where the beneficiary went from ineligible to eligible under the policy.'' The commenter considered the effect of the policy to be a substantial improvement.

Response: We do not have sufficient information about the commenter's analysis to fully address the commenter's statement. However, we do agree with the commenter that the inclusion of a step 3 would increase the number of beneficiaries assigned to ACOs on average. In the analysis we presented in the CY 2024 PFS proposed rule (88 FR 52448 through 52449), we found that the proposed policies added 762,156 newly assignable beneficiaries for PY 2021, growing the national assignable population by about 2.9 percent. Elsewhere in this section of this final rule, we describe the additional simulations we conducted on the proposed step 3 in the beneficiary assignment methodology, which showed that step 3 would have increased the total number of beneficiaries assigned to ACOs by 2.1 percent in PY 2019 and by 2.3 percent in PY 2021.

Comment: One commenter suggested that CMS also revise the existing definition of ''assignable beneficiary'' under § 425.20 using a similar approach as the proposed step 3.

Response: We believe the commenter may have misunderstood the proposal. We proposed to modify the definition of ''assignable beneficiary'' (described in section III.G.3.a.(2)(c). of this final rule) to include use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population and to be consistent with the use of an expanded window for assignment under a new step 3 in the claims-based assignment process (described in section III.G.3.a.(2)(b). of this final rule). We proposed to add a new definition of ''Expanded window for assignment'' in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window (as defined under § 425.20) and the preceding 12 months. See also, section III.G.3.a.(2)(a) of this final rule in which we provide an overview of the proposed revisions to incorporate use of an expanded window for assignment. We proposed that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

Comment: Some commenters expressed concerns that the Shared Savings Program's risk adjustment and benchmarking methodologies would not adequately account for complex and high-needs beneficiaries newly assigned to ACOs under the proposed modifications to the step-wise assignment methodology and the definition of an assignable beneficiary. Some of these commenters suggested the potential need for modifications to the risk adjustment and benchmarking methodologies to mitigate any adverse effects on ACOs that may result from the inclusion of these beneficiaries in their assigned beneficiary populations.

One commenter pointed to concerns about the adequacy of the cap on ACO risk score growth in the context of CMS' proposed step 3 that will assign more underserved individuals who may have complex conditions that are not properly diagnosed to Shared Savings Program ACOs. The commenter explained that these individuals typically have not had an established, stable primary care relationship, and as a result, their risk scores are likely to be unreliable. Once assigned to a Shared Savings Program ACO, these beneficiaries' conditions will be diagnosed and they will begin receiving treatment, which will raise the ACO's per capita costs. However, due to CMS' policy of capping HCC score growth at 3 percent plus changes in demographics, risk scores will not increase to reflect these changes. As a result, according to the commenter, ACOs that are assigned more complex, historically underserved beneficiaries through step 3 in the assignment methodology will experience losses and may be forced to stop participating in the Shared Savings Program.

Some commenters urged CMS to conduct further analysis on the impact of the proposed step 3 and proposed changes to the definition of an assignable beneficiary to determine if modifications to the risk adjustment and benchmarking methodologies are needed to address the effects of adding potentially higher cost and more complex patients to the ACO-assigned and national assignable populations. A few commenters suggested that CMS analyze the distribution of assignable beneficiaries to help determine the need for updates to the risk adjustment and benchmarking methodologies. Another commenter asked for additional data on the impact of the proposed step 3 on ACOs in rural and other different geographic regions in connection with regional trend factors used to establish and update the benchmark. This commenter also stated that CMS should ensure that the addition of step 3 to the assignment methodology would not harm any ACO, indicating that ACOs that are adversely affected would likely exit the program. Another commenter recommended adjusting beneficiaries' risk scores to account for the addition to the assigned beneficiary population of a significant number of patients for whom acuity has not been adequately captured, for example, by assigning a floor on the average risk score, such as 1.0, to avoid unintended consequences. Another commenter similarly requested that CMS make additional risk adjustment or benchmarking changes to mitigate potential negative impacts to ACOs from the inclusion of more complex and high-needs beneficiaries in the expanded ACO-assigned population.

This commenter also suggested a more gradual transition of the proposed changes during the initial performance years in order to smooth potential effects and asked that CMS monitor for unintended consequences and have a plan for addressing any unintended consequences in a timely and responsive manner. Several commenters specified that CMS should investigate the impacts of specialty-driven assignment, including differences in risk scores and costs for beneficiaries assigned as a result of care provided by specialists, but the commenters did not specify whether specialists in this analysis should include non-physician practitioners. If the data show that these beneficiaries have higher risk scores and higher costs, the commenters suggested that CMS consider addressing these factors through changes to the risk adjustment and benchmarking policies.

Response: In responding to comments elsewhere in this section of this final rule, we describe the results of additional simulations we have conducted on the impact of the proposed changes to the assignment methodology and to the definition of an assignable beneficiary. As part of those simulations, we examined the expected impact of the proposed changes on ACO financial performance.

We believe that the additional simulations described in this final rule demonstrate that any downward effects on the average ACO's historical and updated benchmarks as a result of changes in the risk profile of its beneficiary population or the assignable population in the ACO's regional service area are offset by an average increase in the number of beneficiaries assigned to the ACO, allowing the ACO the opportunity to earn a larger shared savings payment. Our findings suggest that the risk ratios used to adjust an ACO's historical benchmark will not be adversely affected by the proposed changes because we would apply the proposed changes when determining assignment for the benchmark years, as well as the performance year. Furthermore, the findings from our simulations suggest that the proposed changes to the assignment methodology and the definition of assignable beneficiary are unlikely to result in adverse impacts on risk adjustment between the ACO's assigned beneficiary population and the ACO's regional service area. Under these simulations, we found that the characteristics of beneficiaries newly added to the ACO-assigned population for PY 2021 resembled those of beneficiaries newly added to the national assignable population in the analysis described in the CY 2024 PFS proposed rule (88 FR 52443).

Under the methodology for capping ACO risk score growth that was finalized for agreement periods starting on January 1, 2024, and in subsequent years in the CY 2023 PFS final rule (87 FR 69932 through 69946), we will use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (herein referred to as the ''aggregate demographics plus 3 percent cap''). When we finalized the aggregate demographics plus 3 percent cap in the CY 2023 final rule (87 FR 69940), we acknowledged that the policy balanced competing concerns between the need to allow for some upward growth in prospective HCC risk scores between the benchmark period and the performance year and the concern that those risk scores, in general, are susceptible to coding initiatives. Specifically, we stated our belief that the policy we were finalizing would be protective of the Trust Funds by limiting incentives for coding intensity as it would retain the 3 percent cap on growth in prospective HCC risk scores after accounting for all changes in demographic risk scores for the ACO's overall assigned beneficiary population, while also allowing for more significant changes in prospective HCC risk scores for certain enrollment types with smaller numbers of assigned beneficiaries and for potentially higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of high risk beneficiaries in the aged/dual eligible, disabled, and ESRD enrollment types. Additionally, as described in section III.G.4.b of this final rule, we are finalizing the proposal to cap regional service area risk score growth for symmetry with the cap on ACO risk score growth, which our modeling suggests will be advantageous to ACOs that see greater risk score growth in their regional service area.

We have not examined differences in the beneficiaries assigned as result of care provided by specialists versus primary care practitioners in connection with the costs and risk scores. However, as we noted elsewhere in this section of this final rule, our analysis suggests that assignment of these beneficiaries to ACOs in step 3 reflects assignment of these beneficiaries based on the ACOs that primarily managed their primary care during the expanded window for assignment. Additionally, our analysis shows that the proposed revision to the definition of assignable beneficiary and the addition of a new step 3 in the assignment methodology would lead the average ACO's total gross savings to increase.

Comment: Some commenters addressed the effective date of the proposed changes to the assignment methodology and the identification of the assignable beneficiary population. A few commenters requested that the proposed changes be finalized to apply beginning with PY 2024. Another commenter urged CMS to allow currently participating ACOs to elect to have beneficiaries assigned to them only under the current assignment methodology until the start of a new agreement period, given their concern that the proposed approach would exacerbate ''ongoing challenges of specialty attribution.'' One commenter requested that CMS share ACO-specific modeling and analysis of the impact of the expanded window for assignment and the proposed revisions to the assignment methodology with sufficient time for review prior to signing a participation agreement for entering an agreement period in the Shared Savings Program beginning on January 1, 2025.

Response: We decline to adopt the commenters' recommendations to implement the proposed changes to the assignment methodology and the definition of assignable beneficiary starting in PY 2024. In the CY 2024 PFS proposed rule (refer to section III.G.3.a.(2)(e) of this final rule), we set forth reasons why we would not be able to apply the expanded window for assignment and revised step-wise beneficiary assignment methodology for the performance year starting on January 1, 2024. We explained that consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the new methodology each time assignment is determined for a given benchmark or performance year and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. For example, applicant eligibility for PY 2024 will be determined during CY 2023. Additionally, we anticipated that the proposed revised approach, if finalized, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. In light of these factors, we continue to believe there is insufficient time to apply the expanded

window for assignment and revised step-wise beneficiary assignment methodology for the performance year starting on January 1, 2024.

We agree with the feedback of commenters in response to our proposals, as described elsewhere in this section of this final rule, that ACOs and other interested parties need time to evaluate the impact of the proposed revised assignment methodology, including the new step 3, and the revised definition of assignable beneficiary, in advance of the start of PY 2025. In response to the commenter who requested that CMS share ACO-specific modeling and analysis of the impact of the expanded window for assignment and the proposed revisions to the assignment methodology with sufficient time for review prior to signing a participation agreement for entering an agreement period in the Shared Savings Program beginning on January 1, 2025, we note that elsewhere in our response to comments in this section of this final rule, and in the Regulatory Impact Analysis (see section VI.E.10. of this final rule), we describe additional analysis we have undertaken to estimate the impact of these proposals on ACOs, including on their financial performance and assigned beneficiary populations. We also provide ACOs with an estimate of their total number of assigned beneficiaries during the application cycle which the ACO can review prior to signing a participation agreement for entering a new agreement period.

We also decline to adopt an alternative approach whereby currently participating ACOs could elect to have beneficiaries assigned to them only under the current assignment methodology until those ACOs enter a new agreement period on or after January 1, 2025. The Shared Savings Program's longstanding approach is to implement changes to the assignment methodology on a performance year basis, and as we describe elsewhere in section III.G.3.a.(2)(e) of this final rule, we believe it is necessary to maintain symmetry between the assignment methodology and the definition of an assignable beneficiary to avoid programmatic inconsistencies that may result in inaccurate benchmarks. Furthermore, we have particular concern about allowing ACOs to ''opt in'' to certain policies that may affect updates and adjustments to their benchmark within an agreement period, as this would create an opportunity for selective behavior without the counterbalance of benchmark rebasing and would introduce significant operational complexity.

Comment: One commenter generally expressed its belief that the ''gold standard'' for assignment is always voluntary, prospective patient attribution, which both empowers patients by placing them at the center of their healthcare decision making and helps providers proactively manage care for the patients they know they are responsible for.

Response: We re-emphasize, as described in the background for our proposals in the CY 2024 PFS proposed rule (see section III.G.3.a.(1) of this final rule), that assignment for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services. To the extent that the commenter may have been referencing the non-claims-based process for voluntary alignment that applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment (as specified in § 425.402(e)), we reiterate that the proposed changes would not change the fact that beneficiary voluntary alignment supersedes claims-based assignment.

Comment: A few commenters suggested changes to increase the extent to which assignment may be based upon services by non-physician practitioners. Specifically, a few commenters suggested that CMS exercise the waiver authority under section 1899(f) of the Act to waive the statutory requirement under section 1899(c)(1)(A) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO, which is the basis for the assignment methodology's pre-step requirement. These commenters suggested that CMS allow beneficiaries to be assigned based on their receipt of primary care services provided by an NP, PA, or CNS who is an ACO professional. One commenter urged CMS to work with Congress to remove the physician-centric assignment language in section 1899 of the Act, a change which the commenter noted they believe would allow for simplification of the beneficiary assignment process.

Response: Section 1899(f) of the Act provides that the Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of the Act as may be necessary to carry out the provisions of section 1899 of the Act. Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. We continue to believe that assigning beneficiaries to an ACO based on their receipt of primary care services furnished by physicians participating in the ACO is consistent with section 1899 of the Act, and that, to be consistent with that section, a claims-based assignment methodology must include a requirement that a beneficiary assigned to an ACO have received a primary care service from a physician participating in the ACO. We thank the commenters for their suggestion regarding possible future statutory changes to the beneficiary assignment requirements.

Comment: Several commenters responded to our request for comments on additional policies we should consider for potential future rulemaking on our assignment methodology, with the goal of increasing the number of Original Medicare FFS beneficiaries assigned to an ACO, particularly in underserved communities.

One commenter suggested lowering the minimum number of assigned beneficiaries required to support participation among smaller ACOs. A few commenters suggested changes to the voluntary alignment methodology, including the use of a paper process for beneficiaries to identify their primary care provider. One commenter also requested that voluntary alignment be a quarterly process and that CMS ''confirm the selection through data.''

A few commenters made several recommendations to address concerns about assignment of beneficiaries receiving facility-based care (such as long-term care from a nursing facility, or short-term rehabilitative and skilled care in nursing facilities), and specifically about beneficiaries who have recently transitioned from receiving care from community-based primary care practitioners to facility-based primary care practitioners. One commenter, an ACO that exclusively serves Medicare beneficiaries who are long-term residents of nursing facilities, explained that the ACO experiences large year-over-year increases in the number of beneficiaries excluded from retrospective assignment as the result of the beneficiary already being prospectively assigned to another Shared Savings Program ACO or already being assigned to another Medicare shared savings initiative. The commenter explained that as a result of

these policies, newly institutionalized beneficiaries are assigned to an ACO based on care from their former community-based primary care practitioners rather than care from facility-based primary care practitioners, creating what the commenter refers to as ''misalignment from an accountability of care and value-based care participation perspective.'' Similarly, another commenter stated that under current Shared Savings Program assignment policies, beneficiaries newly admitted to a nursing facility for long-term care are often ''misaligned'' to their previous community-based primary care practitioner because services received from the new nursing facility-based practitioner are not captured in the assignment window. These commenters recommended CMS exclude the Long-Term Institutionalized (LTI) population from initial assignment algorithms to prevent ''their misalignment to outdated community-based primary care relationships that no longer provide care to these LTI beneficiaries,'' and run a ''separate LTI population assignment process'' that identifies primary care physician visits and calculates the plurality of primary care services provided in facilities identified by place of service codes 31, 32, or 33, excluding primary care services provided during a Part A Skilled Nursing Facility (SNF) stay. Additionally, the commenters requested that CMS provide monthly, detailed beneficiary information to ACOs participating under preliminary prospective assignment with retrospective reconciliation regarding beneficiaries who received at least one primary care service from an ACO provider during the performance year and who have been prospectively assigned to ACOs participating in other shared savings initiatives or to other Shared Savings Program ACOs.

Response: We appreciate these thoughtful comments in response to our comment solicitation. We may consider this information and these suggestions to inform future rulemaking.

After consideration of the public comments, we are finalizing our proposal to use an expanded window for assignment in a new step 3 to the claims-based assignment process to identify additional beneficiaries for ACO assignment (described in section III.G.3.a.(2)(b) of this final rule), for performance year 2025 and subsequent performance years. Specifically, we are modifying subpart E of the Shared Savings Program regulations to specify the revised beneficiary assignment methodology. We are specifying the new step 3 in a new provision at § 425.402(b)(5). We are also finalizing as proposed technical and conforming changes to incorporate the revised methodology. We are amending § 425.402(b)(1), describing the existing pre-step of the assignment methodology that would remain applicable for step 1 and step 2, to refer to the identification of all beneficiaries who had ''at least one primary care service *during the applicable assignment window* with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in [§ 425.402(c)]'' (emphasis added to reflect revised text). In § 425.402(c), which indicates the primary specialty designations used in assignment, we are finalizing our proposal to specify that the listed specialties will be considered for ACO professionals in step 2 (as described in § 425.402(b)(4)) and step 3 (in the new provision at § 425.402(b)(5)) of the assignment methodology. In § 425.400(a)(2)(ii), which generally describes quarterly updates to preliminary prospective assignment with retrospective reconciliation, we are finalizing our proposal to specify that assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404. Lastly, in § 425.400(a)(3)(i), which generally describes prospective assignment of beneficiaries to ACOs at the beginning of each benchmark or performance year, we are finalizing our proposal to amend the reference that specifies that we base prospective assignment on the beneficiary's use of primary care services in the most recent 12 months for which data are available, to specify instead the beneficiary's use of primary care services in the most recent 12 months or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

We are also finalizing our proposed amendments to § 425.20. We are finalizing our proposed modifications of the definition of ''assignable beneficiary'' to be consistent with the use of an expanded window for assignment in the new step 3 of the assignment methodology, to identify additional beneficiaries to include in the assignable population after application of the existing methodology. Specifically, we will continue to utilize the criterion in the existing definition, under which assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). Further, for performance year 2025 and subsequent performance years, a Medicare FFS beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary:

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is an NP (as defined at § 410.75(b)), PA (as defined at § 410.74(a)(2)), or CNS (as defined at § 410.76(b)).

We are finalizing our proposed revisions to the definition of ''assignment window,'' for clarity and consistency, to mean the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both. We are also finalizing our proposal to add a new definition of ''expanded window for assignment'' to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window (as defined under § 425.20) and the preceding 12 months.

We are finalizing our proposal to amend provisions in subpart G of the Shared Savings Program regulations, within §§ 425.652, 425.654, and 425.656, that refer to the assignment window used to identify the assignable beneficiary population in order to incorporate references to the approach to using an expanded window for assignment in identifying the assignable population for performance year 2025 and subsequent performance years. We refer readers to the description of these changes, as proposed, in section III.G.3.a.(2)(c) of this final rule. Similarly, we are also finalizing our proposal to specify in the new provision we are finalizing at § 425.655(b)(1) that the assignable population that will be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the regional risk score growth cap adjustment factor (refer to section III.G.4.b. of this final rule) will be identified for the relevant benchmark year or the performance year (as

applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

b. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by RHCs and FQHCs. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 through 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

For the performance year beginning on January 1, 2023, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(vii) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

- *CPT codes:*

++ 96160 and 96161 (codes for administration of health risk assessment).

++ 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

++ 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

++ 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

++ 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

++ 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

++ 99421, 99422, and 99423 (codes for online digital evaluation and management).

++ 99424, 99425, 99426, and 99427 (codes for principal care management services).

++ 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

++ 99439 (code for non-complex chronic care management).

++ 99483 (code for assessment of and care planning for patients with cognitive impairment).

++ 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

++ 99495 and 99496 (codes for transitional care management services).

++ 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

- *HCPCS codes:*

++ G0402 (code for the Welcome to Medicare visit).

++ G0438 and G0439 (codes for the annual wellness visits).

++ G0442 (code for alcohol misuse screening service).

++ G0443 (code for alcohol misuse counseling service).

++ G0444 (code for annual depression screening service).

++ G0463 (code for services furnished in ETA hospitals).

++ G0506 (code for chronic care management).

++ G2010 (code for the remote evaluation of patient video/images).

++ G2012 and G2252 (codes for virtual check-in).

++ G2058 (code for non-complex chronic care management).

++ G2064 and G2065 (codes for principal care management services).

++ G0317, G0318, and G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

++ G2214 (code for psychiatric collaborative care model).

++ G3002 and G3003 (codes for chronic pain management).

- Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vii)(A) of § 425.400 or a HCPCS code specified in paragraph (c)(1)(vii)(B) of § 425.400, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we proposed to recognize for payment starting in CY 2024, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We proposed to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407; (2) Remote Physiologic Monitoring CPT codes 99457 and 99458; (3) Cervical or Vaginal Cancer Screening HCPCS code G0101; (4) Office-Based Opioid Use Disorder Services HCPCS codes G2086, G2087, and G2088; (5) Complex Evaluation and Management services Add-on HCPCS code G2211, if finalized under the Medicare FFS payment policy; (6) Community Health Integration (CHI) services HCPCS codes GXXX1 and GXXX2, if finalized under the Medicare FFS payment policy; (7) Principal Illness Navigation (PIN) services HCPCS codes GXXX3 and GXXX4, if finalized under the Medicare FFS payment policy; (8) SDOH Risk Assessment HCPCS code GXXX5, if finalized under the Medicare FFS payment policy; (9) Caregiver Behavior Management Training CPT codes 96202 and 96203, if finalized under the

Medicare FFS payment policy; and (10) Caregiver Training services CPT codes 9X015, 9X016, and 9X017, if finalized under the Medicare FFS payment policy. The following provides additional information about the HCPCS codes that we proposed to add to the definition of primary care services used for purposes of beneficiary assignment:

• *Smoking and tobacco-use cessation counseling services CPT codes 99406 and 99407:* Effective January 1, 2008, CPT codes 99406 (*Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*) and 99407 (*Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes*) were implemented for billing for smoking and tobacco-use cessation counseling services. As described in Medicare National Coverage Determinations (NCD) Manual, Publication 100–3, chapter 1, section 210.4.1, tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs. Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1,200 die prematurely each day from tobacco-related diseases. Since these are recognized as preventive services,[236] similar to other preventive services such as alcohol misuse screening and counseling (HCPCS codes G0442 and G0443) which are currently included in the definition of primary care services for purposes of beneficiary assignment, we believe it appropriate to include CPT codes that identify counseling to prevent tobacco use in the definition of primary care services for purposes of beneficiary assignment.

• *Remote Physiologic Monitoring CPT codes 99457 and 99458:* Chronic care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. In the CY 2020 PFS final rule (84 FR 62697) we finalized a revised CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*) and added CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*) to adopt the CPT Editorial Panel revised structure for CPT code 99457. The new code structure retained CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services and uses a new add-on code to describe subsequent 20-minute intervals of the service. We further designated CPT codes 99457 and 99458 as care management services because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely. Because these remote therapeutic monitoring services are designated as care *management* services [237] and because we broadly include care management services (for example, CPT codes 99437, 99487, 99489, 99490 and 99491) in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we stated in the CY 2024 PFS proposed rule (88 FR 52451) that we believed CPT codes 99457 and 99458 should also be included in the definition of primary care services for purposes of beneficiary assignment.

• *Cervical or Vaginal Cancer Screening Code HCPCS code G0101:* Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations.[238] Cervical and vaginal cancer screening and clinical breast examination are important preventive health care services intended to detect early cancer, precancers and sexually transmitted infections. HCPCS code G0101 (*Cervical or vaginal cancer screening; pelvic and clinical breast examination*) can be reimbursed by Medicare Part B every 2 years. For patients who are considered high risk, reimbursement is allowed on an annual basis. Obstetrics/gynecology and gynecology/oncology are identified as physician specialty designations for purposes of identifying primary care services furnished to beneficiaries used in assignment operations according to § 425.402(c), so we believe it appropriate to use wellness and preventive care visits provided by these specialists in our definition of primary care services used in assignment. We consider these to be a preventive health service that can be provided in a primary care setting [239] similar to the annual wellness visit (AWV) HCPCS codes G0438 and G0439, which are already included in the Shared Savings Program definition of primary care services used in assignment, so we believe that they should be included in the definition of primary care services for purposes of beneficiary assignment.

• *Office-Based Opioid Use Disorder Services HCPCS Codes G2086, G2087, and G2088:* In the CY 2020 PFS final rule (84 FR 62568), we finalized our proposal to establish bundled payments for the overall treatment of Opioid Use Disorder (OUD), including management, care coordination, psychotherapy, and counseling activities HCPCS codes G2086 (*Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month*), G2087 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month*), and G2088 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure)*). Refer to the CY 2020 PFS final rule (84 FR 62673) for detailed, technical discussion regarding the description, payment, and utilization of these HCPCS codes.

[236] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#TOBACCO.*

[237] Medicare Physician Fee Schedule Care Management Services Information, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

[238] Medicare National Coverage Determination for Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancers (Pub. No. 100–3, Manual Section 210.2), available at *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=185#:~:text=Section%204102%20of%20the%20Balanced%20Budget%20Act%20of,beneficiaries%2C%20subject%20to%20certain%20frequency%20and%20other%20limitations.*

[239] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#PELVIC.*

The bundled payment under the PFS for office-based treatment for OUD was intended to create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the bundled OUD treatment services benefit, but not furnished by an Opioid Treatment Program (OTP). By creating a separate bundled payment for these services under the PFS, we hoped to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care. In the proposed rule we noted that use of these codes is limited to only beneficiaries diagnosed with OUD and these codes should not be billed for beneficiaries who are receiving treatment at an OTP, as we believe that would be duplicative since the bundled payments made to OTPs cover similar services for the treatment of OUD.

Because the separately reportable initiating visit requirement for the OUD bundle HCPCS codes G2086, G2087 and G2088 is similar to the separately reportable initiating visit requirements for chronic care management (CCM) services, and behavioral health integration services (BHI), as they include overall management and care coordination activities, we stated we believed these services should be considered primary care services for purposes of beneficiary assignment.[240] Additionally, as we stated in the proposed rule, we anticipated that the billing clinician, likely an addiction medicine specialist, would manage the patient's overall OUD care, as well as supervise any other individuals participating in the treatment, such as those billing incident to services of the billing physician or other practitioner, which is similar to the requirements related to the furnishing of psychiatric collaborative care model (CoCM) services. CCM, BHI, CoCM, and alcohol misuse screening and counseling services are included in our definition of primary care services, so we believe that HCPCS codes G2086, G2087 and G2088 are appropriate to be included in the definition of primary care services for purposes of beneficiary assignment. For additional clarity, incident to services are services rendered to a patient by a provider other than the physician treating the patient more broadly, that are an integral, although incidental, part of the patient's normal course of diagnosis or treatment of an injury or illness. These services are billed as Medicare Part B services, as if the original physician personally provided the care using that physician's NPI number. As we stated in the proposed rule, we anticipated that these services would often be billed by addiction specialty practitioners but note that these codes are not limited to use by any particular physician or non-physician practitioner specialty. Further, since addiction medicine is identified as one of the physician specialty designations for purposes of identifying primary care services used in assignment operations according to § 425.402(c)(13), we believed it would be appropriate to include care coordination services provided by these specialists in our definition of primary care services used for purposes of beneficiary assignment.

We further recognized that OUD bundle HCPCS codes G2086, G2087 and G2088 are identified as codes for alcohol and substance abuse-related diagnoses that are excluded from Shared Savings Program Claim and Claim Line Feeds. Given this, we want to make transparent that ACOs will not be able to see the claims that may have been used in assignment for beneficiaries receiving OUD services, and possibly not be able to identify why certain beneficiaries were assigned to their ACO related to these codes.

• *Complex Evaluation and Management Services Add-on HCPCS Code G2211, if finalized under Medicare FFS payment policy:* As discussed in section II.F. of the CY 2024 PFS proposed rule (88 FR 52350 through 88 FR 52356), HCPCS add-on code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) can be reported in conjunction with office/outpatient (O/O) evaluation and management (E/M) visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). Section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for inherently complex E/M visits described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. The moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023, therefore we proposed to make HCPCS code G2211 separately payable effective January 1, 2024. Refer to section II.E of this final rule for finalized detailed, technical discussion regarding the description, payment, and utilization of this HCPCS code.

Since HCPCS code G2211 is an add-on code used in conjunction with O/O E/M services and such services are included in our definition of primary care services, we stated in the CY 2024 PFS proposed rule that we believed that the proposed inclusion of HCPCS code G2211 is consistent with our intent to encompass primary care and wellness services in the definition of primary care services used for purposes of beneficiary assignment.

• *Community Health Integration Services HCPCS Codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policies:* In section II.E of the proposed rule (88 FR 52307 through 88 FR 52350), we proposed separate coding, payment, service elements and documentation requirements for the following CHI services:

GXXX1 Community health integration (CHI) services performed by certified or trained auxiliary personnel including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

• *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

• *Practitioner, Home, and Community-Based Care Coordination*

[240] Medicare Physician Fee Schedule Office-Based Opioid Use Disorder (OUD) Treatment Billing Information, available at *https://www.cms.gov/medicare/physician-fee-schedule/office-based-opioid-use-disorder-oud-treatment-billing.*

++ *Coordination with practitioner; home, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH need(s).*

• Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.

• Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis and treatment.

• Health care access/health system navigation:

++ Helping the patient access care, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

• Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

• Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

As described in section II.E of the proposed rule, all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.[241] A billing practitioner may arrange to have CHI services provided by auxiliary personnel external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. The payment policy described in section II.E of this final rule explains that we would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit. Refer to section II.E of this final rule for the finalized detailed, technical discussion regarding the proposed description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of the proposed rule proposed to designate CHI services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the definition of primary care services used for purposes of beneficiary assignment, we stated that we believed it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since CHI services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the CHI initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we also stated that we believed it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment.

[241] CHW Roles As Outlined In The C3 Project available at *https://chwtraining.org/c3-project-chw-skills/.*

• *Principal Illness Navigation (PIN) Services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policies:* In section II.E of the proposed rule, we proposed new coding for Principal Illness Navigation (PIN) services. In considering the appropriate patient population to receive these services, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high-risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[242] Another study describes a serious illness as a health condition that carries a high-risk of mortality and commonly affects a patient for several years, while some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[243] The navigation services such patients need are similar to CHI services, SDOH need(s) may be fewer or not present. Accordingly, a parallel set of services focused on patients with a serious, high-risk illness who may not necessarily have SDOH-related needs was proposed. PIN services could be furnished following an initiating E/M visit addressing a single high-risk disease.

The following codes would be reported for PIN services:

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

• *Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

[242] Kelley AS, Bollens-Lund E., Identifying the Population with Serious Illness: The ''Denominator'' Challenge. J Palliat Med. 2018 Mar;21(S2): S7–S16. doi: 10.1089/jpm.2017.0548. Epub 2017 Nov 10. PMID: 29125784; PMCID: PMC5756466. available at *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[243] Silver, Alison. Serious Illness: A High Priority for Accountable Care. The American Journal of Accountable Care. 2020;8(2):32–33. available at *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

++ *Facilitating patient-driven goal setting and creating an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

• *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*

• Practitioner, Home, and Community-Based Care Coordination

++ *Coordinating receipt of needed services from healthcare practitioners, providers and facilities; home-, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, and preferences, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*

• *Health education- Helping the patients contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver, if applicable) on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*

• *Health care access / health system navigation.*

++ *Helping the patient access healthcare, identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

• *Facilitating behavioral change necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

• *Facilitating and providing social and emotional support for the patient to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis or treatment goals.*

• *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

As discussed in section II.E of the proposed rule, a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. We will expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition. Refer to section II.E of this final rule for finalized detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of the proposed rule proposed to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the list of primary care services used for purposes of beneficiary assignment, we believed it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since these services are meant to provide assistance to the beneficiary through communication and coordination with practitioners, providers, including referrals to other clinicians and follow-up after emergency or inpatient care, we stated in the CY 2024 PFS proposed rule that we believed that these services can further the ACO's goal of care coordination and the provision of value-based care, and therefore, should be included in the definition of primary care services for purposes of beneficiary assignment. Further, since PIN services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the PIN initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we stated that we believed it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment.

• *SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policies:* In section II.E of the proposed rule, we proposed a new stand-alone G code, GXXX5 (*administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes, at most every 6 months.)* to identify and value the work involved in the utilization of SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs and enables comparisons across populations. The SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's treatment plan that is established during the visit. Finalized required elements are described in detail in the payment policy described in section II.E of this final rule.

Under the proposal described in section II.E. of the proposed rule (88 FR 52307 through 88 FR 52350), the practitioner billing or furnishing the SDOH risk assessment would be required to have the ability to furnish CHI or other care management services. Given the multifaceted nature of SDOH needs, ensuring adequate referral to appropriate services and supports is critical for addressing both the SDOH need and the impact of that need on the patient's health. Refer to section II.E and III.R of this final rule for finalized detailed, technical discussion regarding the description, payment, and utilization of this HCPCS code.

Additionally, the proposal detailed in section III.S. of the proposed rule (88 FR 52548 through 88 FR 52553) proposed to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element with an additional payment. Under that proposal, the SDOH Risk Assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV and would inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments, and conducting

prevention services education and planning.

Since the proposals described in sections II.E. and III.S. of the proposed rule proposed that these services would be provided in conjunction with professional services, such as E/M visits, which can be provided in a primary care setting, we stated in the proposed rule that we believed it would be appropriate to include these services in the definition of primary care services for purposes of beneficiary assignment. Additionally, since these are separately payable services when provided with an AWV and the AWV is included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we stated we believed it would be appropriate to include SDOH risk assessment in the definition of primary care services for purposes of beneficiary assignment. Further, since these services precede the utilization of CHI, PIN, and Care Management services, which are either currently included or proposed to be included in the definition of primary care services for purposes of assignment, we stated that we believed the inclusion of the new SDOH risk assessment HCPCS code would be appropriate as well.

• *Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy:* CPT code 96202 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; each additional 15 minutes (List separately in addition to code for primary service)*) are two new codes created by the CPT Editorial Panel during its February 2021 meeting used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's daily life.

In section II.E. of the proposed rule, an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) was proposed for CY 2024. These codes allow treating practitioners to report training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. Caregiver behavior management/modification training services may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The caregiver behavior management/modification training services themselves need to be congruent with the treatment plan to effectuate the desired patient outcomes.

For purposes of caregiver behavior management/modification training services, our proposal required that a caregiver receiving behavior management/modification training services be a family member, friend, or neighbor who provides unpaid assistance to the patient, assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling). In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, adherence to treatment, and/or general welfare related to the patient's primary clinical diagnoses. Under the proposal, caregiver behavior management/modification training services could be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in § 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Refer to section II.E of this final rule for finalized detailed, technical discussion regarding the description, payment, and utilization of these CPT codes.

Since the proposal described in section II.E. of the proposed rule proposed that these services could be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit, and these services cannot duplicate services provided in conjunction with transitional care management, CCM, BHI services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment, we stated in the proposed rule that we believed that these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to provide coordinated, high quality care to an ACO's Medicare beneficiaries.

• *Caregiver Training Services CPT codes 9X015, 9X016, and 9X017, if finalized under Medicare FFS payment policy:* CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015))*, and 9X017 *(Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers)* are new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADLs). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. As discussed above, we believe training furnished to a caregiver may be reasonable and necessary when it is integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The Caregiver Training Services (CTS) themselves need to be congruent with the treatment plan to effectuate the desired patient outcomes, especially in medical treatment scenarios where the

caregiver receiving CTS is necessary to ensure a successful treatment outcome for the patient.

In section II.E. of the proposed rule, we proposed an active payment status for CPT codes 9X015, 9X016, and 9X017 for CY 2024. CTS may be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in 42 CFR 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Under the proposal, 9X015, 9X016, and 9X017 would be designated as ''sometimes therapy.'' This means that the services represented by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care (that is, where the services are not integral to a therapy plan of care), they can be furnished under a treatment plan by physicians and NPPs. Refer to section II.E of this final rule for finalized, detailed, technical discussion regarding the description, payment, and utilization of these HCPCS codes.

The proposal described in section II.E. of the proposed rule proposed that these services could be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit. Additionally, these services cannot duplicate services provided in conjunction with transitional care management, CCM, BHI services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment and these services are reported to Medicare only when furnished in conjunction with treatment for particular conditions and reflected in a plan of care. In the proposed rule, we stated that we believed they should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to give coordinated, high quality care to an ACO's Medicare beneficiaries.

We proposed to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vii) along with the proposed additional CPT codes 99406 and 99407, and 99457 and 99458, 96202 and 96203, if finalized under the Medicare FFS payment policy; and 9X015, 9X016, and 9X017, if finalized under the Medicare FFS payment policy and HCPCS codes G0101; G2086, G2087, and G2088; G2211, if finalized under the Medicare FFS payment policy; GXXX1 and GXXX2, if finalized under Medicare FFS payment policy; GXXX3 and GXXX4, if finalized under the Medicare FFS payment policy; and GXXX5, if finalized under the Medicare FFS payment policy; as discussed in the preceding paragraphs. We proposed that the new provision at § 425.400(c)(1)(viii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years.

We solicited comments on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2024, and subsequent performance years. We also solicited comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this final rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters were supportive of our proposal to add the following codes to the definition of primary care services used in assignment: (1) Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407; (2) Cervical or Vaginal Cancer Screening HCPCS code G0101; (3) Visit complexity inherent to evaluation and management services add-on (referred to as Complex Evaluation and Management Services Add-on in the proposed rule) HCPCS code G2211; (4) CHI services HCPCS codes GXXX1 and GXXX2; (5) PIN services HCPCS codes GXXX3 and GXXX4; (6) Caregiver Behavior Management Training CPT codes 96202 and 96203; (7) Caregiver Training Services CPT codes 9X015, 9X016, and 9X017; and (8) SDOH Risk Assessment HCPCS code GXXX5. These commenters stated that these codes accurately reflect comprehensive, coordinated, whole-person primary care.

Many commenters expressed support for our proposal to include caregiver training and SDOH risk assessment services in the definition of primary care services used for purpose of beneficiary assignment, noting that they work well together with other CMS initiatives and further support ACOs in providing comprehensive, coordinated, whole-person primary care, recognizing the importance of capturing information on and screening for SDOH. One commenter recognized that considering SDOH risk assessment services in beneficiary assignment could potentially improve the health of a wide swath of Medicare beneficiaries by increasing access to social determinants of health risk assessments and ''making them more affordable''.

One commenter stated their support for inclusion of several behavioral health services, sexual and reproductive health-related services, and several team-based care services as these additions would help primary care practices in ACOs continue to move closer to providing whole-patient, comprehensive primary care.

Response: We agree with commenters who recognize that our proposal to revise the definition of primary care services used for assignment will align well with other CMS initiatives, specifically those that promote health equity, and will help primary care practices to continue to move closer to providing whole-patient, comprehensive primary care. Without additional context, it is not clear how the inclusion of a service in the definition of primary care services used for Shared Savings Program beneficiary assignment would be likely to make a particular included service more affordable for beneficiaries. We interpret the comment from the commenter who supports inclusion of several behavioral health services, sexual and reproductive health-related services, and several team-based care services to be referring to our proposals related to smoking and tobacco-use cessation counseling services, cervical or vaginal cancer screening, OUD services, PIN services, CHI services, SDOH risk assessment services, and caregiver behavior management training services, and caregiver training services, and we appreciate this commenter's support.

Comment: Many commenters, while stating their support for the inclusion of the codes proposed, also urged CMS to continue to monitor the impact of expanding the definition of primary care services to include the ''additional PFS codes'', and to respond to any identified unintended consequences and consider changes to mitigate any unintended consequences in a timely manner. Several commenters urged CMS not to move forward with the proposal to expand the list of primary care services/codes in beneficiary assignment, stating many of the proposed codes would be new codes to the CY 2024 PFS and it is unclear what redistributive impact the proposed codes would have on assignment and encouraged CMS to perform additional analysis on potential

impact of this policy and allow for an appropriate phase-in period. Another commenter recommended ''thorough, multi-year testing to ensure that patients are not aligned to ACOs strictly because of billing practices by clinicians unsuited for patient care coordination''. One commenter recommended a ''phase-in period to better understand how the expanded beneficiary population will impact care delivery and financial assumptions''. The commenter stated that for some ACOs, this newly attributed population may represent a higher risk/acuity with ''no growth option for the ACO's risk score to accurately reflect the change resulting from a CMS rule''. Another commenter did not support the inclusion of the code for SDOH risk assessment as it does not have utilization history and so they noted it is premature to use it in assignment under in the Shared Savings Program.

Response: As described in our proposed rule, we consider these codes to be primary care and wellness services that fit within the definition of primary care services. It is important for the definition of primary care services used for purposes of beneficiary assignment to remain in sync with billing and coding updates and changes and include appropriate new CPT and HCPCS codes as they are implemented. Waiting for a phase-in of new assignment codes or conducting multi-year testing of codes could result in beneficiaries not being assigned to an ACO based on primary care services that are provided by their primary care provider as utilization of these services is implemented. Implementing billing and coding updates and changes as they are finalized under the PFS is important for purposes of assignment to ensure that beneficiaries are assigned appropriately as services billed shifts from already existing CPT/HCPCS codes to new CPT/HCPCS codes. If the Shared Savings Program is out of sync with changes and updates, assignment of beneficiaries could be inaccurate. Commenters were not specific in discussing unintended consequences that could occur should these services be added to the definition of primary care services used in beneficiary assignment. Therefore, we do not know what consequences they are concerned about and so we are not persuaded by these comments.

With regard to the commenter concerned that adding these codes will result in the assignment of higher risk beneficiaries to the ACO and that the higher risk profile of these beneficiaries will not be full recognized as a result of the cap on an ACO's risk score growth during an agreement period, we note that the Shared Savings Program uses the CMS–HCC prospective risk adjustment model which adjusts for changes in severity and case mix and accounts for differences in health status of an ACO's assigned beneficiary population between the benchmark and performance years. Additionally, adding these codes in conjunction with other risk adjustment policies finalized in this rule (section III.G.4) would help mitigate impacts on the cap on prospective HCC risk score growth, and we are providing these updates to increase accountable care for beneficiaries. For more information on risk adjustment in the Shared Savings Program, please review the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications, Version 11.[244] Commenters did not go into detail regarding what redistributive impacts could be or what specifically could be impacted and so we are not persuaded by these comments.

The SDOH Risk Assessment service is an optional, additional element of the AWV with an additional payment and no applicable beneficiary cost sharing, and the AWV is included in the definition of primary care services used for purposes of assignment. Additionally, we note that these services precede the inclusion of current services included in the definition of PCS for purposes of assignment, which are already included in the definition of primary care services for purposes of assignment. Accordingly, we are not persuaded by the comment suggesting we should not include this service in the definition of primary care in light of its limited utilization history.

In section II.E of this final rule, we also recognize the AWV as an initiating visit for PIN services when the AWV is furnished by a practitioner who has identified in the AWV a high-risk condition(s) that would qualify for PIN services under this rule. The AWV is included in the definition of primary care services used for purposes of assignment and so provides further rationale for the inclusion of PIN services in said definition.

Additionally, we are not persuaded by the commenters concerns suggesting that the proposed additional codes could assign patients to ACOs through clinicians unsuited for patient care coordination. For example, as described in section II.E of this final rule, we clarified that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and, as relevant, authorized to perform them under applicable State laws and regulations. For States that do not have applicable requirements for certification and training, it is the billing practitioner's responsibility to ensure the auxiliary personnel have been certified and trained in accordance with our final requirements.

Comment: One commenter cautioned that inclusion of the proposed codes will lead to assignment based on services furnished by specialists who are not positioned to provide comprehensive primary care. Another commenter who supported the inclusion of many of the codes recommended CMS remember the unique considerations related to differentiating assignment between primary care and specialty care services as part of beneficiary assignment and asked that CMS monitor to ensure the services included in the assignment methodology continue to support the delivery of comprehensive, coordinated, whole-person primary care and do not have the unintended consequence of disrupting ongoing patient-physician relationships.

Some commenters expressed support for inclusion of all the proposed revisions with the exception of the code for cervical or vaginal cancer screening since this service is provided by obstetricians or gynecologists and including this code in the assignment methodology risks shifting assignment away from primary care relationships in favor of specialty care. Another commenter urged CMS to consider removing tobacco-use cessation counseling services from the list because they are concerned that it will assign beneficiaries to the ACO that may not accurately reflect patients who are may not be receiving primary care services from ACO physicians, as physicians across different specialties will provide tobacco-use cessation counseling services. Other commenters recommend that we monitor the billing of these codes to ensure that their addition is not shifting beneficiary attribution away from primary care relationships in favor of specialty care.

Response: We acknowledge the commenters who opposed or expressed concerns about inclusion of some of the codes on the basis that they may shifting assignment away from primary care relationships in favor of specialty care. Consistent with our current methodology, if services billed under these codes are provided by specialists not considered for purposes of beneficiary assignment, then the services will not be considered in beneficiary assignment.

The cervical or vaginal cancer screening preventive health service can be provided in a primary care setting similar to the AWV HCPCS codes G0438 and G0439, which are already included in the Shared Savings Program definition of primary care services used in assignment. Additionally, as noted in this section of this final rule, obstetrics/gynecology and gynecology/oncology are identified as physician specialty designations considered for purposes of identifying primary care services furnished to beneficiaries used in assignment operations according to § 425.402(c), so we are not persuaded by these comments.

Smoking and tobacco-use cessation counseling services are recognized as preventive services, like other preventive services such as alcohol misuse screening and counseling, the AWV, and depression screening, which are currently included in the definition of primary care services for purposes of beneficiary assignment. Further, smoking and tobacco-use cessation counseling services encourage comprehensive, coordinated whole person-centered care and can be provided in a primary care setting. Additionally, these services are generally billed in conjunction with an E/M visit which is currently included in the definition of primary care services. Finally, smoking-related diseases are a leading cause of death among individuals with substance use disorders, and individuals who treat their addiction to tobacco and other substances at the same time are 25 percent more likely to sustain their recovery, compared to the individuals who do not address tobacco while in recovery from alcohol and other drugs.[245] In support of the CMS' goal to expand mental health services and SUD treatment, we believe it to be important for us to recognize these services for purposes of beneficiary assignment. For these reasons, and the reasons stated in this section of this final rule, we continue to believe they should be included in our assignment methodology.

Comment: Some commenters expressed opposition to the inclusion of the office-based OUD services until CMS includes these codes in the Claim and Claim Line Feeds (CCLFs) provided to ACOs and further advocated for CMS to provide them with timely, actionable patient data, including data for Substance Use Disorder (SUD), to ACOs. One commenter described ACOs as still lacking access to vital SUD-related data on their patients due to the fact that under current regulations, care coordination is not considered by CMS to fall under treatment, payment, and health care operations. This commenter stated the CARES Act allows sharing of this important data after initial patient consent, which will allow CMS to deliver this critical information to providers operating in ACOs.

Response: As described at § 425.708(c), in accordance with 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and treatment of alcohol and substance abuse without the explicit written consent of the beneficiary. As we explained in the June 2015 final rule (80 FR 32741), beneficiary identifiable information that is made available under § 425.704 would include Parts A, B and D data, but would exclude any information related to the diagnosis and treatment of alcohol or substance abuse. As we discussed in the April 2011 proposed rule (76 FR 19557), 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2 restrict the disclosure of patient records by federally conducted or assisted substance abuse programs. Such data may be disclosed only with the prior written consent of the patient, or as otherwise provided in the statute and regulations. To assist ACOs in identifying the best sources for beneficiary medical record data, we provide the ACO with the TIN and NPI of the ACO participant and ACO professionals that provided the most recent primary care service to the beneficiary on each quarterly report. We also provide ACOs deidentified aggregate information related to substance use that may be helpful for understanding their patient population as described in § 425.702. We encourage ACOs and ACO participants to establish their own processes to access patients' health information directly, in accordance with applicable laws for purposes of care coordination.

As stated in the proposed rule, the OUD bundle HCPCS codes G2086, G2087, and G2088 have similar uses and requirements as other services that are included in our definition of primary care services, such as CCM, BHI, CoCM and alcohol misuse screening and counseling services and as such are appropriate to be included in the definition of primary care services for purposes of beneficiary assignment. Specifically, these services include the overall management and care coordination of beneficiaries being treated for SUD in an office setting.

Comment: Some commenters supported the proposal to include remote physiologic monitoring (RPM) CPT codes 99457 and 99458 and stated their belief that inclusion of these codes builds on support already provided for digital health (for example, adding G2012 and G2252 codes for virtual check-ins). One commenter stated that RPM enables providers to gain a comprehensive understanding of the patients' conditions while at home, facilitating more coordinated and engaged care efforts, which is particularly useful for patients who may have transportation or other barriers to frequent primary care access. One commenter added in their support for inclusion of RPM codes that include remote physiologic and therapeutic monitoring, artificial intelligence, and other tools. Another commenter stated that the proposed inclusion of RPM codes as primary care services for purposes of assignment, similar to how other CCM codes are so included, further aligns remote care and communication and aids in advancing RPM into value-based care models. This commenter welcomes this technical policy fix and appreciates that we have not ''precluded furnishing and billing for the full range of RPM codes while gaining provider/patient entry into shared savings.'' This commenter does ask that we clarify whether the intent is solely to track these services for assignment and eligibility for shared savings, which they state could fall short in expanding the use of RPM in the Shared Savings Program. One commenter stated support for the inclusion of RPM since the devices involved in these codes and the clinicians who read the results are important elements in patient care and care management services but urged CMS to reexamine and clarify the assignment methodology to ensure that third-party device companies and specialists who use the devices involved in these codes do not inadvertently impact Shared Savings Program attribution, cautioning that when these devices are billed by clinicians who do not provide a beneficiary's primary care services, it is important that those billing codes are not used to assign a beneficiary or remove a them from their primary care provider's assignment list. Many commenters supported the inclusion of the RPM services but expressed concern that these codes can also be billed by specialists and that CMS should monitor the billing of RPM to ensure their addition is not shifting

[245] Lung Cancer Screening Billing Guide Addendum for Behavioral Health available at *https://www.lung.org/getmedia/5adda30d-6738-4e3e-8666-621cc5120d4d/ala-billing-guide-addendum.pdf.*

beneficiary attribution away from primary care relationships in favor of specialty care.

Many commenters recommended that CMS not include RPM services in the definition of primary care services used for purposes of assignment. One commenter stated that while these codes may be billed by primary care providers to support the overall management of a patient's care, the codes can also be billed by specialists and can only be billed by one treating provider for a given patient. Therefore, if a specialist is billing these codes to support management of a specific condition, that patient's primary care provider would not be able to also provide RPM treatment management services to the patient. One commenter also stated that since these services are billed monthly, the allowed charges for RPM services furnished by a specialist could surpass the allowed charges for primary care services furnished by the primary care provider. A few commenters suggested the proposal to add RPM be terminated, or not finalized, since not all groups/clinicians who utilize these codes contribute to an ACO's population health practice, or initiatives to care for its patients. One commenter, while universally supportive of an expanded set of primary care services, cited their analysis that showed that RPM has an uptake by certain physician specialties (that is, cardiology) and recommended that CMS monitor utilization to ensure that the specialty of clinicians continues to be considered in determining whether a service is considered to be a primary care service for purposes of beneficiary assignment. This commenter further stated that many cardiologists are enrolled in Medicare under an internal medicine specialty but function as a cardiologist. Since internal medicine is one of the specialties identified as a primary care physician in step 1 of the Shared Savings Program assignment methodology while cardiologists are not included until step 2, this could result in inappropriate assignment under the Shared Savings Program. With the continued proliferation of care management services, this commenter also urged CMS to monitor utilization to ensure clinician specialty is considered in determining whether a service is considered to be a qualifying primary care service for purposes of beneficiary assignment. Another commenter cautioned against using RPM for ACO assignment given the significant rise in its use among certain medical specialties. They stated that, while well intended, addition of this service code could result in increased beneficiary churn and assignment of beneficiaries who do not have a true primary care relationship with ACO professionals in the ACO. Some commenters recommended that CMS collect experience from ACOs before adding RPM to the list of services used in assignment. They noted that they believe that it has the potential to ''pull attribution away from ACO providers'' and could attribute more patients based on services received from specialists due to the quantity of billing done for specific chronic conditions and the amounts of those bills.

A few commenters expressed concern about the intended purpose of including RPM codes in the definition of primary care services used for assignment. One commenter noted that they believe that if reimbursement for these codes counts ''towards the ACO's benchmark for purposes of determining whether the ACO is eligible for shared savings,'' it could be a disincentive for some practitioners to order these services. This commenter suggested that services billed under RPM and Remote Therapeutic Monitoring codes be reimbursable to providers that participate in an ACO without the cost of services billed under the codes being factored into the determination of an ACO's eligibility for shared savings.

Response: We are persuaded by comments concerned about or opposed to adding RPM services to the definition of primary care services for purposes of assignment, and thus are not finalizing the proposed inclusion of CPT codes 99457 and 99458 for RPM services in the definition of primary care services. As commenters stated, while these services can be billed for both primary and specialty care, the services can only be billed by one provider in a 30-day period and are more often billed by specialty providers. As a result, including these codes in the definition of primary care services for purposes of assignment could inappropriately impact the determination of where a beneficiary received a plurality of their primary care services.

After further consideration, we believe that it would be inappropriate to include these services in the definition of primary care services used for purposes of beneficiary assignment in the Shared Savings Program. Although we are not finalizing our proposal to add RPM services to the definition of primary care services used for purposes of beneficiary assignment, we do want to clarify that these services will be reflected in the calculation of expenditures for ACO-assigned beneficiaries for each benchmark year and each performance year.[246]

Comment: One commenter responded to our solicitation of comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in the proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking. This commenter urged us to include Care Management Services for Behavioral Health Conditions HCPCS code G0323 in the definition of primary care services used for purposes of beneficiary assignment, as it is not only similar to services already included in the definition, such as BHI services (codes 99484, 99492, 99493 and 99494) and HCPCS code G2214 for psychiatric collaborative care model, it would also help recognize the participation of clinical psychologists in the Shared Savings Program.

Response: We agree that HCPCS code G0323 is a BHI service; however, this code describes general BHI that a clinical psychologist or clinical social worker performs to account for monthly care integration.[247] Under section 1899(c)(1)(A) of the Act, beneficiaries must be assigned to an ACO based on their receipt of primary care services furnished by an ACO professional who is a physician (as defined in section 1861(r)(1)) of the Act), or a practitioner that is a PA, NP, CNS (as defined in section 1842(b)(18)(C)(i) of the Act). We continue to believe that assigning beneficiaries to ACOs based on their receipt of primary care services furnished by an ACO professional who is a physician, and in addition, based on their receipt of primary care services furnished by a PA, NP, or CNS, consistent with the definition in § 425.20 of an ACO professional, is consistent with requirements of the Act. Section 1899 of the Act does not specifically allow for assignment of beneficiaries to an ACO based on their receipt of primary care services from clinical social workers or clinical psychologists (as defined in sections

[246] See Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.1, ''Calculating ACO-Assigned Beneficiary Expenditures'').

[247] Medicare Learning Network (MLN909432, May 2023) Behavioral Health Integration Services, available at *https://www.cms.gov/files/document/mln909432-behavioral-health-integration-services.pdf.*

1842(b)(18)(C)(iv) and 1842(b)(18)(C)(v) of the Act).

After consideration of public comments, we are finalizing a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vii) along with the following additions: CPT codes 99406 and 99407; 96202 and 96203; and 9X015, 9X016, and 9X017 (which are being finalized as 97550, 97551, and 97552, respectively) and HCPCS codes G0101; G2086, G2087, and G2088; G2211; GXXX1 and GXXX2 (which are being finalized as G0019 and G0022, respectively) and; GXXX3 and GXXX4 (which are being finalized as G0023 and G0024, respectively); and GXXX5 (which is being finalized as G0136), as discussed in the preceding paragraphs. We are not finalizing our proposal to include CPT codes 99457 and 99458. We are finalizing as proposed that the new provision at § 425.400(c)(1)(viii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years.

In section II.E of this final rule, certain code descriptions are being finalized with revisions:

(1) *G0019 Community health integration (CHI) services performed by certified or trained auxiliary personnel including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:*

- *Person-centered assessment, performed to better understand the individualized context of* the *intersection between* the *SDOH need(s) and problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- Practitioner, Home, and Community-Based Care Coordination

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH need(s).*

- *Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis and treatment.*
- *Health care access/health system navigation:*

++ *Helping the patient access care, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

(2) *G0023 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:*

- *Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).*

++ *Facilitating patient-driven goal setting and creating an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- Practitioner, Home, and Community-Based Care Coordination

++ *Coordinating receipt of needed services from healthcare practitioners, providers and facilities; home-, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, and preferences, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*

- *Health education—Helping the patients contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver, if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ *Helping the patient access healthcare, identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

++ *Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.*

- *Facilitating behavioral change necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support for the patient to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis or treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

4. Benchmarking Methodology

a. Overview

In section III.G.4 of the CY 2024 PFS proposed rule (88 FR 52456 through 52483), we proposed modifications to the benchmarking methodology under the Shared Savings Program. We proposed a combination of modifications to the Shared Savings Program's benchmarking methodology to encourage sustained participation by ACOs in the program. Specifically, we proposed to revise the benchmarking methodology by modifying the existing calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (section III.G.4.b of the proposed rule). We also proposed to further mitigate the impact of the negative regional adjustment to the historical benchmark (section III.G.4.c of the proposed rule). Additionally, we proposed refinements to the prior savings adjustment calculation methodology (section III.G.4.d of the proposed rule), that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of issuance of a revised initial determination under § 425.315. Finally, we proposed to specify in the regulations an approach to calculating prospective HCC risk scores used in Shared Savings Program benchmark calculations, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e of the proposed rule). Our specific proposals are discussed in detail in the following sections.

b. Cap Regional Service Area Risk Score Growth for Symmetry With ACO Risk Score Cap

(1) Background

In the June 2016 final rule (81 FR 37977 through 37981), we established a policy of utilizing a regional growth rate to update the benchmark annually. In that rule, we finalized a policy that, for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark would be calculated as a growth rate that reflects growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area, for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (refer to § 425.603(d)).

In proposing and finalizing the regional growth rate policy, we explained that incorporating regional expenditures in the benchmark would make the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region. We also explained that the use of regional trend factors to trend forward BY1 and BY2 to BY3 in resetting ACO benchmarks and regional growth rates used to update the historical benchmark to the performance year annually would likely result in relatively higher benchmarks for ACOs that are low growth relative to their region compared to benchmarks for ACOs that are high growth relative to their region (refer to 81 FR 37955).

In the December 2018 final rule (83 FR 68013 through 68031), we finalized a proposal to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year for all agreement periods beginning on or after July 1, 2019 (refer to § 425.601(a) and (b)). Under this policy, the national component of the blended trend and update factors receives a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed by taking a weighted average of county-level shares. The regional component of the blended trend and update factors receives a weight equal to 1 minus the national weight. Calculations are made separately for each Medicare enrollment type. In the December 2018 final rule (83 FR 68024), we acknowledged that, for an ACO that serves a high proportion of beneficiaries in select counties making up its regional service area (referred to herein as having ''high market share''), a purely regional trend would be more influenced by the ACO's own expenditure patterns, making it more difficult for the ACO to outperform its benchmark and conflicting with our goal to move ACOs away from benchmarks based solely on their own historical costs. Incorporating national trends that are more independent of an ACO's own performance was therefore intended to reduce the influence of the ACO's assigned beneficiaries on the ultimate blended trend and update factors applied.

In the CY 2023 PFS final rule (87 FR 69881 through 69899), we finalized a policy for agreement periods starting on or after January 1, 2024, under which we will update the historical benchmark between BY3 and the performance year for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) (refer to § 425.652(b)). Under this policy, we will make separate calculations for expenditure categories for each Medicare enrollment type. We explained that incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

For ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we account for changes in severity and case mix of the ACO's assigned beneficiary population

when establishing the benchmark for an agreement period and also in adjusting the benchmark for each performance year during the agreement period. In accordance with § 425.601(a)(3) and § 425.652(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using CMS Hierarchical Condition Category (CMS–HCC) prospective risk scores (herein referred to as prospective HCC risk scores). Pursuant to § 425.601(a)(10) and § 425.652(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In performing this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

As finalized in the CY 2023 PFS final rule (87 FR 69932 through 69946), for agreement periods beginning on or after January 1, 2024, we will use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (herein referred to as the ''aggregate demographics plus 3 percent cap'') (refer to § 425.605(a)(1)(ii); § 425.610(a)(2)(ii)). This cap applies only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) exceeds this cap. If the cap is determined to apply, the value of the cap is the maximum increase in prospective HCC risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the aggregate demographics plus 3 percent cap for any of the Medicare enrollment types. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.

In the CY 2023 PFS final rule, we further explained that we were finalizing the aggregate demographics plus 3 percent cap to address concerns with the prior approach to risk adjustment, which used prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, subject to a cap of positive 3 percent for the agreement period that was applied separately by Medicare enrollment type (referred to herein as the ''3 percent cap'') (refer to § 425.605(a)(1)(i); § 425.610(a)(2)(i)). The 3 percent cap was finalized through the December 2018 final rule (83 FR 68013) and is applicable to ACOs in agreement periods beginning on or after July 1, 2019, and prior to January 1, 2024.

We believe that the aggregate demographics plus 3 percent cap addresses several concerns raised by interested parties [248] about the 3 percent cap by: accounting for higher volatility in prospective HCC risk scores for certain Medicare enrollment types due to smaller sample sizes; allowing for higher benchmarks than the prior risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are frequently subject to the 3 percent cap); and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. However, the demographics plus 3 percent cap does not address concerns from certain interested parties that the current policy places a cap on an ACO's risk score growth between BY3 and the performance year but does not place a cap on the regional prospective HCC risk score growth between BY3 and the performance year, which is reflected in the regional growth rate used to calculate the update factor (pursuant to § 425.652(b)(2)(ii)).[249]

Under the methodology finalized in CY 2023 PFS final rule, as described in § 425.652(b), we express the regional update factor, used to update the historical benchmark to the performance year, as the ratio of an ACO's performance year regional service area risk adjusted expenditures to its BY3 regional service area risk adjusted expenditures for each Medicare enrollment type. Table 36 provides a numeric example of the current methodology for calculating the regional update factor for the ESRD Medicare enrollment type for a hypothetical ACO with a regional service area that includes counties A, B, C, and D.

Under § 425.654, an ACO's regional expenditures are calculated using risk adjusted county FFS expenditures. The counties included in the ACO's regional service area are based on the ACO's assigned beneficiary population for the applicable benchmark or performance year. We determine average county FFS expenditures based on expenditures for the assignable population [250] of beneficiaries in each county in the ACO's regional service area. We make separate calculations for each Medicare enrollment type. We adjust these county-level FFS expenditures (refer to Table 36, rows [A] and [F]) for severity and case mix of assignable beneficiaries in the county using county-level prospective HCC risk scores (refer to Table 36, rows [B] and [G]). The adjustment is made by dividing the county-level FFS expenditures for the Medicare enrollment type by county-level prospective HCC risk scores for the Medicare enrollment type, resulting in risk adjusted county-level FFS expenditures shown in Table 36 rows [C] and [H].

We then calculate an ACO's regional expenditures for each Medicare enrollment type by weighting these risk adjusted county-level FFS expenditures according to the ACO's proportion of assigned beneficiaries [251] in the county for that Medicare enrollment type (refer to Table 36, rows [D] and [I]), determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year. We

[248] For summaries of these concerns of interested parties, refer to the CY 2022 PFS final rule (86 FR 65302 through 65306), CY 2023 PFS final rule (87 FR 69932 through 69934).

[249] For summaries of these concerns of interested parties, refer to the CY 2021 PFS final rule (85 FR 84783 through 84785), the CY 2022 PFS final rule (86 FR 65302 through 65306), and the CY 2023 PFS final rule (87 FR 66942 and 69943).

[250] Assignable beneficiary expenditures are calculated using the payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year that corresponds to the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. These expenditure calculations exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and consider individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. Refer to § 425.654(a)(2). The assignable population of beneficiaries is identified for the assignment window corresponding to the relevant benchmark or performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). Refer to § 425.654(a)(1)(i). We refer readers to the discussion of the proposed changes to the methodology for identifying the assignable beneficiary population in section III.G.3.a of the proposed rule.

[251] Proportions are calculated using beneficiary person years.

then aggregate those values for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area [252] (refer to Table 36, rows [E] and [J]).

We then calculate the regional update factor as the ratio of an ACO's performance year expenditures to BY3 regional expenditures. This calculation is performed separately for each Medicare enrollment type. Refer to Table 36, row [K] for an example of how the regional update factor would be calculated for the ESRD Medicare enrollment type. This calculation would then be repeated for each of the other Medicare enrollment types.

TABLE 36: Example Calculation of the Regional Update Factor for the ESRD Medicare Enrollment Type for a Hypothetical ACO

	County A	County B	County C	County D	Regional
BY3 ESRD Calculations					
[A] County FFS Expenditures	72,000	108,000	86,400	79,200	
[B] County Prospective HCC Risk Scores	0.980	1.100	1.050	1.100	
[C] Risk Adjusted County FFS Expenditures, [A]/[B]	73,469	98,182	82,286	72,000	
[D] Proportion of Assigned Beneficiaries	0.55	0.30	0.15	0.00	
[E] Regional Risk Adjusted Expenditures, weighted average of [C] using weights [D]					**82,206**
PY ESRD Calculations					
[F] County FFS Expenditures	74,880	112,320	89,856	82,368	
[G] County Prospective HCC Risk Scores	1.000	1.210	1.124	1.166	
[H] Risk Adjusted County FFS Expenditures, [F]/[G]	74,880	92,826	79,943	70,642	
[I] Proportion of Assigned Beneficiaries	0.58	0.26	0.15	0.01	
[J] Regional Risk Adjusted Expenditures, weighted average of [H] using weights [I]					**80,263**
ESRD Regional Update Factor Calculation					
[K] ESRD Regional Update Factor, [J]/[E]					**0.976**

While the regional expenditures for BY3 and the performance year are risk adjusted, as described previously in this section, there is currently no cap on prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year. As discussed previously in this section, ACOs and other interested parties have expressed concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and that there is not an equivalent cap on regional risk score growth. High prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year has the effect of decreasing the regional update factor, resulting in a lower updated benchmark for the ACO than if the regional risk score growth was capped (assuming that the risk score growth was high enough to be capped). In past rulemaking, some commenters have encouraged CMS to adopt a policy of applying a cap on ACO risk score growth after accounting for regional increase in risk scores.[253] Others have suggested more generally that CMS align the use of a risk adjustment cap for the ACO and its region by applying a consistent capping policy to both.[254]

In the CY 2022 PFS proposed rule (86 FR 39294 through 39295), we sought comment on an alternate approach to capping ACO prospective HCC risk score growth between BY3 and the performance year in relation to the prospective HCC risk score growth in the ACO's regional service area. The option we presented was to allow an ACO's risk score growth cap to increase above 3 percent by a percentage of the difference between the 3 percent cap and risk score growth in the ACO's regional service area for a given Medicare enrollment type. In this alternate approach (herein referred to as the ''3 percent cap plus regional difference''), the percentage applied would be equal to 1 minus the ACO's regional market share for the Medicare enrollment type. For example, if regional risk score growth for a particular Medicare enrollment type was 5 percent and the ACO's regional market share was 20 percent, we would increase the cap on the ACO's risk score growth for that Medicare enrollment type by an amount equal to the difference between the regional risk score growth and the 3 percent cap (2 percent) multiplied by one minus the ACO's regional market share (80 percent). Thus, the ACO would face a cap for this Medicare enrollment type equal to 4.6 percent instead of 3 percent (3 percent + (2 percent × 80 percent)). This approach would raise the 3 percent cap while limiting the ability for ACOs

[252] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), sections 4.1.1 ''Determining Regional FFS Expenditures'' and 4.1.4 ''Risk Adjusting and Updating the Historical Benchmark'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2.*

[253] Refer to CY 2021 PFS final rule (85 FR 84784).

[254] Refer to CY 2021 PFS final rule (85 FR 84784) and CY 2023 PFS final rule (87 FR 69943).

with high market share to increase their cap by engaging in coding intensity initiatives that raise the regional prospective HCC risk score. As discussed in the CY 2022 PFS final rule, a few commenters noted their support for this 3 percent cap plus regional difference methodology.[255] However, MedPAC expressed concern that increasing the cap beyond 3 percent could effectively reward ACOs for greater coding intensity in their region, particularly for those with higher market share.[256] [257]

In the CY 2023 PFS final rule (87 FR 69932 through 69946), we indicated that we had considered the 3 percent cap plus regional difference methodology described in the CY 2022 PFS proposed rule when developing policies for the CY 2023 PFS proposed rule. However, we opted not to propose this policy and instead proposed, and ultimately finalized, the aggregate demographics plus 3 percent cap. One reason we did not propose the 3 percent cap plus regional difference was that a relatively small share of ACOs affected by the 3 percent cap operated in regional service areas where regional risk score growth was greater than 3 percent, indicating that this was not a widespread issue impacting ACO performance. Additionally, we explained that we still had concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those with high market share, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. Under the 3 percent cap, ACOs with high market share have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. We noted that raising the 3 percent cap based on risk score growth in an ACO's regional service area could change these incentives and encourage ACOs to engage in coding initiatives. In addition to finalizing the aggregate demographics plus 3 percent cap, in the CY 2023 PFS final rule, we noted that we declined to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area (87 FR 69932 through 69947). As with the 3 percent cap plus regional difference, we were concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs with high market share.

In response to the discussion of the cap on prospective HCC risk score growth in the CY 2023 PFS proposed rule, commenters took the opportunity to reiterate their concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and suggested ways to incorporate a cap on regional risk score growth. A couple of commenters requested that the risk score cap be allowed to further increase for ACOs in regions where risk score growth exceeds the cap, with one stating that a flat percentage cap will always disadvantage ACOs in regions where risk score growth exceeds the cap and another stating that this additional flexibility would ensure ACOs are not disadvantaged by operating in underserved communities. Additionally, many commenters supported capping regional risk score growth in addition to capping ACO risk score growth. Several of those commenters stated that it was critical that, whatever policy CMS adopted for capping ACOs' risk score growth, the same policy must also apply to regional risk score growth. Several commenters noted that CMS should not apply adjustments to only one side of the equation, that is, capping ACO risk ratios without capping regional risk ratios, with many commenters saying this would lead to unintended consequences and another commenter stated it would have inequitable results. Several commenters stated that not capping increases in regional risk scores would stifle growth in exactly the areas CMS wants growth the most. A few commenters explained that lack of regional risk score growth caps incentivizes ACOs not to grow in places with certain types of populations, such as those with increasing health burdens, higher needs, or higher numbers of aged/dual and disabled enrollees.[258] In response to these comments, we indicated that we would continue to monitor the impacts of regional risk score growth and might propose further refinements to our risk adjustment policies in future rulemaking.[259]

(2) Revisions

Since the publication of the CY 2023 PFS final rule, we have performed further analysis on prospective HCC risk score growth in ACOs' regional service area between BY3 and the performance year and considered ways in which we could reduce impacts to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own complete and accurate coding, while also limiting the impact from coding initiatives, particularly among ACOs with high market share. Based on this additional analysis, which is detailed later in this section, in the CY 2024 PFS proposed rule (88 FR 52459 through 52465), we proposed to modify the calculation of the regional update factor used to update the historical benchmark between BY3 and the performance year. The proposed approach would cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor to the regional update factor. This cap on regional risk score growth would be applied independently of the cap on an ACO's own prospective HCC risk score growth between BY3 and the performance year, meaning that this proposed cap on prospective HCC risk score growth in an ACO's regional service area would be applied whether or not the ACO's prospective risk score growth was capped when updating the benchmark between BY3 and the performance year. We explained that applying these caps independently would be more equitable to ACOs serving high-risk patients in regions with high risk score growth and avoid creating incentives for ACOs to avoid high-risk and more medically complex patients. Adjusting the regional service area risk score growth cap based on the percentage of original Medicare FFS beneficiaries the ACO serves in the region would help to mitigate the impact an ACO's own coding initiatives have on risk score growth in the ACO's regional service area, particularly when the ACO has a greater influence on its regional service area risk score growth rate.

To determine the cap on prospective HCC risk score growth in an ACO's regional service area, we proposed to follow a similar methodology as the one adopted in the CY 2023 PFS final rule [260] for capping ACO risk score growth, codified at §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii), while additionally accounting for an ACO's aggregate

[255] Refer to 86 FR 65304.

[256] Refer to 86 FR 65303 through 65305.

[257] Refer to Letter from MedPAC to Chiquita Brooks-LaSure, Administrator, CMS (September 9, 2021), regarding File code CMS–1751–P (pages 16–18 ''Risk adjustment methodology''), available at *https://www.medpac.gov/wp-content/uploads/2021/10/09092021_PartB_CMS1751_MedPAC_Comment_V2_SEC.pdf*.

[258] Refer to 87 FR 69942 through 69943.

[259] Refer to 87 FR 69943.

[260] 87 FR 69932 through 69946.

market share. The effect of the regional risk score growth cap would be to increase the regional component of the update factor for ACOs in regions with aggregate regional prospective HCC risk score growth above the cap, with ACOs with higher aggregate market shares seeing smaller increases, all else being equal. ACOs in regions with aggregate regional prospective HCC risk score growth below the cap would not be affected by the proposed policy.

As we explained in the CY 2024 PFS proposed rule, by symmetrically limiting risk score growth within both an ACO's assigned beneficiary population and its region, this proposed approach is expected to improve the accuracy of the regional update factors for ACOs operating in regional service areas with high risk score growth, particularly in later years of the 5-year agreement period where the difference between an ACO's BY3 and performance year regional risk scores is expected to be the greatest. We explained our belief that capping regional risk score growth would strengthen incentives for ACOs to form or continue to operate in regions with high-risk score growth and thereby incentivize ACOs to care for higher risk beneficiaries. This approach would also offer an incentive for potential applicant ACOs that may be examining recent risk score growth in their region and making the decision whether to participate in the Shared Savings Program. Additionally, by adjusting the regional risk score growth cap based on ACO market share, we noted that the proposal would also maintain a disincentive against coding intensity for ACOs with high market share.

To implement the new cap on regional risk score growth, we proposed to multiply the original regional update factor used to update the historical benchmark between BY3 and the performance year (determined in accordance with § 425.652(b)(2)(ii)) by a regional risk score growth cap adjustment factor. The regional risk score growth cap adjustment factor would be calculated as follows:

- *Step 1:* Calculate county-level risk scores. We would calculate county-level prospective HCC and demographic risk scores by Medicare enrollment type for both BY3 and the performance year. To do this for a given benchmark or performance year, we would first determine the renormalized, prospective HCC and demographic risk score for each assignable beneficiary [261] in each county in the ACO's regional service area. For both HCC and demographic risk scores, we would then compute the weighted average risk score for each county for each Medicare enrollment type by multiplying each assignable beneficiary's risk score for that Medicare enrollment type by the beneficiary's person years enrolled in that Medicare enrollment type, summing these weighted risk scores across all assignable beneficiaries for that Medicare enrollment type in the county, and then dividing by total person years for that Medicare enrollment type among assignable beneficiaries in the county. We noted that this approach would be similar to the approach that is currently used to determine county-level prospective HCC risk scores as an intermediate step in calculating risk adjusted regional expenditures under the current methodology.[262]
- *Step 2:* Calculate regional risk scores. We would calculate regional-level BY3 and performance year prospective HCC and demographic risk scores as a weighted average of county-level HCC and demographic risk scores for the Medicare enrollment type (calculated in step 1), with weights reflecting the proportion of the ACO's assigned beneficiaries [263] in the county. This proportion is determined by the number of the ACO's assigned beneficiaries (by Medicare enrollment type) residing in each county in relation to the ACO's total number of assigned beneficiaries for that Medicare enrollment type for the relevant benchmark or performance year. These would be the same weights as used to calculate regional expenditures under § 425.654(b).
- *Step 3:* Determine aggregate growth in regional risk scores. To calculate aggregate growth in regional risk scores, we would first calculate growth in prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type, expressed as the ratio of the performance year regional risk score for a Medicare enrollment type (calculated in step 2) to the BY3 regional risk score for that enrollment type (calculated in step 2). We would next take a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, where the weight applied to the growth in risk scores for each Medicare enrollment type would be the ACO's performance year assigned beneficiary person years for the Medicare enrollment type multiplied by the ACO's regionally adjusted historical benchmark expenditures for the Medicare enrollment type.[264]
- *Step 4:* Determine the cap on regional risk score growth. We would first calculate the non-market share adjusted cap on the ACO's regional risk score growth as the sum of the aggregate growth in regional demographic risk scores (calculated in step 3) and 3 percentage points.[265]

We would next adjust the cap to reflect the ACO's aggregate market share. We would calculate an ACO's aggregate market share as a weighted average of the ACO's market share across the four Medicare enrollment types. An ACO's market share for each Medicare enrollment type would be equal to the weight that is applied to the national component of the blended update factor in the two-way blend that is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year (refer to § 425.652(b)(2)(iv)). The weights for each Medicare enrollment type used to compute the weighted average would be the ACO's performance year assigned person years for the Medicare enrollment type.

We would adjust the cap on regional risk score growth to reflect the ACO's aggregate market share by adding to the non-market share adjusted cap the product of:

++ The ACO's aggregate market share, and

++ The difference (subject to a floor of zero) between:

—The aggregate regional prospective HCC risk score growth (calculated in step 3), and

[261] Consistent with our proposal to revise the definition of an assignable beneficiary (refer to section III.G.3.a of the proposed rule), we proposed that the assignable population of beneficiaries for a benchmark or performance year would be identified using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the applicable performance year according to § 425.400(a)(4)(ii).

[262] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), section 4.1.1 ''Determining Regional FFS Expenditures'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*.

[263] Proportions are calculated using beneficiary person years.

[264] These are the same weights that are to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology adopted in the CY 2023 PFS final rule (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C).

[265] This is similar to the calculation of the cap on ACO prospective HCC risk score growth finalized in the CY 2023 PFS (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A).

—The non-market share adjusted cap (calculated first in this step).

This adjustment of the cap on regional risk score growth using the ACO's aggregate market share creates a sliding scale. Assuming that an ACO has aggregate regional prospective HCC risk score growth above the non-market share adjusted cap, an ACO with close to 0 percent aggregate market share would receive a market share adjusted cap on regional risk score growth close to the aggregate growth in regional demographic risk scores plus 3 percentage points and an ACO with 100 percent aggregate market share would receive a market share adjusted cap on regional risk score growth equal to the aggregate regional prospective HCC risk score growth calculated in step 3 (which is effectively no cap at all). Under this approach, as an ACO's aggregate market share increases, so does the cap on the ACO's regional risk score growth, ultimately limiting the potential increase to the regional update factor for ACOs with high market share.

• *Step 5:* Determine the regional risk score growth cap adjustment factor. First, we would determine if the ACO's regional risk score growth is subject to a cap by comparing the ACO's aggregate regional prospective HCC risk score growth (calculated in step 3) to the market share adjusted cap on regional risk score growth (calculated in step 4).

++ If the aggregate regional prospective HCC risk score growth does not exceed the cap on regional risk score growth, the ACO's regional risk score growth would not be subject to the cap. For these ACOs we would set the risk score growth cap adjustment factor equal to 1 for each Medicare enrollment type (which is effectively no adjustment).

++ If the aggregate regional prospective HCC risk score growth exceeds the market share adjusted cap, the ACO's regional risk score growth is subject to the cap. For these ACOs we would next determine whether the cap on regional risk score growth applies for each Medicare enrollment type. To do this, we would compare regional prospective HCC risk score growth for each Medicare enrollment type (calculated in step 3) with the market share adjusted cap (calculated in step 4). If the regional risk score growth for a Medicare enrollment type does not exceed the cap, the enrollment type is not subject to the cap and the regional risk score growth cap adjustment factor for that Medicare enrollment type is set equal to 1 (effectively no adjustment). Otherwise, the Medicare enrollment type is subject to the cap and we would set the adjustment factor for the Medicare enrollment type equal to the regional prospective HCC risk score growth for the Medicare enrollment type (calculated in step 3) divided by the market share adjusted cap calculated in step 4. In this case, the adjustment factor for the Medicare enrollment type would represent a measure of how far above the cap the regional prospective HCC risk score growth is.

Table 37 provides a numeric example of the calculation of the regional risk score growth cap adjustment factor for a hypothetical ACO that is determined to be subject to the market share adjusted cap. Table 37 begins at the end of step 2 of the calculation, and therefore only reflects regional-level calculations and does not include the county-level calculations:

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TABLE 37: Example of Calculation of the Regional Risk Score Growth Cap Adjustment Factor for a Hypothetical ACO

Regional Level Measure	ESRD	Disabled	Aged/dual	Aged/non-dual	Weighted Average
Results of Step 2 (Regional Risk Scores (Calculation not shown))					
[A] BY3 Prospective HCC Risk Scores	1.027	1.016	1.037	1.006	
[B] PY Prospective HCC Risk Scores	1.075	1.049	1.043	1.053	
[C] BY3 Demographic Risk Scores	1.016	0.996	1.047	1.007	
[D] PY Demographic Risk Scores	0.962	1.012	1.054	0.983	
Step 3 (Determine growth in aggregate risk scores)					
[E] Prospective HCC Risk Ratio, [B] / [A]	1.047	1.032	1.006	1.047	
[F] Demographic Risk Ratio, [D] / [C]	0.947	1.016	1.006	0.977	
[G] Risk Score Weights (ACO performance year assigned person years multiplied by regionally adjusted historical benchmark expenditures, as a proportion)	0.010	0.090	0.150	0.750	
[H] Weighted Average HCC Risk Ratio, weighted average of [E] using weights [G]					1.039
[I] Weighted Average Demographic Risk Ratio, weighted average of [F] using weights [G]					0.984
Step 4 (Determine the cap on regional risk score growth)					
[J] Non-market Share Adjusted Cap, [I] + 0.030					1.014
[K] Market Share Weights (ACO performance year assigned person years, as a proportion)	0.007	0.085	0.120	0.788	
[L] ACO Market Share	0.150	0.200	0.180	0.300	
[M] Weighted Average Market Share, weighted average of [L] using weights [K]					0.276
[N] Market Share Adjusted Cap, [J]+([M]*([H]-[J])), Note that [H]-[J] is subject to a floor of 0					1.021
Step 5 (Determine the regional risk score growth cap adjustment factor)					
[O] Is the ACO Subject to Cap? [H] > [N]?					Yes
[P] Is the Enrollment Type Subject to Cap, If [O] = Yes, is [E]>[N]? If [O] = No, then No	Yes	Yes	No	Yes	
[Q] Regional Risk Score Growth Cap Adjustment Factor, If [P] =Yes, then [E]/[N], else 1	1.025	1.011	1.000	1.025	

Table Note: This numeric example shows only three decimal places and so attempting to replicate the calculations may result in slight differences due to rounding. In actual calculations all decimal places would be used.

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In this example, the hypothetical ACO was in a regional service area with aggregate prospective HCC risk score growth (a weighted average risk ratio of 1.039, refer to row [H]) above the market share adjusted cap of 1.021 (refer to row [N]). The ACO's regional prospective HCC risk score growth (shown in row [E]) was above this cap for three of the four Medicare enrollment types (all but the aged/dual eligible Medicare enrollment type). Therefore, the regional risk score growth cap adjustment factor (refer to row [Q]) calculated for those three capped Medicare enrollment types was above one, and the regional risk score growth cap adjustment factor calculated for the one uncapped Medicare enrollment type was equal to one. Once the regional risk score growth cap adjustment factors are multiplied by the original regional update factors used to update the historical benchmark between BY3 and the performance year, the regional update factor would increase for the three capped Medicare

enrollment types. For example, if the original regional update factor for the ESRD Medicare enrollment type was 0.976, then the final regional ESRD update factor after the application of the regional risk score growth cap adjustment factor would be 1.000 (the product of 0.976 and the regional risk score growth cap adjustment factor of 1.025). There would be no change to the original regional update factor for the uncapped aged/dual eligible Medicare enrollment type as it would be multiplied by one. Because of the increase in original regional update factor for the three capped Medicare enrollment types, this hypothetical ACO would have a higher updated benchmark under this proposed policy than under current policy.

However, if an ACO was in a regional service area with aggregate prospective HCC risk score growth that was not above the regional risk score growth cap, the regional risk score growth cap adjustment factor for all Medicare enrollment types would be equal to one, thus resulting in no change to the original regional update factor for any Medicare enrollment type, and therefore, no change to the ACO's updated benchmark compared to current policy.

As we described in the CY 2024 PFS proposed rule, this proposed policy would help increase the accuracy of the regional update factor for ACOs operating in regional service areas with high risk score growth, including those serving more medically complex beneficiaries, therefore increasing incentives for ACOs to form or continue participation in such areas. We further explained that incorporating the market share adjustment helps to mitigate concerns related to coding intensity for ACOs with high market share and thus a relatively high level of influence over risk scores in their regional service area as discussed in section III.G.4.b.(1) of the proposed rule, and therefore, would protect the Trust Funds by continuing to limit incentives for this behavior.

We simulated the impact of the proposed policy using PY 2021 financial reconciliation data for ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 38 of the 332 ACOs (11 percent) would have been subject to the cap on regional risk score growth determined in step 4 of the proposed methodology, and therefore, would have had a higher regional update factor than under current policy for at least one Medicare enrollment type. Thirty-six of those 38 ACOs were subject to the 3 percent cap on their own risk score growth for at least one enrollment type in actual PY 2021 results. Table 38 shows the percentage of ACOs determined to be subject to the cap on regional risk score growth for each Medicare enrollment type and the average increase in the regional update factor for that enrollment type among those ACOs.

TABLE 38: Share of ACOs Subject to Regional Risk Score Growth Cap and Average Increase in Regional Update Factor among those ACOs by Medicare Enrollment Type

	ESRD	Disabled	Aged/Dual	Aged/Non-Dual
Share of ACOs Capped in Simulation	2%	5%	10%	11%
Average Change in Regional Update Factor	0.011	0.015	0.035	0.016

In the proposed rule, we explained that while this modeling shows that only a small proportion of ACOs would have benefitted from this policy in PY 2021, our analyses have also shown that this proportion is predicted to increase as more ACOs advance farther into their 5-year agreement period. This prediction was supported by the finding that ACOs in the simulation were significantly more likely to be impacted if their agreement period started in 2019 with a BY3 of 2018 (16 percent) than if their agreement period started in 2020 with a BY3 of 2019 (6 percent).[266] Because the analysis of PY 2021 data demonstrates that circumstances like the PHE for COVID–19 and progression along a 5-year agreement period can interact to increase the share of ACOs in regional service areas with aggregate regional risk score growth above the cap, we determined that our initial concerns about creating adverse incentives for coding behavior by capping regional risk score growth, as discussed in section III.G.4.b.(1) of the proposed rule, were outweighed by the potential harm to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own coding activities. Additionally, we stated that the market share adjustment to the cap on regional risk score growth would limit overly advantaging ACOs with high market share if they participate in coding initiatives.

Table 39 displays information on the impact of the market share adjustment on the cap on regional risk score growth within our simulation of the application of the proposed policy in PY 2021 for the ACOs with the minimum, median, and maximum aggregate market share that were found to be subject to the cap on regional risk score growth.

[266] While analysis of average FFS risk score changes at the hospital referral region (HRR) level further supports the assumption that more ACOs would be impacted toward the end of their 5-year agreement period, such analysis also indicates that variation from the PHE for COVID–19 likely accentuated this phenomenon in the simulation on PY2021 data. For this reason, the finding in the PY2021 simulation that 16 percent of 2019 starters were impacted is likely indicative of an upper bound for the share of ACOs potentially impacted by PY5 in agreement periods that start in 2024 or later (that is, where the impact of the PHE for COVID–19 on risk score growth between BY3 and the PY is minimal relative to risk score growth from 2018 to 2021 and from 2019 to 2021 in this simulation). This footnote has been revised, from footnote 187 in the CY 2024 PFS proposed rule (88 FR 52463), to clarify how findings from the PY 2021 simulation may be relevant in projecting risk score growth for agreement periods starting in 2024 or later.

TABLE 39: Aggregate Market Share and Impact of Market Share Adjustment on Cap on Regional Risk Score Growth among ACOs Subject to Regional Risk Score Growth Cap (N=38)

	Aggregate Market Share (proportion)	Non-Market Share Adjusted Cap	Market Share Adjusted Cap	Difference between Market Share Adjusted and Non-Market Share Adjusted Cap
Minimum	0.009	1.036	1.036	<0.001
Median	0.127	1.034	1.034	0.001
Maximum	0.536	1.008	1.028	0.020

Note: The minimum, median, and maximum refer to the minimum, median and maximum aggregate market share. The non-market share adjusted cap, market share adjusted cap, and difference between market share adjusted and non-market share adjusted cap represent data from the ACOs with the minimum, median, and maximum market shares. Because there are an even number of impacted ACOs, there are two ACOs comprising the median of 0.127. These two ACOs have the same non-market share adjusted and market share adjusted caps and have been combined into a single row for simplicity.

Based on this data in Table 39, the majority of ACOs found to be impacted in this simulation had a relatively small aggregate market share, with a median of about 13 percent. Because of this, the median increase to the cap on regional risk score growth from the market share adjustment was small (0.001). (This is both the median increase among all 38 impacted ACOs and the increase for the impacted ACOs with the median market share). Further analysis showed that results were similar among both rural and urban ACOs. Of the 38 impacted ACOs, 34 were classified as urban and had a median aggregate market share of about 12 percent. The remaining four impacted ACOs were rural ACOs with a median aggregate market share of about 24 percent. While the market share was higher on average among rural ACOs, average market share for both types of ACOs was under 25 percent and both groups had only a small median increase to the cap on regional risk score growth from the market share adjustment of 0.001.[267]

ACOs with a larger aggregate market share received a larger increase in the cap on regional risk score growth due to the market share adjustment. For example, in Table 39, the ACO with the highest market share of 53.6 percent (an ACO that has a regional service area in an urban area), had a 20 percent increase in its cap from the market share adjustment, going from a non-market share adjusted cap of 1.008 to an adjusted cap of 1.028. As we explained in the CY 2024 PFS proposed rule, while the impact of the market share adjustment on the cap on regional risk score growth would be small for the majority of ACOs, this market share adjustment was important to address both our own concerns related to incentives for coding intensity and the similar concerns raised by MedPAC in the CY 2023 PFS final rule, as discussed in section III.G.4.b.(1) of the proposed rule. The market share adjustment to the cap limits the adverse coding incentives that can arise when allowing larger benchmark increases when an ACO increases its coding, especially for ACOs with high market share. Specifically, ACOs with high market share would still have a disincentive to engage in coding initiatives, as these initiatives could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor.

We explained that apart from the market share adjustment, the calculation of the proposed cap on regional risk score growth between BY3 and the performance year would be calculated in the same way as the aggregate demographics plus 3 percent cap on ACO risk score growth under §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A). Specifically, the cap would be calculated as the aggregate growth in regional demographic risk scores between BY3 and the performance year plus 3 percentage points, prior to application of the market share adjustment. Additionally, we noted that as a result of incorporating the risk adjustment into the regional update factor at the county level, the current methodology does not directly calculate a regional risk ratio that can be directly modified. The proposed approach of modifying the regional update factor by multiplying by an adjustment factor would achieve the goal of reducing the impact of regional risk score growth while leaving the existing methodology for calculating risk-adjusted regional expenditures intact.

In the CY 2024 PFS proposed rule, we explained that in earlier rulemaking (see 87 FR 69887 and 69888) we have used our authority under section 1899(i)(3) of the Act to adopt a three-way blended benchmark update factor (weighted one-third ACPT, and two-thirds national-regional blend) for agreement periods beginning on January 1, 2024, and in subsequent years, in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act. We also acknowledged that the changes we were proposing to the regional component of the three-way blended update factor would similarly require continued use of our statutory authority under section 1899(i)(3) of the Act. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. We explained our belief that the changes to the methodology for updating the benchmark that we were proposing pursuant to section 1899(i)(3) of the Act would improve the quality and efficiency of items and services furnished under the Medicare Program. More specifically, we explained our belief that the proposed changes to the

[267] For this analysis, ACOs were classified as rural if the plurality of their assigned beneficiaries resided in either micropolitan or noncore counties and urban if the plurality of their assigned beneficiaries resided in either large central metro, large fringe metro, medium metro, or small metro counties as defined by The United States Census Bureau and the Office of Management and Budget (OMB).

regional component of the update factor would—in the context of the downward effects on the benchmark resulting from elevated variation in regional average prospective HCC risk score growth as shown in the PY 2021 analysis—reinforce the incentive for ACOs to enter and remain in the Shared Savings Program, particularly in regions with changing populations. Moreover, we stated our belief that the proposed approach, by encouraging ACOs to enter and continue participation in the Shared Savings Program, would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs have an incentive to perform well on quality measures in order to maximize the shared savings they may receive. In addition, as discussed in the Regulatory Impact Analysis (section VII. of the proposed rule), it was our belief that the proposed changes to the regional component of the three-way blended update factor, in combination with the other proposals for which we were required to use our authority under section 1899(i)(3) of the Act, would result in a marginal impact that we estimated would result in $330 million in lower net spending over the 10-year projection window, which supported our finding that the relatively minor changes to program spending resulting from these proposed changes would not violate the requirements of section 1899(i)(3)(B) of the Act. We stated that we would continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We proposed to revise the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between BY3 and the performance year at § 425.652(b)(2)(ii)(C) to incorporate a regional risk score growth cap adjustment factor. (In the preamble of the CY 2024 proposed rule (88 FR 52465), we inadvertently referred to § 425.652(c) instead of § 425.652(b)(2)(ii)(C); however, the proposed changes to the regulations text correctly reflected the intended revisions to § 425.652(b)(2)(ii)(C).) We also proposed to add a new section to the regulations at § 425.655 to describe the calculation of the adjustment factor.

We solicited comments on the proposed changes to calculation of the regional component of the update factor for agreement periods beginning on or after January 1, 2024.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the overall proposal to cap regional service area risk score growth for symmetry with the ACO risk score cap. A couple of commenters appreciated CMS' receptiveness to the concerns of interested parties while another thanked CMS for ensuring physicians in certain geographies are not disincentivized from participating in the Shared Savings Program.

Commenters cited a variety of reasons for their support of the proposal. Several commenters discussed the effect that the policy would have on ACOs that care for underserved beneficiaries or medically complex, high-risk beneficiaries, with many saying that it would strengthen incentives to continue providing care to such beneficiaries and another saying that it would bolster the financial stability of ACOs caring for that population. Multiple commenters stated the proposal supports CMS' strategic objective to increase the number of beneficiaries in care relationships with more accountability for quality care.

Several commenters discussed the effect that the policy would have on health care providers or ACOs that operate in regions with high risk score growth. Several commenters stated that the proposal would strengthen incentives for new ACOs to form or for current ACOs to continue participating in the Shared Savings Program, and one commenter stated that the proposal would be equitable for such ACOs. Another commenter stated that the policy would create a more equitable marketplace for all and incentivize ACO growth in rural and underserved markets. One commenter stated the policy would prevent ACOs with higher risk score growth from ''getting hit twice'' with regional risk score growth. One commenter noted they believed the policy would guard against a small number of health systems dramatically altering the financial landscape of a region. One commenter tentatively supported the proposal but requested that CMS monitor closely to ensure the policy does not unduly penalize certain ACOs in regions with changing demographics beyond the ACOs' control, such as an elderly population approaching the peak years for Medicare spending.

Several commenters described the policy as addressing what they considered flaws with existing policy for updating the benchmark. A couple of commenters suggested that the policy would address unfairness or inequity that exists under current policy. Another commenter stated that the policy would improve accuracy in accounting for regional service area risk score growth. Another commenter appreciated that CMS intends to make methodology changes that substantively address the commenter's underlying concerns with the balance of national and regional trends in Shared Savings Program ACO benchmarks.

MedPAC supported the proposal to cap regional risk score growth with an adjustment for an ACO's market share, stating that the proposal reasonably protects ACOs from coding that may be out of their control, depending on an ACO's share of the market. MedPAC suggested the proposal was a reasonable approach in the absence of an alternative policy for updating the historical benchmark by using administrative update factors or a policy to address the underlying differences between ACOs' risk scores and the average risk score for the assignable beneficiary population. However, MedPAC stated that the proposed approach should be viewed as an interim step because it does not address the underlying issues with coding incentives and regional benchmarking. We further summarize MedPAC's comments on the proposed modifications to the benchmarking methodology elsewhere in section III.G.4 of this final rule.

Response: We agree with commenters that the proposed policy would encourage participation by ACOs in regions with changing beneficiary demographics and health status beyond the ACOs' control and improve the accuracy of the regional update factors for ACOs operating in regional service areas with high risk score growth. We also agree with commenters that the proposed policy would incentivize ACOs to care for higher risk beneficiaries.

Comment: Some commenters specifically stated support for adjusting the cap based on market share, with one commenter stating that the adjustment would maintain a disincentive against coding intensity for ACOs with high market share and another recognizing the need to limit the impact of coding

initiatives, particularly among ACOs with high market share, to avoid potentially adverse incentives.

Response: We agree with commenters that adjusting the regional service area risk score growth cap based on the percentage of assignable beneficiaries the ACO serves in the region would help to mitigate the impact of the ACO's own coding initiatives on risk score growth in the ACO's regional service area, particularly when the ACO has a greater influence on its regional service area risk score growth rate. As an ACO's aggregate market share increases, so does the cap on the ACO's regional risk score growth, ultimately limiting the potential increase to the regional update factor for ACOs with high market share. This adjustment to the cap would have the effect of ACOs with higher aggregate market shares seeing smaller increases in the regional component of the update factor, all else being equal.

Comment: Many commenters supporting the proposal requested that the policy be made effective for all ACOs, not just ACOs in agreement periods starting on or after January 1, 2024, and a few commenters recommended that ACOs in existing agreement periods should be given the option of whether to receive the new policy. Some of these commenters described limiting the policy to ACOs entering new agreement periods as ''unfair.'' A few commenters noted that because the CY 2024 PFS proposed rule was issued after the application deadline for agreement periods starting on January 1, 2024, ACOs in the middle of a current agreement period missed the opportunity to submit applications for early renewal that would allow them to take advantage of this and other proposed changes to the program's benchmarking policies in PY 2024, if finalized. A few other commenters opined that requiring ACOs to go through the early renewal process to benefit from the policy was burdensome for ACOs. One commenter noted that the early renewal process also created burden for CMS and additionally suggested that it could risk disruption to the program and lead to large swings in cohort sizes.

Response: We decline commenters' suggestions to modify the timing of applicability for this policy and the other changes to the financial benchmarking methodology discussed in sections III.G.4.c–e of this final rule. The revisions we are making in this final rule to the benchmarking methodology, including the cap on regional service area risk score growth, will apply to all ACOs entering a new agreement period beginning on or after January 1, 2024. In section III.G.4.e of this final rule, we explain our concerns with applying benchmarking changes to ACOs within an agreement period in responding to similar suggestions in connection with the proposed revisions to the risk adjustment methodology.

Comment: Multiple supportive commenters urged CMS to adopt a higher cap for an *ACO's* risk score growth. Several commenters urged CMS to increase the current aggregate demographics plus 3 percent cap on ACO risk score growth between BY3 and the performance year to 5 percent and to apply a symmetrical cap on decreases in risk scores. These commenters stated that ''the current methodology of normalizing risk adjustment in a region can penalize ACOs that have been coding accurately and that maintain the same level of risk over their agreement period.'' Another commenter requested that CMS increase the ''regional cap'' to 5 percent and cap negative risk score growth at 5 percent, saying that the ''current practice of normalizing regional risk adjustment penalizes ACOs that code accurately and maintain the same level of risk.''

One commenter expressed support for the proposal to cap regional risk score growth but also urged CMS to ''remove'' the cap on ACO risk score growth, but their comment also included a request that the cap be increased to 5 percent after accounting for demographics.

One commenter requested that CMS review whether the ''3 percent cap in risk score growth'' is a fair policy throughout a 5-year agreement period. The commenter reasoned that HCC scores are based on a previous year's data and ''may not reflect active changes in acuity among the population.'' The commenter stated their belief that this disadvantages ACOs that treat the most serious or complex Medicare beneficiaries and recommended that CMS consider additional guardrails for years of high volatility—as seen post COVID–19—to protect ACOs that experience growth in the risk of the population they serve. The commenter also suggested CMS adjust prior year financial settlements, particularly PY 2021 and PY 2022, for ACOs that experienced high risk score growth.

Response: In some cases, it was not clear if the commenters were referring to the cap on an ACO's own risk score growth or the proposed cap on an ACO's regional service area risk score growth. However, because a higher cap on increases in risk scores in an ACO's regional service area would not provide the same level of protection to ACOs against risk score increases in their regional service area, we interpret these comments to be requesting a higher cap on HCC risk score increases and a cap on prospective HCC risk score decreases within an ACO's own assigned beneficiary population. We appreciate these commenters' suggestions but note that their suggestions go beyond the scope of the proposed modifications to the Shared Savings Program's benchmarking methodology. The policy of capping risk score growth for an ACO's assigned beneficiaries during an agreement period using the demographics plus 3 percent cap was finalized in the CY 2023 PFS final rule (87 FR 69932 through 69946). We refer these commenters to the discussion in the CY 2023 PFS final rule (87 FR 69942) for an explanation of why we have concluded that it would be inappropriate to increase the demographics plus 3 percent cap or to limit the impact of prospective HCC risk score decreases.

Comment: One commenter expressed concern over CMS's existing and proposed risk adjustment policies, stating that the policies are founded on a perspective that ACO participants are routinely and consistently over coding. The commenter suggested that there are ACOs that serve populations whose health risks do increase substantially over time or whose historical health risks were not fully documented by reported diagnoses, and that they note no evidence to indicate that most physicians in the Shared Savings Program are deliberately manufacturing codes to improve reimbursement.

Response: As we described in section III.G.4.b.(1) of this final rule, it is important to consider the incentives a risk adjustment methodology may introduce for coding intensity. In the CY 2023 PFS final rule (87 FR 69932 through 69946), we highlighted recent research that provided evidence that a majority of CMS–HCC risk score growth for beneficiaries assigned to ACOs may come from coding initiatives and not from changes in beneficiary demographics or deteriorating health status. As a result, we acknowledge the need to limit the upward growth in prospective HCC risk scores in the ACO's regional service area between the benchmark period and the performance year, given that those risk scores are also susceptible to coding initiatives. The proposed policy for capping risk score growth in an ACO's regional service area would limit potential harm to ACOs in regions with high risk score growth when such growth is not due to the ACO's own coding activities while also protecting the Trust Funds by ensuring that benchmarks do not become overly inflated such that an

ACO would have to do very little to continue to earn a shared savings payment.

Comment: One commenter requested that CMS exclude beneficiaries that are aligned to ACO REACH ACOs from the regional risk score calculation. The commenter stated their belief that the ACO REACH model's concurrent risk scoring methodology incentivizes ACOs participating in that model to do more coding, driving up risk scores in the region and thus negatively effecting Shared Savings Program ACOs operating in the same region.

Response: We decline to consider an approach that would exclude certain assignable beneficiaries from the calculation of regional risk score growth. We have concerns that removing certain FFS beneficiaries, such as beneficiaries assigned to Medicare Shared Savings Program ACOs or aligned to ACOs participating in the ACO REACH Model, from the population of assignable beneficiaries included in an ACO's regional service area could lead regional growth rates for areas with high ACO penetration to be based on very small sample sizes such that the resulting regional update factor determined for these ACOs could lack validity. We also have concerns that removing certain FFS beneficiaries from an ACO's regional service area could incentivize ACOs—including Shared Savings Program ACOs and ACOs in the ACO REACH Model—to work in combination to favorably influence their regional spending. We noted similar concerns in the CY 2023 PFS final rule (87 FR 69926 and 69927) when discussing an alternative benchmarking policy that would remove an ACO's own assigned beneficiaries, or all Shared Savings Program assigned beneficiaries, from financial calculations based on the ACO's regional service area. However, in the CY 2023 PFS final rule (87 FR 69899) we finalized a three-way blended update factor that incorporates the Accountable Care Prospective Trend (ACPT). The ACPT is a prospectively projected administrative growth factor that is not influenced by actual performance by a single ACO, multiple ACOs in a region, or all ACOs nationally, and therefore, will help address the wider issue of multiple neighboring ACOs influencing the regional trend.

Comment: One commenter recommended that CMS control for the new prospective HCC risk score model phase-in, if finalized, in determining the regional risk score growth cap.

Response: We believe this comment could be interpreted in multiple ways and would require additional clarity before we could further consider the commenter's suggestion. However, we note that for agreement periods beginning January 1, 2024, and in subsequent years, the proposed policy to cap regional risk score growth would provide symmetry with how we will cap ACO risk score growth and is expected to improve the accuracy of the regional update factor for ACOs operating in regional service areas with greater risk score growth. In addition, the use of a consistent risk score model for the performance year and all benchmark years, as described in section III.G.4.e of this final rule, is intended to more accurately assess changes in the level of risk for an ACO's assigned beneficiary population over time.

After consideration of the public comments, we are finalizing our proposal to cap regional service area risk score growth for symmetry with the ACO risk score growth cap and to adjust the cap on regional risk score growth to reflect the ACO's aggregate market share without modification. This change will apply to agreement periods beginning January 1, 2024, and subsequent years. We are revising the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between BY3 and the performance year at § 425.652(b)(2)(ii)(C) to incorporate a regional risk score growth cap adjustment factor. We are also finalizing our proposal to add a new section to the regulations at § 425.655 to describe the calculation of this adjustment factor. We have made one minor editorial change to the text of § 425.655(f)(2)(i) as it appeared in the proposed rule to remove a misplaced word.

c. Mitigating the Impact of the Negative Regional Adjustment on the Benchmark To Encourage Participation by ACOs Caring for Medically Complex, High-Cost Beneficiaries

(1) Background

In earlier rulemaking we have discussed our use of the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area (81 FR 37962). We initially established a regional adjustment in a benchmark rebasing methodology that applied to ACOs entering a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019 (§ 425.603(c) through (g)), before modifying our policy to apply this adjustment program wide beginning with agreement periods starting on July 1, 2019, and in subsequent years (§ 425.601(a)(8)). In the CY 2023 PFS final rule (87 FR 69915 through 69923) we modified the way we would calculate the regional adjustment for ACOs in agreement periods starting on January 1, 2024, and in subsequent years (§ 425.656). We also finalized a policy that would modify the way we would apply the regional adjustment to the benchmark that would also take into account a new adjustment for prior savings that would be available to eligible ACOs (§ 425.652(a)(8)).

In accordance with § 425.601(a)(8), for ACOs in agreement periods beginning on or after July 1, 2019 and before January 1, 2024, we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark (referred to herein as the ''regional adjustment''). The percentage applied in calculating the regional adjustment depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of applicable weights. We cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (referred to herein as positive or negative 5 percent of national per capita FFS expenditures for assignable beneficiaries, and as the ''symmetrical cap,'' terms which we consider to be synonymous). We then apply the capped regional adjustment for each Medicare enrollment type by adding it to the historical benchmark expenditure for that enrollment type. A positive regional adjustment for a given Medicare enrollment type increases the benchmark for that enrollment type, whereas a negative regional adjustment

decreases the benchmark for that enrollment type.

With the policies finalized in the CY 2023 PFS final rule (87 FR 69915 through 69923), we sought to reduce the impact of negative regional adjustments in several ways for agreement periods beginning on January 1, 2024, and subsequent years. First, we finalized a policy that replaced the negative 5 percent cap on the negative regional adjustment with a negative 1.5 percent cap. Under this policy, we would continue to cap positive adjustments for each Medicare enrollment type at a dollar amount equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type but would cap negative adjustments for each enrollment type at a dollar amount equal to negative 1.5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type. Additionally, after applying the negative 1.5 percent cap, we would apply an offset factor that would gradually decrease the negative regional adjustment amount for a given Medicare enrollment type as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases. Finally, for an ACO eligible for the prior savings adjustment for which the regional adjustment expressed as a single value (based on taking a person year weighted average across the four Medicare enrollment types) is negative, we would further offset the regional adjustment by the prior savings adjustment. In the CY 2023 PFS final rule (87 FR 69919) we expressed our belief that by reducing the impact of negative regional adjustments, these policies would incentivize ACOs that serve high-cost beneficiaries to join or continue to participate in the Shared Savings Program.

These policies to reduce the impact of negative regional adjustments are reflected in several new sections of the regulations. Section 425.652 is the main provision that describes the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, including the interaction of the regional adjustment and the prior savings adjustment. Sections 425.656 and 425.658 provide additional detail on the calculations of the regional adjustment and the prior savings adjustment, respectively.

Table 40 illustrates how the caps on the regional adjustment would be calculated and applied to positive and negative regional adjustments at the Medicare enrollment type level under the policy finalized in the CY 2023 PFS final rule. Note that the uncapped regional adjustment values would be calculated using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending as compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d). For example, if an ACO is considered to have lower spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 35 percent when applying the regional adjustment. If an ACO is considered to have higher spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 15 percent when applying the regional adjustment.

TABLE 40: Hypothetical Example of Cap on Regional Adjustment

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Uncapped Regional Adjustment ($)	Positive Regional Adjustment Cap: - 5% of National Assignable Per Capita Expenditures ($)	Negative Regional Adjustment Cap: -1.5% of National Assignable Per Capita Expenditures ($)	Capped Regional Adjustment ($)
ESRD	0.015	932	4,437	-1,331	932
Disabled	0.190	-185	639	-192	-185
Aged/dual	0.100	258	974	-292	258
Aged/non-dual	0.695	-307	553	-166	-166
Weighted Average		-209			-111

The hypothetical ACO in this example has a mix of positive and negative regional adjustments across the four enrollment types. The ACO's uncapped aged/non-dual eligible adjustment is outside the negative 1.5 percent cap and thus changes from −$307 to −$166 when the cap is applied. The ACO's adjustments for the other three enrollment types are all within the applicable positive or negative caps, and thus, are unaffected. The ACO's overall weighted average regional adjustment (calculated by multiplying the adjustment for each enrollment type by the corresponding enrollment type proportion and then summing across the four enrollment types) changes from −$209 to −$111 when the negative regional adjustment cap is applied, reducing the per capita impact of the negative regional adjustment by $98.

Under the methodology adopted in the CY 2023 PFS final rule (87 FR 69917 and 69920), after we apply the caps, we next apply an offset factor to any negative regional adjustments at the enrollment type level. The offset factor is based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) [268] and [B] the ACO's

[268] In computing this proportion, we use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types.[269] Before taking this weighted average, the risk score for each enrollment type is first renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Specifically, the offset factor is calculated as:

Offset factor = [A] + ([B] − 1)

We apply the offset factor, which is subject to a minimum of zero and a maximum of one, by subtracting its value from 1 and multiplying this difference by the negative regional adjustment for each Medicare enrollment type, calculated as:

Final regional adjustment = Negative regional adjustment × (1 − Offset factor)

The higher an ACO's proportion of dually eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment for any enrollment type, because each negative adjustment would be multiplied by a value of 1 minus the offset factor, or 0. For these ACOs, the overall weighted average regional adjustment would either be 0 (if the ACO had negative adjustments for all four enrollment types prior to the application of the offset factor) or positive (if the ACO had a mix of positive and negative adjustments at the enrollment type level prior to the application of the offset factor). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

To illustrate how the offset factor would be calculated and applied, assume that the hypothetical ACO from Table 40 had a proportion of dually eligible beneficiaries of 0.130 and a weighted average prospective HCC risk score for BY3 of 1.240. The offset factor for this ACO would be calculated as:

Offset factor = 0.130 + (1.240 − 1) = 0.370

This factor would be applied as illustrated in Table 41 by multiplying the negative regional adjustment for each applicable Medicare enrollment type by 1 minus the offset factor or 0.630.

TABLE 41: Hypothetical Example of Offset Factor Applied to Negative Regional Adjustments

Medicare Enrollment Type	Enrollment Proportion	Capped Regional Adjustment (Before Offset) ($)	Offset Factor	1 – Offset Factor	Final Regional Adjustment ($)
ESRD	0.015	932	N/A	N/A	932
Disabled	0.190	-185	0.370	0.630	-117
Aged/dual	0.100	258	N/A	N/A	258
Aged/non-dual	0.695	-166	0.370	0.630	-105
Weighted Average		-111			-55

Here, the offset factor is applied to the regional adjustments for the disabled and aged/non-dual eligible populations, as both are negative, but not to the regional adjustments for the ESRD and aged/dual eligible populations, which are both positive. Taking the weighted average across the enrollment types following application of the offset factor shows that the ACO's overall weighted regional adjustment changes from −$111 before the offset to −$55 after the offset, further reducing the per capita impact of the negative regional adjustment by $56. The overall per capita impact of both the cap and offset factor for this ACO would be $154.

In the CY 2023 PFS final rule (87 FR 69918 and 69921), we presented simulations of the combined impact of the cap and offset factor relative to the symmetrical positive and negative 5 percent cap then in place for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. The results of these simulations, which used data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019, and from PY 2022 historical benchmarks for ACOs starting an agreement period on January 1, 2022, found the negative regional adjustment for almost every ACO that had an overall negative regional adjustment in the PY 2020 and PY 2022 data under the symmetrical cap would have been reduced (or eliminated), with an average per capita impact of approximately $114 for PY 2020 and $48 for PY 2022. ACOs with higher weighted average BY3 prospective HCC risk scores and higher proportions of dually eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. Four ACOs in the PY 2020 simulation and one in the PY 2022 simulation had an offset factor of 1, meaning they would have received a full offset to their negative regional adjustments.

Under a separate policy also finalized in the CY 2023 PFS final rule, an ACO beginning an agreement period on January 1, 2024, and in subsequent years that is a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period. A full discussion of this policy can be found in that earlier rulemaking (87 FR 69899 through 69915). The policy was designed such that an eligible ACO would receive the higher of its overall positive regional adjustment or its prior savings adjustment, or a combination of the two if its overall regional adjustment is negative and it had prior savings. ACOs ineligible for the prior savings adjustment would receive the regional adjustment (computed as described earlier in this section applying a 5 percent cap on positive regional adjustments and a −1.5 percent cap and offset factor on negative regional adjustments). Specifically, if the regional adjustment, expressed as a single value, is positive, the ACO would receive a final adjustment equal to the

[269] In computing this weighted average, we apply a weight to the risk score for BY3 for an enrollment type that is equal to the product of the ACO's BY3 per capita expenditures for that enrollment type and the ACO's BY3 person years for that enrollment type.

higher of the regional adjustment or an adjustment based on the ACO's prior savings (see § 425.652(a)(8)(iii)(B)). If the regional adjustment, expressed as a single value, is negative, we would calculate the final adjustment as described in § 425.652(a)(8)(iii)(A), with the ACO receiving either a smaller negative regional adjustment or a positive adjustment for prior savings depending on the relative size of the negative regional adjustment and the ACO's pro-rated prior savings.

Based on further consideration, in the CY 2024 PFS proposed rule (88 FR 52467) we expressed our belief that it was important and timely to revisit the policy that allows for negative adjustments to be applied in establishing the benchmark for ACOs. While we did not consider eliminating negative regional adjustments program-wide in CY 2023 PFS rulemaking, one commenter noted that there is an argument for doing so. We explained our belief that further mitigating the impact of the negative regional adjustment for ACOs with high-cost populations, thereby resulting in higher benchmarks for ACOs compared to the recently finalized methodology, could further bolster the business case for Shared Savings Program participation by such ACOs.

As we discussed in the CY 2023 PFS proposed rule (87 FR 46161), there is evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may deter participation among ACOs with spending above their regional service area including those serving medically complex, high-cost populations. High-cost ACOs are underrepresented in the Shared Savings Program, with around 86 percent of all participating ACOs receiving an overall positive regional adjustment in PY 2022 indicating that a majority of ACOs are lower spending than their regional service area. We also observed that ACOs that received an overall negative regional adjustment for PY 2022 were less likely to continue participation in the program in PY 2023 than were ACOs that received an overall positive regional adjustment, with 22 percent of ACOs with a negative overall adjustment leaving the program compared to 12 percent of ACOs with a positive overall adjustment. Since PY 2017 the overall annual average share of ACOs that leave the program has been 12 percent. A recent academic study also found evidence suggesting selective participation among ACOs in response to the original adoption of a regional adjustment in 2017, with the composition of ACOs between 2017 to 2019 increasingly shifting to providers with lower preexisting levels of spending.[270] The authors attributed these changes to a combination of the entry of new ACOs with lower baseline spending, the exit of higher-spending ACOs, and the reconfiguration of ACO participant lists to favor lower-spending practices among ACOs continuing participation in the program.

Relatedly, we have observed that negative regional adjustments may make it more difficult for ACOs to succeed in the program financially. Between PY 2017, when regional adjustments were first introduced in the Shared Savings Program, and PY 2021, ACOs that received negative regional adjustments have been consistently less likely to share in savings than ACOs that received positive regional adjustments. For example, in PY 2021 we observed that 37 percent of ACOs that received a negative regional adjustment shared in savings compared to 63 percent among those with a positive adjustment.

In the CY 2024 PFS proposed rule (88 FR 52468), we stated that eliminating the possibility that an ACO will receive an overall negative regional adjustment to its benchmark in combination with the other elements of the benchmarking methodology finalized in the CY 2023 PFS final rule, would work together to further our efforts to ensure sustainability of the benchmarking methodology. More specifically, we believed this policy change would further encourage continued participation among high-cost ACOs that serve medically complex beneficiaries by eliminating the potential of a lower benchmark due to an overall negative regional adjustment. It may also encourage ACOs serving such populations that may have otherwise been discouraged from participating in the Shared Savings Program by the idea of a lower benchmark to join. We noted that the implementation of this policy would allow ACOs to serve the most vulnerable populations while lessening the concern of how their patient population may affect their performance in the program. We also stated our belief that program participation by ACOs serving these populations has the potential, over time, to produce cost savings for the Medicare Trust Funds by improving care coordination and quality of care for such beneficiaries.

[270] Lyu P, Chernew M, McWilliams J. Benchmarking Changes And Selective Participation In The Medicare Shared Savings Program. *Health Affairs.* May 1, 2023. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01061.*

Additionally, we stated that eliminating overall negative regional adjustments could further incentivize greater participation among ACOs whose ACO participants have historically been less efficient than other providers and suppliers in their regions. Such ACOs may have the greatest potential to generate cost savings for the Medicare Trust Funds by adopting more efficient practices, and therefore, their participation in the program should not be discouraged.

(2) Revisions

In light of these considerations, in the CY 2024 PFS proposed rule (88 FR 52468 through 52472) we proposed to modify the policies we adopted in the CY 2023 PFS final rule so as to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. Specifically, we proposed the following approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, and in subsequent years:

- We would continue to calculate the original uncapped regional adjustment by Medicare enrollment type using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d).
- We would continue to apply the 5 percent cap on positive regional adjustments and the −1.5 percent cap and offset factor on negative regional adjustments at the enrollment type level, as finalized in the CY 2023 PFS final rule and described in § 425.656(c). For the performance year beginning on January 1, 2025, and subsequent performance years, the national assignable FFS population used to calculate the caps would reflect the revised definition of assignable beneficiary that incorporates the expanded window for assignment. (See section III.G.3.a of this final rule for a description of the proposed revisions to the definition of assignable beneficiary.)
- After applying the cap and offset factor (if applicable), we would express the regional adjustment as a single per capita value by calculating a person year weighted average of the Medicare enrollment type-specific regional adjustment values.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is positive, the ACO would

receive a regional adjustment, according to the approach we finalized in the CY 2023 PFS final rule. That is, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the ACO is also eligible for a prior savings adjustment, the ACO would receive the higher of the two adjustments. If the regional adjustment amount (expressed as a single per capita value) is higher, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the prior savings adjustment is higher, we would apply the adjustment in the manner finalized in the CY 2023 PFS final rule as a flat dollar amount applied separately to the historical benchmark expenditures for each Medicare enrollment type.

- If the ACO's regional adjustment amount (expressed as a single per capita value) is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type. If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment, without any offsetting reduction for the negative regional adjustment.

Under the proposed approach, ACOs that would face a negative overall adjustment to their benchmark based on the methodology adopted in the CY 2023 PFS final rule would benefit, as they would now receive no downward adjustment. Additionally, ACOs that have a negative regional adjustment amount (expressed as a single value) and are eligible for a prior savings adjustment under the policy adopted in the CY 2023 PFS final rule (§ 425.658) would also be expected to benefit from the proposed policy. Specifically, these ACOs could receive a larger positive adjustment to their benchmark or a positive adjustment instead of a negative adjustment, as we would no longer offset the prior savings amount by the negative regional adjustment amount when determining the final adjustment that would apply to the ACO's benchmark as described in the current regulations in § 425.652(a)(8)(iii)(A).[271] In the proposed rule, we stated our belief that by increasing the potential benefit of the prior savings adjustment in this manner, our proposed policy would be responsive to the comments discussed in the CY 2023 PFS final rule recommending that CMS make the prior savings adjustment more favorable, particularly for ACOs serving high-risk populations (see 87 FR 69910 through 69914).

Importantly, no ACO would be made worse off under the proposed policy. ACOs that have an overall positive regional adjustment amount would continue to receive the same adjustment to their benchmark as they would under the methodology finalized in the CY 2023 PFS final rule calculated and applied as described in the current regulations at §§ 425.656 and 425.652(a)(8), respectively. For these ACOs, the regional adjustment would continue to reflect the percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d) and we would continue to allow negative adjustments to be applied at the enrollment type level for those ACOs that receive a positive overall regional adjustment. We explained our belief that this would be appropriate because these ACOs would continue to receive a positive overall adjustment to their benchmark and thus should already have greater incentive to join or continue participation in the program than ACOs that might otherwise face an adjustment that reduces their benchmark.

Tables 41 and 42 present hypothetical examples to demonstrate how we would determine the final adjustment to an ACO's benchmark under the proposed policy. Both tables include two hypothetical ACOs. The first ACO, ACO A, is the same hypothetical ACO as illustrated in Tables 39 and 40 within this section and has an overall negative regional adjustment. The second ACO, ACO B, has an overall positive regional adjustment. Table 42 assumes that both ACOs are ineligible for a prior savings adjustment, whereas Table 43 shows how the calculation would change if both ACOs were eligible for such an adjustment.

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[271] For examples of the calculation of the final adjustment when an ACO is eligible for a prior savings adjustment and the overall regional adjustment is negative under the policy adopted in the CY 2023 PFS final rule, please refer to Tables 65 and 66 of the CY 2023 PFS final rule (87 FR 69904 and 69905). In Table 65 the hypothetical ACO receives a positive final adjustment and in Table 66 a negative final adjustment.

TABLE 42: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Not Eligible for a Prior Savings Adjustment

Calculation Step	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment proportion [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) ($) [D] = Sum of [B] x [C]	-55	150
Final adjustment ($) [E]= N/A if [D] is negative, otherwise [D]	N/A	150
Historical benchmark expenditures by enrollment type, after adjustment ($) [F] = [A] if [E] is N/A, otherwise [A] + [C]		
ESRD	90,000	99,669
Disabled	16,000	12,158
Aged/dual	18,000	18,790
Aged/non-dual	10,000	9,179

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In Table 42, because ACO A had an overall negative regional adjustment and was not eligible for a prior savings adjustment, the ACO ultimately receives no adjustment, upward or downward, to its benchmark. For ACO B, whose overall regional adjustment is positive, the final adjustment is the regional adjustment, which is applied by adding the regional adjustment specific to each enrollment type (reflecting the percentage weight determined for the ACO and after the application of the cap and offset factor, if applicable) to the ACO's pre-adjustment historical benchmark expenditures for that enrollment type.

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TABLE 43: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Eligible for a Prior Savings Adjustment

	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment type proportions [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) [D] = Sum of [B] x [C]	-55	150
Prior savings adjustment* ($) [E]	58	239
Final adjustment ($) [F]= [E] if [D] is negative, otherwise higher of [D] or [E]	58	239
Historical benchmark expenditures by enrollment type, after adjustment [G] = [A] + [C] if [E] = [D], otherwise [A] + [E] for each enrollment type		
ESRD	90,058	101,239
Disabled	16,058	12,239
Aged/dual	18,058	19,239
Aged/non-dual	10,058	9,239

*As provided in the proposed new provision at § 425.658(c)(1) of the regulations, the prior savings adjustment would be calculated as the lesser of 50 percent of the pro-rated positive average per capita savings amount, calculated as described in § 425.658(b)(3)(ii), and a cap equal to 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values.

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In Table 43, both ACO A and ACO B are eligible for a prior savings adjustment. Because ACO A has a negative overall regional adjustment, its final adjustment is automatically set equal to the prior savings adjustment of $58. The adjustment is applied as a flat dollar amount by adding the $58 to the ACO's historical benchmark expenditures (row [A]) for each enrollment type. For ACO B, by contrast, the final adjustment is determined by comparing the regional adjustment amount (expressed as a single value) to the prior savings adjustment amount and using the higher of the two. In this case the ACO would receive a final adjustment equal to the prior savings adjustment of $239. Like with ACO A, this would be applied to the ACO's historical benchmark expenditures for each enrollment type as a flat dollar amount.

In revisiting simulations done with the PY 2020 data described earlier in this section, there were 36 ACOs (of the 43 ACOs with a negative regional adjustment under the policy with the symmetrical cap) simulated to have a negative overall regional adjustment after the application of the cap and offset factor. Among these, 31 would not have been eligible for a prior savings adjustment and would have had this negative regional adjustment applied to their benchmark under the policy adopted in the CY 2023 PFS final rule. Under the new proposed policy, these ACOs would receive no adjustment to their benchmark. The average per capita benefit of eliminating the downward adjustment would be $30.

The remaining five ACOs would have been eligible for the prior savings adjustment. These ACOs would have received a positive final adjustment to their benchmark under the methodology adopted in the CY 2023 PFS final rule but would receive a larger positive adjustment under the new proposed policy, with an average per capita increase of $26. This is because we would no longer be offsetting the prior savings amount by the negative regional adjustment as part of determining the final adjustment to the ACO's benchmark as would happen under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.652(a)(8)(iii)(A).

In the PY 2022 simulation described earlier in this section, there were 26 ACOs (of the 27 ACOs with a negative regional adjustment under the policy

with the symmetrical cap) that would have had a negative regional adjustment, expressed as a single per capita value, after the application of the policy adopted in the CY 2023 PFS final rule. Among these, 14 ACOs would not have been eligible for a prior savings adjustment and would have their full negative regional adjustment eliminated under the new proposed policy, with an average impact of $66. The remaining 12 ACOs that would have been eligible for a prior savings adjustment would see a larger positive adjustment under the proposed policy, with an average increase of $14.

In the CY 2024 PFS proposed rule (88 FR 52472), we explained our belief that the proposed changes to the calculation and application of the regional adjustment, including its interaction with the prior savings adjustment, would strengthen incentives for participation among ACOs that may otherwise be subject to a downward adjustment to their benchmark due to the negative regional adjustment. We noted that the proposed policy, if finalized, would not adversely impact any ACO's benchmark relative to the policy that was finalized in CY 2023 PFS final rule, all else being equal, but would tend to increase benchmarks for ACOs that have historically had higher spending than their regional service area. Based on our simulations using data from PY 2020 and PY 2022, the estimated average increase to the overall benchmark would be between 0.2 and 0.4 percent but could be larger in future years when more ACOs would be subject to higher phase-in weights for calculating the negative regional adjustment that would apply (alone or in combination with the prior savings adjustment) under the policy adopted in the CY 2023 PFS final rule. We also noted that ACOs that would benefit from the proposed policy are likely to include those that serve high-cost, medically complex patients or those whose ACO participants have historically been less efficient than their regional counterparts but may have the potential to generate the greatest savings to Medicare through their participation in the Shared Savings Program.

We proposed to implement the changes described in this section through revisions to §§ 425.652, 425.656, and 425.658. Specifically, within § 425.652, which is the section that sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we proposed revisions to § 425.652(a)(8). As revised, this provision would describe how we would determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. This provision would also establish that if an ACO is not eligible to receive a prior savings adjustment and has a regional adjustment, expressed as a single value that is negative or zero, the ACO will not receive an adjustment to its benchmark.

We proposed to revise § 425.656 (which describes the calculation of the regional adjustment) and § 425.658 (which describes the calculation of the prior savings adjustment) to include certain elements of each calculation that were previously described in § 425.652(a)(8). Specifically, we proposed to revise § 425.656 to redesignate paragraphs (d) and (e) as paragraphs (e) and (f) (respectively) and to specify in a new paragraph (d) that we would express the regional adjustment as a single value, and use this value in determining whether a regional adjustment or a prior savings adjustment would be applied to the ACO's benchmark in accordance with § 425.652(a)(8) (as revised under the proposed rule). We also proposed modifications to update certain cross-references within § 425.656 for accuracy and consistency with the proposed revisions to the section.

We proposed to revise § 425.658 to redesignate paragraph (c) as paragraph (d). We proposed to add a new paragraph (c) under § 425.658 specifying that we would calculate the per capita savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values. We proposed to revise newly redesignated paragraph (d) of § 425.658 to specify CMS would compare the per capita prior savings adjustment with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that would be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

Additionally, we proposed to make the following conforming changes:

- In § 425.600(f)(4)(ii), we proposed to remove the reference ''425.656(d)'' and add in its place the reference ''425.656(e)''.
- In § 425.611(c)(2)(iii), we proposed to remove the reference ''§ 425.652(a)(8)(iv)'' and add in its place the reference ''§ 425.658(c)(1)(ii)''.
- In § 425.652(a)(9)(v), we proposed to remove the wording that references CMS redetermining the adjustment to the benchmark based on ''a combination of'' the redetermined regional adjustment and the prior savings adjustment.
- In § 425.658(b)(3)(i), which specifies that the ACO is not eligible to receive an adjustment for prior savings if the average per capita amount computed in § 425.658(b)(2) is less than or equal to zero, we proposed to remove the sentence: ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.''

We solicited comments on these proposed changes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to further mitigate the impact of negative regional adjustment to the benchmark. A number of these commenters suggested that the policy would increase program participation among ACOs with higher costs than their region by removing disincentives or barriers to entry, and would encourage more ACOs to care for underserved, medically complex and high-cost patients. Another commenter suggested that eliminating the regional adjustment, along with the proposed cap on HCC risk score growth in an ACO's regional service area, would ensure that physicians in certain geographies are not disincentivized from participating.

MedPAC indicated that they concurred with the proposal to remove negative regional adjustments, though they expressed more general concerns about the regional adjustment overall, as discussed later in this section. In explaining their support for the policy, they noted their agreement with CMS that better incentives are needed to induce participation among health care providers serving beneficiaries with relatively higher spending. Another commenter stated their belief that the policy presented a near term solution for addressing selective participation by encouraging high cost ACOs to participate and, by doing so, would enable larger aggregate savings for Medicare.

Several commenters opined on the types of ACOs that would likely benefit from the proposed policy, if finalized. Among those mentioned were ACOs caring for medically complex, high cost,

or high-risk patients, ACOs serving high proportions of dually eligible patients, and ACOs with rural ACO participants. Some of these commenters indicated the policy, together with the other benchmarking proposals, would ''level the playing field'' for health care providers serving at-risk populations.

Other commenters noted that under the proposal, ACOs eligible for a prior savings adjustment would not have those savings offset by a negative regional adjustment, with one commenter explaining that this would make the prior savings adjustment more favorable, particularly for ACOs serving high-risk populations and a few commenters citing the favorable impact on the prior savings adjustment as the reason for their support of the proposal.

Expressing tentative support for this and the other proposed benchmarking policies, one commenter recommended that CMS move to finalize these proposals but warned that none had yet been tested via real world application. Another commenter suggested that the proposed modifications to the negative regional adjustment, similar to the proposal to cap regional risk score growth, would improve coding accuracy, although they did not explain why they held this belief.

Response: We agree with commenters that the proposed approach to further reducing the impact of the negative regional adjustment will facilitate participation of ACOs in the Shared Savings Program, particularly ACOs with spending above spending in their regional service area and those serving medically complex, high-cost populations, which are the beneficiaries that can benefit the greatest from better care coordination offered by ACOs. We expect this policy will help to promote agency goals of promoting health equity and having 100 percent of people with Original Medicare in an accountable care relationship by 2030, while also benefitting the Trust Funds by encouraging participation from ACOs serving populations and beneficiaries with highest potential for reducing spending and improving quality and patient experience through better care coordination.

Comment: Many commenters supported the proposal and requested that the policy be made effective for all ACOs, not just ACOs in agreement periods starting on or after January 1, 2024. A few commenters recommended that ACOs in existing agreement periods should be given the option of whether to receive the new policy. Some commenters described limiting the policy to ACOs entering new agreement periods as ''unfair.'' One commenter argued that the proposed methodology to further mitigate the impact of negative regional adjustments would be beneficial for new ACOs serving high cost, high-risk populations, but would not provide any new protection for existing ACOs in the midst of current agreement periods or for renewing ACOs that already expected a full offset of the negative regional adjustment per the policy finalized in the CY 2023 PFS final rule. A few commenters noted that because the CY 2024 PFS proposed rule was issued after the application deadline for agreement periods starting on January 1, 2024, ACOs in the middle of a current agreement period missed the opportunity to submit applications for early renewal that would allow them to take advantage of this and other proposed changes to the program's benchmarking policies in PY 2024, if finalized.

A few other commenters opined that requiring ACOs to go through the early renewal process to benefit from the policy was burdensome for ACOs. One commenter noted that the early renewal process also created burden for CMS and additionally suggested that it could risk disruption to the program and lead to large swings in cohort sizes. Several commenters indicated that failure to apply the policy to all ACOs in the program would penalize current ACOs serving costlier patients, work against the program's health equity goals, or add unnecessary confusion and complexity. A few commenters cited the benefits of applying the policy to all ACOs, with one commenter noting that this would promote consistency across the program and avoid disparate impacts across ACOs and another suggesting this would encourage ACO growth and recognize challenges current ACOs are facing.

Response: We decline commenters' suggestions to modify the timing of applicability for this policy and the other changes to the financial benchmarking methodology policies discussed in sections III.G.4.b-e of this final rule. The revisions we are making in this final rule to the benchmarking methodology, including the changes to mitigate the impact of the negative regional adjustment, will apply to ACOs entering a new agreement period beginning on or after January 1, 2024. In section III.G.4.e of this final rule, we explain our concerns with applying benchmarking changes to ACOs within an agreement period in responding to similar suggestions in connection with the proposed revisions to the risk adjustment methodology.

Comment: Several commenters expressed concern that none of the benchmark proposals in the proposed rule, including the proposal to further mitigate the impact of negative regional adjustments, would solve the ratchet effect where ACOs' benchmarks will continue to be lower over time as they reduce spending in their populations and future benchmarks are rebased using lower historic spending. A few commenters cautioned that if the policy to further mitigate negative regional adjustments is successful in bringing more inefficient ACOs into the program, this could increase the rate at which a given region becomes more efficient. They claimed that this, in turn, could exacerbate the ratchet effect for ACOs that are already efficient and now would be competing against a region getting more efficient at a faster pace. One such commenter strongly recommended that the policy to eliminate the negative regional adjustments be coupled with changes to address benchmark ratcheting that they claim occurs for regionally efficient ACOs at rebasing, particularly as ACOs enter later agreement periods. Another commenter encouraged CMS to monitor for possible unintended consequences of any of the proposed benchmarking policies if finalized in this final rule, including any disproportionate impacts on certain types of ACOs or patient populations, and to be receptive to feedback from industry partners and to look for additional ways to continuously improve benchmarking and risk adjustment methodologies. In particular, these commenters urged CMS to look for ways to address the ratcheting effect and to retain high performing ACOs in the program.

One commenter stated that they do not believe that the additional modifications to the benchmarking methodology proposed in the CY 2024 PFS proposed rule go far enough to protect existing ACOs serving high cost, underserved populations, like themselves, from experiencing dramatic ratchets to their benchmarks upon their next agreement renewal. In light of this belief, the commenter offered multiple recommendations related to the prior savings adjustment and administratively set benchmarks, determinations of Qualifying Alternative Payment Model Participants (QPs), quality reporting and measures, risk adjustment, and beneficiary assignment (all summarized elsewhere in this final rule) that would allow their ACO to sustainably continue its participation in the program. Another commenter also urged CMS to develop a long-term vision for benchmarks that relies on an administrative benchmarking approach.

Response: Among the benchmarking policies finalized in the CY 2023 PFS final rule were two policies that were aimed at limiting the extent to which an ACO's own past success or the past success of other ACOs, at reducing expenditures would affect the ACO's benchmark in future agreement periods. First, the prior savings adjustment (see 87 FR 69898 through 69915) provides for a positive adjustment to be applied to the historical benchmark for ACOs that generated savings in the 3 years immediately preceding their current agreement period. This adjustment is directly connected to an ACO's own success at reducing expenditures, as ACOs achieving greater savings can potentially receive larger positive adjustments. We expect that eliminating the impact of negative regional adjustments on the prior savings adjustment, as proposed, will increase the effectiveness of the prior savings adjustment in addressing concerns about ratcheting. Second, the inclusion of a prospectively-determined component, the Accountable Care Prospective Trend (ACPT), in the factor used to update the benchmark to the performance year for agreement periods starting on or after January 1, 2024 (see 87 FR 69881 to 69898) will help to address the ratchet effect by insulating a portion of the update factor from the impact that ACO savings can have on retrospective national and regional spending trends. In May 2023, we published specifications detailing the methodology for computing the ACPT and explaining how it will be incorporated into the update factor.[272] We expect that the ACPT will help to address ratcheting concerns raised regarding the negative regional adjustment policy, that were interpreted to suggest if less efficient ACOs join the program and are successful in reducing expenditures for their assigned beneficiaries, regional trends facing already-efficient ACOs will be lower than they otherwise would.

As the prior savings adjustment and the three-way blended update factor that includes the ACPT apply only for agreement periods starting on or after January 1, 2024, we have not yet had a chance to gauge their success in meeting their intended aims in practice or to assess whether they have unintended consequences. We have continued to actively solicit feedback on what additional measures should be taken in the Shared Savings Program to further assuage concerns held by ACOs and other interested parties regarding the ratchet effect and the need for appropriate incentives to encourage ACOs to join the program and remain in the program over multiple agreement periods. For example, in the CY 2024 PFS proposed rule (see 88 FR 52494 through 52496), we sought comment on potential future modifications to both the prior savings adjustment and the benchmark update factor. As discussed in section III.G.8 of this final rule, we will take these suggestions and recommendations into consideration as we assess changes to propose in future notice and comment rulemaking.

Comment: One commenter requested that CMS make the data used to make the calculations of adjustments transparent to ACOs, which they believed would aid ACOs and their ACO participants in planning how to care for these patients. The same commenter also opined that ACOs should have a reliable way to appeal CMS's determination with enough time to have any appeals resolved prior to payment and participation in subsequent performance years but did not specify whether they were referring to determinations of shared savings payments or some other aspect of the payment methodology.

Response: ACOs receive historical benchmark reports which transparently detail the historical benchmark calculation, including the computation of positive and negative regional adjustments and, when it was applicable in the past, the prior savings adjustment. Modifications to the methodology for calculating the historical benchmark finalized in this rule will be reflected in such reports to provide additional transparency of benchmark calculations for ACOs beginning agreement periods on January 1, 2024, and in subsequent years. Additionally, we make various data available to ACOs to further promote transparency of our benchmarking calculations. For example, ACOs receive information on county of residence for all assigned beneficiaries in the Assignment List Report that is provided for each benchmark and performance year. ACOs can use this information in conjunction with public use files containing per capita expenditures and average risk scores for assignable beneficiaries (available on *data.cms.gov*) to estimate regional expenditures used in benchmark calculations.

The reconsideration review process for the Shared Savings Program is codified in 42 CFR part 425, subpart I of the program regulations. Consistent with section 1899(g) of the Act, § 425.802(a) states that an ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official. The initial determination or revised initial determination of the benchmark for an ACO in accordance with section 1899(d) of the Act is listed among the Shared Savings Program determinations that are prohibited from reconsideration, appeal, or other administrative or judicial review as specified in § 425.800. Additional information regarding the reconsideration review process is provided in the Medicare Shared Savings Program, Requesting Technical Assistance And Reconsideration Review Guidance (version #9, August 2022), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Reconsideration-Review-Process-Guidance.pdf*.

Comment: Several commenters, as part of their comments on our proposal to mitigate the impact of the negative regional adjustment, also recommended that CMS take additional action to support ACOs serving medically complex beneficiaries, including dual eligible beneficiaries or those in underserved areas, and to further strengthen incentives for high-cost providers and suppliers to participate in the Shared Savings Program. One commenter encouraged CMS to continue to update its benchmarking methodologies to account for unfair financial outcomes realized by ACOs treating medically complex patients, many of whom they noted, are dual-eligible, but did not offer specific suggestions for achieving this goal. Several other commenters offered suggestions that went beyond the scope of the proposed modifications, or beyond the scope of the program's benchmarking methodology, including the following:

- ''Lowering the cap'' based on the share of the ACO's population that is attributed through Step 2 assignment to support ACOs that include a significant portion of high needs beneficiaries or beneficiaries aligned through specialists, although it was unclear which cap the commenter was referencing in this suggestion.
- Supporting facilities serving medically complex beneficiaries such as by facilitating partnerships with community organizations.

[272] See Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor (version #1, May 2023), available at *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf*.

• Providing positive incentives to ACOs serving dually eligible and other medically complex beneficiaries.

• Incorporating a positive adjustment to the benchmark to accommodate increased spending that will occur when an ACO increases access to care for underserved areas.

Response: The commenters' suggestions go beyond the scope of the modifications proposed to mitigate impacts of the negative regional adjustment, including the proposed modifications of the interaction between the regional adjustment and the prior savings adjustment. However, we note that in the CY 2023 PFS final rule we finalized other changes to the program's financial methodologies (in addition to the modifications to the negative regional adjustment) that we expect will benefit ACOs serving complex or underserved beneficiaries. For example, we finalized changes to the risk adjustment methodology to better account for medically complex, high-cost beneficiaries (see 87 FR 69932 through 69946) and a new policy to provide increased opportunities for low revenue ACOs, which may include smaller rural ACOs, to share in savings (see 87 FR 69946 through 69952). We also note that in the CY 2024 PFS proposed rule we sought comment on how to promote collaboration between ACOs and community-based organizations and refer readers to section III.G.8. of this final rule where we summarize the feedback we received.

Comment: Several commenters called on CMS to consider providing support for ACOs receiving a positive regional adjustment that have already lowered costs in the communities they serve. Some suggested that the caps on the positive regional adjustment and the new prior savings adjustment effectively serve as a further cap on savings, which they believe should be addressed to ensure that successful ACOs remain in the Shared Savings Program. Another commenter recommended several modifications to positive regional adjustments, including applying a factor that would take into account the proportion of an ACO's assigned beneficiary population that is underserved, setting the cap on positive regional adjustments equal to 5 percent of BY3 risk-adjusted regional expenditures by Medicare enrollment type, and using a 50 percent weight to calculate positive regional adjustments starting with the first agreement period.

Response: We decline to make any modifications to the methodology for calculating positive regional adjustments, including the calculation of the cap on positive regional adjustments or the phase-in of weights used to calculate the adjustment, or to the calculation of the cap on the prior savings adjustment at this time. Such suggestions go beyond the scope of the proposed policy which was focused on encouraging participation by ACOs caring for medically complex, high-cost beneficiaries. Furthermore, the caps on positive regional adjustments and prior savings adjustments are an important mechanism to protect the Trust Funds by ensuring that benchmarks are not overly inflated such that an ACO would have to do very little to continue to earn a shared savings payment.

Comment: While supporting our specific proposal to mitigate the impact of negative regional adjustments, MedPAC, consistent with their comments on the CY 2023 PFS proposed rule (see 87 FR 69913), urged CMS to use the prior savings adjustment as a means to phase out the regional adjustment to the benchmark entirely. They suggested that the factor used in computing the prior savings adjustment (currently 50 percent) could be scaled up based on an ACO's regional efficiency. In addition to incorporating regional efficiency into the scaling factor used for the prior savings adjustment, MedPAC suggested that CMS could provide other incentives for current ACOs to remain in the program, such as scaling the shared savings rate based on efficiency and assuring protection from shared losses up to an amount equivalent to the current regional adjustment calculation.

Response: These comments go beyond the scope of policies proposed in the CY 2024 PFS proposed rule. However, we will take these suggestions for alternative approaches to incorporating regional efficiency into the program's financial methodology into consideration along with other feedback we have received in response to our comment solicitation (refer to section III.G.8 of this final rule) as we contemplate potential future changes to the program's financial methodology. Should we decide that additional modifications to the program's financial methodology are needed, we would propose such changes through future notice and comment rulemaking.

After consideration of the public comments, we are finalizing our proposal to further mitigate impacts of negative regional adjustments. We are also finalizing our proposed revisions to provisions of the Shared Savings Program regulations specifying the calculation of the regional adjustment (§ 425.656), the calculation of the prior savings adjustment (§ 425.658), and the interaction between these adjustments (§ 425.652(a)(8)), with minor non-substantive modifications to the provisions at § 425.652(a)(8)(ii), (iii), and (iv)(B), and § 425.658(c) introductory text, for improved clarity and to ensure consistency of terminology across provisions.

Specifically, we are revising § 425.652 to specify how we will determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. If the ACO is not eligible to receive a prior savings adjustment and the regional adjustment is positive, the ACO will receive an adjustment equal to the positive regional adjustment. If the ACO is eligible to receive a prior savings adjustment and the regional adjustment is positive, the ACO will receive an adjustment equal to the higher of the two adjustments. If the ACO is not eligible to receive a prior savings adjustment and the regional adjustment is zero or negative, the ACO will not receive an adjustment to its benchmark. If an ACO is eligible to receive a prior savings adjustment and the regional adjustment is zero or negative, the ACO will receive an adjustment equal to the prior savings adjustment.

We are revising § 425.656 to specify how we will express the regional adjustment as a single value and use this value in determining whether a regional adjustment or prior savings adjustment will be applied to the ACO's benchmark. We are revising § 425.658 to specify that we will calculate the per capita prior savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value. We are also finalizing as proposed the conforming revisions to provisions of subpart G, described in greater detail previously in this section of this final rule.

These changes will apply to agreement periods beginning on January 1, 2024, and in subsequent years.

d. Modifications to the Prior Savings Adjustment

(1) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B

services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by such other factors as the Secretary determines appropriate. Under this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for new and renewing ACOs. In the CY 2023 PFS final rule (87 FR 69899), we explained that reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance year's corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule (87 FR 69899), we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. Additionally, we believed it would be appropriate to use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. We noted that this would permit ACOs that are subject to a negative regional adjustment, but that have generated savings in prior years, to receive a relatively higher benchmark.

In the CY 2024 PFS proposed rule (88 FR 52473 and 52474), we explained that under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.658 of the regulations, the prior savings adjustment that will apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, would be calculated as follows: [273]

- *Step 1:* Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period. For each performance year we will determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS will apply the following requirements in determining the amount of per capita savings or losses for each performance year:

++ The per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

++ If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with Shared Savings Program requirements, the per capita savings for that year will be set to zero.

++ For a new ACO that is identified as a re-entering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO participants in the re-entering ACO were participating.

- *Step 2:* Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. We will use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

++ If the average per capita value is less than or equal to zero, the ACO will not be eligible for a prior savings adjustment. The ACO will receive the regional adjustment to its benchmark.

++ If the average per capita value is positive, the ACO will be eligible for a prior savings adjustment.

- *Step 3:* Apply a proration factor to the per capita savings calculated in Step 2 equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. If the ACO was not reconciled for one or more of the 3 years preceding the start of the ACO's current agreement period, the person years from that year (or years) will be excluded from the averages in the numerator and the denominator of this ratio. For a new ACO that is identified as a re-entering ACO, the person years of the ACO in which the majority of the ACO participants of the re-entering ACO were participating will be used in the numerator of the calculation. This ratio will be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection, or changes to the beneficiary assignment methodology.

- *Step 4:* Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment, determined as specified in the regulation at § 425.656, expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

++ If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings value and determine the final adjustment as follows:

—If the sum is positive, the ACO will receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment and 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year

[273] Because the discussion that follows describes the methodology for determining the prior savings adjustment as adopted in the CY 2023 PFS final rule, it does not reflect the changes to further mitigate the negative regional adjustment that we proposed in the CY 2024 PFS proposed rule. Please see section III.G.4.c of this final rule for a discussion of those proposals and our final policies to mitigate the negative regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years.

corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—If this sum is negative, this will constitute the amount of the negative regional adjustment applied to the ACO's historical benchmark. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ If the regional adjustment, expressed as a single value, is positive, the ACO will receive an adjustment to the benchmark equal to the higher of the following:

—The positive regional adjustment amount. The adjustment will be applied separately to the historical benchmark expenditures for each of the following populations of beneficiaries in accordance with § 425.656(c): ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings value and 5 percent of national per capita FFS expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

As we explained in the CY 2023 PFS final rule (87 FR 69900) in calculating an ACO's average per capita prior savings over the 3 performance years immediately preceding the start of its agreement period, we believe that a safeguard is needed to ensure that ACOs that achieved savings for a performance year that serves as a benchmark year for the current agreement period, but were ineligible to receive a shared savings payment due to noncompliance with Shared Savings Program requirements, are not subsequently eligible to have a portion of those savings included in their historical benchmark. Without such a safeguard, we would be rewarding an ACO, despite its noncompliance, through a higher benchmark in its subsequent agreement period. This would conflict with the sanction imposed on the ACO for its noncompliance during the performance year(s) of its prior agreement period. Accordingly, under the prior savings adjustment policy we finalized in the CY 2023 PFS final rule, if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements, we will set at zero the per capita amount of savings for the affected performance year(s) when calculating the prior savings adjustment.

There are a variety of reasons that could result in an ACO's ineligibility to receive a shared savings payment due to noncompliance. In accordance with §§ 425.605(c)(2), and 425.610(c)(2), an ACO does not qualify to receive shared savings for a performance year if it failed to meet the quality performance standard as specified under § 425.512 or otherwise did not maintain its eligibility to participate in the Shared Savings Program. Furthermore, an ACO will not receive any shared savings payments during the time it is under a corrective action plan (CAP) for avoidance of at-risk beneficiaries and is not eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at-risk beneficiaries) (refer to § 425.316(b)(2)(ii)(B) and (C)).

In the CY 2023 PFS rulemaking to establish the current prior savings adjustment, we did not describe how we would account for certain circumstances where there could be changes to the values used in calculating the prior savings adjustment. Such changes could occur for changes in savings earned by ACOs in accordance with § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action to address avoidance of at-risk beneficiaries or issuance of a revised initial determination of financial performance under § 425.315. If CMS determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries and requires the ACO to submit a CAP, the ACO will not receive any shared savings payments during the time it is under the CAP (§ 425.316(b)(2)(ii)(B)), and it will not at any time be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (§ 425.316(b)(2)(ii)(C)). Upon completion of an ACO's CAP for avoidance of at-risk beneficiaries, CMS may release shared savings payments withheld from an ACO during the time it was under a CAP under § 425.316(b)(2)(ii)(B), so long as the shared savings are not attributable to the time that necessitated the CAP (that is, the time period during which the ACO avoided at-risk beneficiaries). Thus, depending on the timing of compliance actions undertaken by CMS, the amount of savings eligible for inclusion in the prior savings adjustment under § 425.658(b)(1), may change as a result of the compliance action. For instance, the total savings eligible for inclusion in the prior savings adjustment may increase after the completion of a CAP and release of a shared savings payment withheld under § 425.316(b)(2)(ii)(B). Further, if an initial determination of financial performance was already made and shared savings payments distributed and then the ACO was found to have avoided at-risk beneficiaries, and therefore, ineligible to receive a shared savings payment for the performance year, CMS would recoup the shared savings for the time period during which the ACO avoided at-risk beneficiaries. This latter scenario would result in a decrease in the total amount of savings eligible for inclusion in the prior savings adjustment calculation.

Further, if we determine that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, under § 425.315 CMS may reopen its prior determination and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. If these situations—changes in the amount of shared savings for a prior performance year under § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action due to the avoidance of at-risk beneficiaries, or the issuance of a revised initial determination based on a reopening of ACO shared savings or shared losses under § 425.315—impact one of the 3 years prior to the start of the ACO's current agreement period, it is possible that the prior savings adjustment would no longer reflect the savings or losses achieved by the ACO during the applicable years. In the CY 2023 PFS rulemaking, we did not adopt a mechanism to account for these changes in the prior savings adjustment, but

rather focused on changes to the prior savings adjustment related to changes in an ACO's participant list, changes to the ACO's assignment methodology selection, or changes to beneficiary assignment methodology under the Shared Savings Program as a whole.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52474 through 52476), we proposed refinements to the prior savings adjustment calculation methodology, specified in 42 CFR part 425, subpart G, that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for circumstances where the amount of savings or losses for a performance year used in the prior savings adjustment calculation changes retroactively. Specifically, we proposed to modify the list of circumstances for adjusting the historical benchmark in § 425.652(a)(9) to include two additional scenarios: a change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315. In these situations, the amount of savings or losses that an ACO may have generated in the 3 performance years prior to the start of the current agreement period and that would have been eligible for inclusion in the calculation of the prior savings adjustment may change. The refinements we proposed would allow for the prior savings adjustment to be recalculated and the historical benchmark to be adjusted to reflect the any change in the amount of savings earned or losses incurred by the ACO in the 3 performance years prior to its current agreement period that are eligible for inclusion in the calculation of the prior savings adjustment.

We proposed to modify the process described in § 425.652(a)(9) for adjusting the historical benchmark. Under the current regulation, an ACO may receive an adjusted historical benchmark because of changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1),[274] or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E. We proposed to modify § 425.652(a)(9) to indicate that an ACO would receive an adjusted historical benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. More specifically, an ACO would receive an adjusted benchmark for the following reasons: (1) a change in the amount of savings calculated for any of an ACO's 3 benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action taken to address avoidance of at-risk beneficiaries, or (2) CMS issues a revised initial determination under § 425.315 that impacts the amount of savings or losses calculated for 1 of the ACO's benchmark years. In the proposed rule, we noted that a compliance action taken to address avoidance of at-risk beneficiaries may lead to a change in the amount of savings earned by an ACO for a previous performance year when CMS releases savings previously withheld under § 425.316(b)(2)(ii)(B) for a time period other than the time period during which the ACO avoided at-risk beneficiaries following completion of a CAP or CMS recoups shared savings previously disbursed to an ACO under § 425.316(b)(2)(ii)(C) for a time period during which the ACO is later determined to have avoided at-risk beneficiaries.

Only ACOs whose current benchmark includes a prior savings adjustment or whose benchmark would include an adjustment for prior savings following a change in the amount of savings earned for a previous performance year that is a benchmark year for the ACO's current agreement period would receive an adjusted benchmark under these proposed changes. Furthermore, we proposed to modify the process described in § 425.652(a)(9) to indicate that if either of these two conditions occur after the ACO has already received its historical benchmark for the first performance year of its agreement period, an ACO could receive an adjusted historical benchmark for the first year of its agreement period.

[274] Refer to section III.G.7.a of the proposed rule for a description of the proposal to revise the current reference to § 425.400(a)(4)(ii) in § 425.652(a)(9)(iv) to a reference to § 425.226(a)(1).

We also proposed to add a new paragraph (e) to § 425.658 to indicate that, when either of the two aforementioned scenarios occurs, the prior savings adjustment itself would be recalculated. We explained that without this addition there would be no mechanism for recalculating the prior savings adjustment to address changes in ACO's savings or losses for a performance year within an agreement period. Further, we proposed that, absent any other triggers for receiving an adjusted benchmark, an ACO would only receive an adjusted historical benchmark due to a change in the ACO's savings or losses for a performance year under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) if the change would result in a change to the prior savings adjustment as determined under § 425.652(a)(8). In other words, the ACO would not receive an adjusted historical benchmark following recalculation of the prior savings adjustment if the recalculation of the prior savings adjustment would not result in a change to the historical benchmark.

In the CY 2024 PFS proposed rule (88 FR 52475), we explained our belief that, to issue adjusted benchmarks and complete financial reconciliation in a timely fashion, it would be necessary to establish a timing cutoff for when the determination to issue an adjusted historical benchmark for these two additional reasons would be made. Each of the two scenarios for which we proposed to recalculate the prior savings adjustment may occur at any point during any performance year of the ACO's agreement period, as well as after the end of that agreement period. We proposed that for an adjusted benchmark due to the two conditions being considered to be used in financial reconciliation for a performance year, any determination under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) that changes the amount of the ACO's savings or losses in any of the benchmark years must be issued no later than the date of the initial determination of shared savings or shared losses through financial reconciliation for the relevant performance year under § 425.605(e) or § 425.610(h). We noted, however, that if we become aware of a potential change under § 425.316(b)(2)(ii)(B) or (C) in the savings earned in a benchmark year by an ACO eligible for the prior savings adjustment or an upcoming revised initial determination under § 425.315 that could impact the determination of the ACO's savings or losses for a benchmark year, we might delay the initial determination of shared savings or shared losses for the ACO for the

relevant performance year beyond when initial determinations would otherwise be issued in order to assess whether the ACO should receive an adjusted historical benchmark. Under this framework, changes to savings or losses for a benchmark year that are finalized after notification to the ACO of the initial determination of shared savings or shared losses for a given performance year would be reflected in the adjusted benchmark applied to any subsequent performance year during the relevant agreement period but would not be retroactively applied to completed performance years in the agreement period.

We considered several alternatives to the timing of when we could incorporate new information about a change in savings earned by an ACO in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 into the prior savings adjustment. The two primary alternatives we considered were: (1) requiring information about a change to the amount of savings calculated for a previous year in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 to become available by December 31st of the year prior to the performance year; and (2) considering this information at any time it becomes available. An advantage of the former option of requiring information by December 31st is that it would allow us to issue the adjusted benchmark in March of the performance year, consistent with when adjusted benchmarks are otherwise issued to ACOs. A disadvantage of this approach is that it would provide less flexibility for when new information impacting savings or losses in the benchmark years could be applied to the benchmark used in financial reconciliation for a given performance year. An advantage of the latter approach of considering such information at any time that it becomes available is that an ACO could receive an adjusted benchmark and a revised initial determination of shared savings or shared losses even after receiving its initial determination for a performance year. However, a disadvantage of this approach is that it would generate significant operational complexities. If, for instance, information becomes available during performance year four of an ACO's agreement period that would potentially impact financial reconciliation results in the first 3 performance years of the agreement period, we would need to simultaneously issue adjusted benchmarks and revised initial determinations for several performance years. In the proposed rule, we stated that on balance, we believed it would be appropriate to consider new information that could impact the prior savings adjustment up to the point at which an ACO receives its initial determination for a particular performance year. We noted that we were continuing to consider the complexities surrounding reopening initial determinations for multiple prior performance years throughout the program's benchmarking and financial reconciliation methodologies and may address this issue in future rulemaking.

We recognized that under § 425.658(b)(1)(iii), for a new ACO identified as re-entering ACO, the prior savings adjustment is based on the prior savings or losses of the ACO in which the majority of the ACO's ACO participants were participating. Accordingly, in the case of a re-entering ACO, we proposed to consider whether this prior ACO is impacted by the following when determining whether to issue an adjusted benchmark: (1) a change in the amount of savings calculated for any of the ACO's benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries; or (2) a revised initial determination issued under § 425.315 that impacts the determination of the ACO's savings or losses for one of the benchmark years. In this case, other aspects of the proposal would apply similarly, including the timing cutoff for issuing an adjusted benchmark and issuing an adjusted benchmark only if the change in savings or losses determined for the applicable benchmark year would result in a change to the prior savings adjustment as determined under § 425.652(a)(8).

We included two examples to illustrate how an ACO could receive an adjusted historical benchmark that incorporates additional savings as a result of the changes we were proposing.

- *Example 1:* An ACO renews to begin a new agreement period on January 1, 2025 but is under a corrective action plan under § 425.316(b) for avoidance of at-risk beneficiaries during performance year 2023. In accordance with § 425.316(b)(2)(ii)(B) the ACO did not receive a shared savings payment for performance year 2024, which represents the third benchmark year of its new agreement period. Therefore, the ACO's prior savings adjustment for its new agreement period would be calculated by setting the gross savings and losses for the third benchmark year equal to 0 as described in § 425.658(b)(1)(ii). However, in November of 2026 the corrective action plan for avoidance of at-risk beneficiaries is closed and CMS determines that the ACO is eligible to receive payment for shared savings for performance year 2024. In this example, the ACO would have previously received notification of the initial determination of shared savings or shared losses for performance year 2025. Because the change in the status of the corrective action plan occurred after the ACO received its initial determination of shared savings and shared losses for performance year 2025, savings from the ACO's third benchmark year would be included in the calculation of the prior savings adjustment beginning with the benchmark used to determine financial performance for performance year 2026. That is, the ACO would receive an adjusted historical benchmark for performance year 2026 reflecting the recalculated prior savings adjustment, and financial reconciliation for performance year 2026 and subsequent performance years of the ACO's current agreement period would reflect that adjusted historical benchmark. However, financial reconciliation for performance year 2025 would not be reopened to reflect savings from the third benchmark year in the calculation of the prior savings adjustment because the corrective action plan was not lifted until after the ACO received its initial determination of shared savings or shared losses for that performance year.
- *Example 2:* An ACO begins a new agreement period on January 1, 2026, and receives its historical benchmark, which includes a prior savings adjustment. In February of 2027, information is identified that leads to a revised initial determination of shared savings and shared losses for benchmark year 2 of the ACO's new agreement period. Because the issue was identified in February of the second performance year of the new agreement period, which is prior to the ACO receiving an initial determination of its shared savings and shared losses for performance year 2026, the ACO would receive an adjusted historical benchmark for performance year 2026. Shared savings and shared losses calculations for performance year 2026 would reflect the recalculated prior savings adjustment included in this adjusted benchmark. All subsequent performance years in the agreement period would also reflect the recalculated prior savings adjustment.

In summary, we proposed revisions to § 425.652(a)(9) to indicate that we

would adjust the benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of the issuance of a revised initial determination under § 425.315. We also proposed to add new paragraph (e) to § 425.658 to specify that the ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. Further, the new provision § 425.658(e) would also establish that for new re-entering ACOs, the prior savings adjustment will be recalculated for changes in savings or losses for a performance year used in the prior savings adjustment for the ACO in which a majority of the new ACO's ACO participants were previously participating.

We solicited comments on the proposal to adjust the historical benchmark to reflect changes in savings or losses for a performance year that constitutes a benchmark year for an ACO's current agreement period. These changes would be applicable for agreement periods beginning on or after January 1, 2024.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: We received several comments pertaining to the proposal to adjust the historical benchmark to reflect changes in savings or losses for a performance year that constitutes a benchmark year for an ACO's current agreement period. All comments supported the proposed changes, with several noting that the proposed policy increases program integrity without imposing undue burden on ACOs. We did not receive any comments opposing these changes.

Response: We agree with the commenters that the proposed provisions will improve the accuracy of the prior savings adjustment without placing additional burden on ACOs.

After consideration of the public comments, we are finalizing without modification the proposed refinements to the prior savings adjustment calculation methodology, specified in § 425.658, to account for circumstances where the amount of savings or losses for a performance year used in the prior savings adjustment calculation changes retroactively. This change will apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years.

We are finalizing the proposed revisions to § 425.652(a)(9) to include two additional circumstances under which we will adjust the historical benchmark: a change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315.

We also refer readers to section III.G.8.c. of this final rule for a summary of comments received in response to the RFI in the CY 2024 PFS proposed rule regarding potential increases to the prior savings adjustment.

e. Update How Benchmarks Are Risk Adjusted

(1) Overview of Risk Adjustment Within Shared Savings Program Benchmark Calculations

When establishing, adjusting, and updating an ACO's historical benchmark, CMS makes certain adjustments to account for the severity and case mix of, and certain demographic factors for, the ACO's assigned beneficiary population and the assignable beneficiary population. We use prospective HCC risk scores and (as applicable) demographic risk scores to perform this risk adjustment.

To follow is a summary of the calculations in which we will account for the severity and case mix of the ACO's assigned beneficiary population or the assignable beneficiary population when establishing, adjusting, and updating the historical benchmark, for agreement periods beginning on January 1, 2024, and in subsequent years, including as proposed elsewhere in the CY 2024 PFS proposed rule.

- We risk adjust benchmark year expenditures used to establish the historical benchmark for changes in severity and case mix using prospective HCC risk scores, in accordance with § 425.652(a)(3). In making this adjustment, we account for changes in severity and case mix in the ACO's assigned beneficiary population between the first and third benchmark years and between the second and third benchmark years.[275]
- We calculate the ACO's regional FFS expenditures using risk adjusted county-level FFS expenditures, which are determined in accordance with § 425.654(a)(4) by adjusting FFS expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores and by making separate expenditure calculations for populations of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). The ACO's risk adjusted regional FFS expenditures are utilized in determining the regional adjustment to the historical benchmark (in accordance with § 425.656), the regional component of the national-regional blended trend factor (in accordance with § 425.652(a)(5)), and the regional component of the three-way blended benchmark update factor (in accordance with § 425.652(b)(2)).
- We calculate the regional adjustment to the historical benchmark in accordance with § 425.656, including the following calculations to account for severity and case mix:

++ We adjust for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3 in accordance with § 425.656(b)(3).

++ In calculating the negative regional adjustment, we apply an offset factor based on the ACO's overall proportion of BY3 assigned beneficiaries who are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) and the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types, in accordance with § 425.656(c)(4).

- We adjust the ACO's historical benchmark to account for changes in severity and case mix in the ACO's assigned beneficiary population between BY3 and the performance year in accordance with §§ 425.652(a)(10), 425.605(a)(1) and (2) (BASIC track), and 425.610(a)(2) and (3) (ENHANCED track), at the time of financial reconciliation for a performance year. We use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and

[275] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies'').

the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (refer to §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii), and section III.G.4.b.(1) of the proposed rule).

- In calculating the regional component of the three-way blended update factor, we proposed to cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor, as discussed in section III.G.4.b.(2) of the proposed rule and the proposed new provision at § 425.655.
- We adjust the flat dollar amounts of the ACPT component of the three-way blended update factor for each performance year, for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3, in accordance with § 425.660(b)(4).

(2) Background on Calculation of Prospective HCC Risk Scores Used to Risk Adjust Shared Savings Program Benchmark Calculations

(a) Historical Practices

We detailed how CMS performs Shared Savings Program risk adjustment calculations in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies''). While we have specified the details of these practices in guidance, we have not previously codified these practices in regulation.

In the CY 2024 PFS proposed rule (88 FR 52477), we described that CMS maintains the CMS–HCC risk adjustment models for the Medicare Advantage (MA) program. CMS maintains CMS–HCC risk adjustment models for populations of beneficiaries based on age, disability status, gender, institutional status, eligibility for Medicaid, and health status (see section 1853(a)(1)(C)(i) of the Act), including a separate MA risk adjustment model for the ESRD population, and a Part D risk adjustment model (known as the RxHCC model). Over time, CMS has implemented revised versions of the CMS–HCC risk adjustment models (also referred to generally as the ''CMS–HCC model''). Historically, transitions to a revised version of the CMS–HCC model have been gradually phased-in over time by blending the old risk adjustment model and the revised risk adjustment model. We specify the CMS–HCC risk adjustment models applicable for a calendar year in the annual MA Rate Announcement (see sections 1853(a)(1)(C) and (b)(1) of the Act). Prior to doing so, we solicited comments on the CMS–HCC risk adjustment methodology (see section 1853(b)(2) of the Act). Using the specified model, or blend of models (if applicable), we calculated prospective HCC risk scores for all Medicare beneficiaries, including FFS beneficiaries. These prospective HCC risk scores are then used to set MA capitation rates and Part C and D payment policies for the applicable calendar year.

To perform risk adjustment calculations for the Shared Savings Program, we calculate prospective HCC risk scores for Medicare FFS beneficiaries for the relevant benchmark year or performance year. In doing so, we use the CMS–HCC risk adjustment model(s) that are applicable for the particular calendar year corresponding to the benchmark or performance year to identify a Medicare FFS beneficiary's prospective HCC risk score for that benchmark or performance year. Prospective HCC risk scores used in financial calculations for the Shared Savings Program have the MA coding pattern adjustment of 5.90 percent removed, if applicable.[276] Additionally, all prospective HCC risk scores are renormalized by Medicare enrollment type based on a national assignable FFS population to ensure that the mean risk score among assignable beneficiaries is equal to one. Renormalization helps to ensure consistency in risk scores from year to year, given changes made to the underlying risk score models. All risk adjustment calculations for the Shared Savings Program, including risk score renormalization, are performed separately for each Medicare enrollment type for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid.[277]

Under the Shared Savings Program, we calculate demographic only risk scores using a separate model than those used to calculate prospective HCC risk scores. For agreement periods beginning on January 1, 2024, and subsequent years, CMS will use demographic risk scores to determine the cap on risk score growth between BY3 and the performance year. Demographic risk scores consider only certain specified patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability, or ESRD), without incorporating diagnostic information. As such, demographic risk scores are not subject to changes in coding intensity or coding accuracy in the same way that prospective HCC risk scores are. We note that while the Shared Savings Program uses the same demographic factors as those used in MA, Shared Savings Program demographic factor coefficients are calibrated based on the entire Medicare FFS population instead of new Medicare enrollees as is used by MA.

Currently, when establishing, adjusting, and updating the benchmark, we account for changes in severity and case mix between benchmark years or between BY3 and the performance year by multiplying the expenditures for the applicable year by a quotient of two ACO-level renormalized risk scores, known as the risk ratio. For example, to risk adjust the expenditures for an ACO's assigned beneficiary population to account for changes in case mix and severity from the first benchmark year to the third, we multiply BY1 expenditures by a risk ratio equal to the mean renormalized risk score among the ACO's assigned beneficiaries in BY3 divided by the mean renormalized risk score among the ACO's assigned beneficiaries in BY1 for each Medicare enrollment type. For instance, a one percent rate of growth in renormalized risk scores between these benchmark years would be expressed by a risk ratio of 1.010. This ratio reflects growth in risk for the ACO's assigned beneficiary population relative to that of the national assignable population. Because the risk ratios used in benchmarking

[276] The MA risk adjustment models used for beneficiaries classified as ESRD for the Shared Savings Program (that is, beneficiaries in long-term dialysis or transplant status, no more than three months post-graft) do not currently employ a coding intensity adjustment, therefore no adjustment is currently removed from risk scores for beneficiaries in the ESRD enrollment type.

[277] A beneficiary's final risk score for each month is the risk score determined for that beneficiary based on the beneficiary's risk adjustment model status for that month. There are risk adjustment models for MA subpopulations (for example, community model versus institutional model versus new enrollee model for aged/non-dual eligible beneficiaries), and the risk scores used by the Shared Savings Program for beneficiaries in a Medicare enrollment type may be derived from more than one risk adjustment model.

calculations may be determined using risk scores calculated from different underlying CMS–HCC risk adjustment models, depending on the CMS–HCC risk adjustment model(s) applicable to the corresponding benchmark or performance year, this approach allows for the possibility that differences in risk models between the benchmark years and the performance year could impact an ACO's financial performance.

Since the inception of the Shared Savings Program in 2012, there have been several CMS–HCC model changes. Several factors reduce the impact of using different risk adjustment models to calculate prospective HCC risk scores for benchmark and performance years when performing Shared Savings Program risk adjustment calculations. One factor is that the Shared Savings Program renormalizes prospective HCC risk scores by Medicare enrollment type, which ensures that the mean risk score for the national assignable FFS population for each enrollment type is equal to one. If a new CMS–HCC model leads to a shift in the mean of the distribution of prospective HCC risk scores for the national assignable FFS population for a particular Medicare enrollment type, then renormalizing the risk scores would counterbalance this effect. Because renormalization factors are calculated across the assignable beneficiary population for each enrollment type, any adverse or beneficial impact for an ACO from a change in CMS–HCC model would derive from the mean risk score for the ACO's assigned beneficiaries within a given enrollment type being impacted in a systematically different way than the mean for the national assignable population for that enrollment type.

A second factor is that risk scores are used in multiple ways that balance their effects when establishing, adjusting, or updating a benchmark. Risk scores are used to adjust ACO expenditures and also to adjust regional expenditures used in calculating the regional adjustment to the benchmark and regional growth rates in benchmark calculations. Any impact of a new CMS–HCC model that could increase or decrease an ACO's risk scores used to establish, adjust, or update a benchmark may differ directionally from the impact that risk scores for the assignable FFS population in an ACO's regional service area might have on risk-adjusted regional expenditure calculations. For example, if a new CMS–HCC model lowers the risk ratio between BY3 and the PY, and therefore, lowers the benchmark for an ACO, all else equal, then the new risk adjustment model may also lower the risk scores for the ACO's regional service area assignable beneficiary population, which would increase risk-adjusted regional expenditures.[278] This would put upward pressure on the benchmark by increasing the regional update factor. Any changes to the ACO's risk ratio may be thus reduced by changes to the ACO's regional update factor. This would reduce the impact of CMS–HCC model changes on ACO financial performance.

A third factor is that CMS–HCC model transitions have been gradually phased-in over time by blending the old risk adjustment model and the new risk adjustment model, thereby constraining the magnitude of any change in risk ratios resulting from differences in the risk adjustment models used to calculate prospective HCC risk scores. That is, as a result of this blending, the risk ratios used to adjust expenditures between BY3 and the PY may have some degree of overlap in underlying risk adjustment models used to calculate both the numerator and denominator of the risk ratios.

(b) Introduction of the 2024 CMS–HCC Risk Adjustment Model, Version 28

On March 31, 2023, CMS released the Announcement of CY 2024 MA Capitation Rates and Part C and Part D Payment Policies,[279] which finalized the transition to a revised CMS–HCC risk adjustment model. The revised 2024 CMS–HCC risk adjustment model, Version 28 (V28), has the same structure as the 2020 CMS–HCC risk adjustment model currently used for payment in that it has eight model segments as first implemented for payment for CY 2017 and condition count variables as first implemented for payment for CY 2020. It incorporates the following technical updates: (1) updated data years used for model calibration, (2) updated denominator year used in determining the average per capita predicted expenditures to create relative factors in the model, and (3) a clinical reclassification of the hierarchical condition categories (HCCs) using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) codes. In addition, as part of the clinical reclassification, CMS conducted an assessment on conditions that are coded more frequently in MA relative to FFS. This assessment is consistent with Principle 10 of CMS's longstanding model principles, described in more detail initially in the December 2000 report titled, ''Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report)'' (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/pope_2000_2.pdf*). As a result of this assessment, in addition to the technical updates, the revised model includes additional constraints and the removal of several HCCs to reduce the impact on risk score variation in coding between MA and FFS.[280]

For CY 2024, MA risk scores will be calculated as a blend of 67 percent of the risk scores calculated under the 2020 CMS–HCC risk adjustment model, Version 24 (V24), and 33 percent of the risk scores calculated with the 2024 CMS–HCC risk adjustment model (V28). CMS expects that for CY 2025, MA risk scores will be calculated using a blend of 33 percent of the risk scores calculated with V24 and 67 percent of the risk scores calculated with V28, and for CY 2026, 100 percent of risk scores will be calculated with V28.[281]

With the transition to the use of the V28 CMS–HCC model beginning in CY 2024 in MA, it is timely to revisit how we apply the CMS–HCC risk adjustment model(s) to calculate risk scores used in Shared Savings Program calculations. As summarized in the CY 2024 Rate Announcement, some commenters questioned if the updated MA risk adjustment model will affect lines of business outside of Medicare Advantage such as the ACO REACH Model and Medicare Shared Savings Program. In response to these comments, we explained that we were considering the implications of these changes to the CMS–HCC risk adjustment model for these initiatives.[282]

In the CY 2024 PFS proposed rule we described our initial analysis of the impact of the V28 CMS–HCC model on Shared Savings Program calculations, including modeling of an alternative approach to calculating benchmark year

[278] For each county and Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible) in the ACO's regional service area, CMS divides average per capita county-level FFS expenditures by the county average renormalized CMS–HCC risk score to obtain risk-adjusted county expenditures.

[279] For more details, refer to Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023) (herein CY 2024 Rate Announcement), available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf.*

[280] See Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023), available at *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[281] See CY 2024 Rate Announcement, available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf* at 3.

[282] *See id.* at 97.

risk scores (88 FR 52479 through 52481). We proposed an approach to making such calculations for agreement periods beginning on January 1, 2024, and in subsequent years.

(3) Initial Analysis of the Impact of Risk Adjustment Model Changes on Shared Savings Program Calculations and Modeling of an Alternative Approach to Calculating Benchmark Year Risk Scores

In the CY 2024 PFS proposed rule (88 FR 52479), we noted that to further evaluate the potential impact of the V28 CMS–HCC model transition on Shared Savings Program ACOs, we analyzed the following:

- Our current approach in which we apply the CMS–HCC risk adjustment model(s) applicable for a particular calendar year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the corresponding benchmark or performance year. This approach could lead to different CMS–HCC risk adjustment models being used to calculate prospective HCC risk scores for the benchmark years as compared to a particular performance year of the ACO's agreement period when there is a transition to a new CMS–HCC risk adjustment model between one or more benchmark years and the performance year.
- An alternative approach in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period.[283] This approach ensures consistency between the CMS–HCC risk adjustment methodology used to calculate the prospective HCC risk scores for the benchmark years relative to a particular performance year.

To conduct this analysis, we calculated prospective HCC risk scores and risk ratios for CY 2018 (treated as BY3) and CY 2021 (treated as the PY) for all 275 ACOs that participated in both PY 2018 and PY 2021. Risk ratios between BY3 and the PY were calculated under the current approach, in which we used the V24 CMS–HCC model to calculate BY3 prospective HCC risk scores and the V28 CMS–HCC model to calculate PY prospective HCC risk scores, and under the alternative approach of calculating both BY and PY prospective HCC risk scores using V28.[284]

We performed this analysis to roughly estimate how V28 would have impacted payment to ACOs in PY 2021 using weighted average risk scores calculated across the three non-ESRD Medicare enrollment types (disabled, aged/dual eligible, aged/non-dual eligible). The analysis provides insight into the impact of a fully phased-in V28, which is expected to occur in PY 2026 (particularly for ACOs that would at that point have a BY3 prior to 2024). For the 275 ACOs in the sample, combined PY 2021 shared savings payments would have been about 11 percent lower than actual payments if V28 had been fully phased-in for the performance year, when using V24 to calculate BY3 prospective HCC risk scores (reflecting the current approach to applying CMS–HCC risk adjustment models). Alternatively, combined shared savings payments would have been about 2 percent higher than actual if V28 were used for BY3 calculations, as well as for PY 2021 calculations (reflecting the alternative approach to applying CMS–HCC risk adjustment models).

Table 44 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY prospective HCC risk scores.

TABLE 44: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Minimum	-6.6%	-1.6%	-6.7%
10th percentile	-1.4%	-0.4%	-1.1%
25th percentile	-0.4%	0.0%	-0.5%
Median	0.0%	0.0%	0.0%
Mean	-0.2%	0.1%	-0.2%
75th percentile	0.1%	0.2%	0.0%
90th percentile	0.9%	0.6%	0.5%
Maximum	2.3%	2.2%	2.2%

Estimated decreases in PY 2021 shared savings payments are more extreme at the tail of the distribution when using the current approach. Over 10 percent of ACOs showed more than 1.4 percent in reduced shared savings payments relative to benchmark under the modeling of the current approach, in which we used V24 to calculate BY3 prospective HCC risk scores and V28 to calculate PY prospective HCC risk scores. In contrast, about 3 percent of ACOs showed declines of such magnitude in shared savings payments relative to the benchmark using the alternative approach to calculating prospective HCC risk scores for BY3 and PY 2021 with the V28 CMS–HCC model. Compared to the alternative approach, the current approach is estimated to result in a reduction in shared savings of about 0.2 percent per ACO on average, relative to benchmark. These impacts would be smaller, potentially

[283] A similar approach was suggested by commenters in earlier rulemaking for the Shared Savings Program. See, for example, the December 2018 final rule (83 FR 68013), in which we summarize commenters' recommendation that CMS modify the current methodology to use the same CMS–HCC risk score model to calculate risk scores for both the benchmark years and the performance year.

[284] The V24 CMS–HCC model was not applicable to CY 2018 but was used in this analysis to calculate BY3 prospective HCC risk scores under the current approach to measure the impact of the transition from V24 to V28 on Shared Savings Program ACOs.

one-third of the magnitude, if the use of V24 in BY3 was compared to the blend of 33 percent V28 and 67 percent V24 for the PY (reflecting the blend applicable for CY 2024).

Table 45 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY risk scores (expressed as percentage of benchmark), based on the following ACO characteristics: ACO average renormalized prospective HCC risk scores for aged/disabled beneficiaries, ACO participation in performance-based risk, and year of entry into the Shared Savings Program. We observed that the current approach would have the greatest adverse effect on ACOs with the highest average risk scores (calculated with the V24 CMS–HCC model), ACOs participating in two-sided models, and ACOs that have been in the Shared Savings Program longer. ACOs that would not have been harmed by the current approach had an average renormalized risk score for their non-ESRD populations roughly equal to 1.00. The 5 percent of ACOs in the modeling with the most adverse impact from the current approach had an average renormalized risk score for their non-ESRD populations of 1.22. For ACOs with the highest average risk scores, the modeling showed the current approach would have resulted in reduced shared savings of about 2 percent (relative to benchmark) per ACO, as compared to the alternative approach. The most adversely impacted ACOs in the modeling also were roughly 40 percent more likely to participate in a two-sided model and to have participated in the Shared Savings Program nearly 2 years longer than ACOs not harmed. The modeling demonstrates that the alternative approach would reduce the negative impact that the current approach shows for ACOs with high-risk scores, with earlier entry dates into the Shared Savings Program, and with participation in a two-sided model.

TABLE 45: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation, Based on ACO Characteristics (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Average HCC (Aged/Disabled)			
>1.20	-2.0%	0.0%	-2.1%
1.10 to 1.20	-0.5%	-0.1%	-0.4%
1.025 to 1.10	-0.4%	0.0%	-0.4%
0.975 to 1.025	-0.1%	0.1%	-0.2%
0.90 to 0.975	0.2%	0.2%	0.1%
<0.90	0.5%	0.2%	0.3%
PY21 Track/Level			
Two-sided Model	-0.5%	0.0%	-0.5%
One-sided Model	0.1%	0.1%	0.0%
Program Entry			
On/before 2013	-0.6%	0.1%	-0.7%
On/after 2014	-0.1%	0.1%	-0.1%

In the context of the transition to the V28 CMS–HCC model, the results of this analysis show that the current approach to calculating prospective HCC risk scores is expected to adversely impact ACO financial performance, particularly for ACOs that serve a high-risk beneficiary population, when compared to the stated alternative approach. We explained that factors discussed in the proposed rule (as described in section III.G.4.e.(2) of the proposed rule)—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model—will reduce the impact of a risk adjustment model transition. However, these factors will be insufficient to prevent adverse effects on ACO financial performance due to the larger impact from the transition to V28 relative to prior CMS–HCC model transitions. The alternative policy under which CMS would apply the same CMS–HCC risk adjustment model used in the performance year to calculate prospective HCC risk scores for all benchmark years would strengthen risk adjustment in the Shared Savings Program and consistently apply the CMS–HCC model in the Shared Savings Program context as it is applied in MA.

(4) Revisions

The adoption of the alternative approach to calculating prospective HCC risk scores for the performance year and each benchmark year of an ACO's agreement period would allow us to more accurately measure the change in severity and case mix for an ACO's assigned beneficiary population or the assignable beneficiary population. Under such an approach, there would be no potential for distortion from using different CMS–HCC risk adjustment models in calculating prospective HCC risk scores for benchmark years and the performance year that could occur under the current policy. For this reason, we proposed to modify our current use of the CMS–HCC risk adjustment model and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years for agreement periods beginning on January 1, 2024, and in subsequent years.

We proposed to add a new section to our regulations at § 425.659, which would codify our existing framework for calculating risk scores used in Shared

Savings Program benchmark calculations and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years (88 FR 52481 through 52483). We proposed in paragraph (a) of § 425.659 to codify our current practice of accounting for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting, and updating the ACO's historical benchmark.

We proposed to set forth in paragraph (b) of § 425.659 our approach to determining Medicare FFS beneficiary prospective HCC risk scores for Shared Savings Program benchmark and performance year calculations (88 FR 52481). In paragraph (b)(1) of § 425.659, we proposed to codify our current policy under which CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations. Additionally, we proposed:

- To codify our current practice of calculating risk scores for Medicare FFS beneficiaries for a performance year, which provides that CMS uses the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.
- To codify our current practice for agreement periods beginning before January 1, 2024, of applying the CMS–HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.
- For agreement periods beginning on January 1, 2024, and in subsequent years, CMS would apply the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

We proposed at § 425.659(b)(2) to codify our current practices for calculating prospective HCC risk scores for a benchmark or performance year (88 FR 52482). Specifically, in calculating prospective HCC risk scores, we would remove the MA coding intensity adjustment, if applicable. Further, we would renormalize prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for the relevant benchmark or performance year. We would calculate the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) in order to risk adjust benchmark calculations also performed by Medicare enrollment type.

We did not propose to modify the current approach to calculating demographic risk scores under the Shared Savings Program (88 FR 52482).

We also proposed to adjust the benchmark to account for CMS–HCC risk adjustment model changes during the term of the agreement period to maintain uniformity between the calculation of prospective HCC risk scores for the performance year and each benchmark year (88 FR 52482). We proposed to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under proposed, new § 425.659. We further proposed to add a new paragraph (a)(9)(vi) to § 425.652 to specify that we would redetermine factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with proposed § 425.659(b)(1).

We also proposed a technical and conforming change to § 425.650(a), which generally describes the organization of the sections on the benchmarking methodology within subpart G of the Shared Savings Program regulations (88 FR 52482). In the description of the benchmarking methodology applicable for agreement periods beginning before January 1, 2024, we proposed to update the list of referenced sections to include the proposed new § 425.659.

We stated in the CY 2024 PFS proposed rule (88 FR 52482), that this proposed policy would address the concerns of ACOs and other interested parties regarding the transition to the V28 CMS–HCC model or other similar future changes to CMS–HCC risk adjustment methodology that could occur during the term of an ACO's agreement period. Under the proposal, both the numerator and denominator in the PY/BY3 risk ratio would be calculated using a consistent risk model, and any distributional impacts should, on average, be balanced. This would prevent distortion to historical benchmarks resulting from model changes. This conclusion was informed by the data analysis described in the proposed rule (88 FR 52479 through 52481), which shows that on average ACOs would have earned roughly 0.2 percent in additional PY 2021 shared savings payments relative to benchmark when both benchmark year and performance year prospective HCC risk scores are calculated under V28 compared to calculations under both V24 and V28.

Our analysis showed that ACOs with higher than average risk scores would benefit from using the proposed approach to calculate BY and PY prospective HCC risk scores relative to the current policy. The proposal would therefore help the Shared Savings Program retain ACOs serving the highest risk beneficiaries. This is a priority for CMS as high-risk beneficiaries may benefit the most from better care coordination and quality improvement activities, particularly by ACOs with above average duration of participation in the program. Similarly, the proposed approach would support potential participation from new ACOs that would consider whether risk adjustment calculations in the Shared Savings Program benchmarking methodology would be adequate for beneficiaries with the highest risk.

The proposal would not affect how prospective HCC risk scores are calculated for ACOs in agreement periods that began prior to January 1, 2024, consistent with our historical practice of incorporating changes to the benchmarking methodology only at the start of an ACO's agreement period. We explained that ACOs in an existing agreement period that includes performance year 2024, 2025 or 2026 may benefit from the factors discussed in the proposed rule (88 FR 52478 through 52479)—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model. These factors would diminish adverse effects of using the new CMS–HCC risk adjustment methodology in Shared Savings Program calculations.

In the CY 2024 PFS proposed rule (88 FR 52482), we stated that if we finalized the proposed approach for agreement periods beginning on January 1, 2024, and in subsequent years, an ACO in an existing agreement period could choose

to terminate its participation agreement early, to early renew under a new participation agreement to be under the revised approach. For instance, an ACO under an existing agreement period with the current methodology (with a 2022 or 2023 start date) could apply to early renew with the application cycle for the January 1, 2025 agreement period start date, which would occur during CY 2024. For an existing ACO that applied to early renew and enters a new agreement period beginning on January 1, 2024, the proposed policy, if finalized, would apply to the ACO's new agreement period. Any ACO that early renews would have its benchmark rebased at the start of the new agreement period.

The following examples, based on the first 3 years of a 5-year agreement period beginning on January 1, 2024, illustrate the applicability of the current approach to calculating BY and PY prospective HCC risk scores using different CMS–HCC risk adjustment model(s), as compared to the proposed approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s). Under the current policy an ACO beginning a new agreement period on January 1, 2024, would have its prospective HCC risk scores for BY1 (2021) calculated using a blend of 25 percent under the 2014 CMS–HCC model, Version 22 (V22), and 75 percent V24,[285] and for BY2 (2022) and BY3 (2023) calculated using V24.[286] [287] For PY1 (2024), prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. For PY2 (2025), prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. For PY3 (2026), prospective HCC risk scores are expected to be calculated using V28. Under the current methodology, the risk ratios used to risk adjust expenditures would have the numerator and denominator calculated using different underlying CMS–HCC risk adjustment models. Specifically, to risk adjust BY1 expenditures to BY3 when establishing or adjusting the ACO's historical benchmark, the risk ratio would include risk scores calculated under V24 (BY3) and a blend of 25 percent V22 and 75 percent V24 (BY1). To risk adjust BY3 expenditures to the performance year when updating the historical benchmark during financial reconciliation, risk ratios would include risk scores calculated under V24 (as applicable to BY3) and either a blend of V24 and V28 (for PY1 and as expected for PY2) or fully calculated with V28 (as expected for PY3).

Under the proposed approach, BY and PY prospective HCC risk scores would be calculated under the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the relevant performance year. For an ACO beginning a new agreement period on January 1, 2024, in PY1 (2024) all benchmark year and PY1 prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. In PY2 (2025), all benchmark year and PY2 prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. In PY3 (2026), all benchmark year and performance year prospective HCC risk scores are expected to be calculated using V28. In the case of an ACO in an existing agreement period that early renews for a new agreement period beginning on January 1, 2025, the calculations described in this paragraph regarding the blend of V24 and V28 for 2025 and the fully phased-in V28 CMS–HCC model for 2026 would be expected to apply for the ACO's first and second performance years (respectively).

We solicited comments on these proposals regarding the prospective HCC risk scores to be used in risk adjustment for purposes of benchmark calculations under the Shared Savings Program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed general support for and appreciation of the proposed changes to how risk adjustment is performed for purposes of benchmark calculations under the Shared Savings Program. These commenters noted that they believe that using a consistent risk score model for both benchmark years and the performance year will improve predictability in risk scores, as well as prevent distortion to an ACO's historical benchmark resulting from changes in the risk score model.

Response: We agree with commenters that using a consistent risk score model for both benchmark years and the performance year will more accurately assess changes in an ACO's assigned beneficiary population across years.

Comment: Many commenters supported the proposed changes but urged CMS to apply the proposed changes to all ACOs and not just to ACOs in agreement periods beginning on or after January 1, 2024. Other commenters urged CMS to allow ACOs in existing agreement periods that began prior to January 1, 2024, be given an option to choose whether the proposed changes to the risk adjustment methodology will apply to them. Many commenters stated that the proposed rule was made public after the deadline to early renew to begin a new agreement period on January 1, 2024. They stated that knowledge of the proposed changes to risk adjustment methodology would have informed any decision to early renew. Several commenters referred to CMS' data analysis in section III.G.4.e.(3) of the proposed rule which showed that total PY 2021 shared savings payments would have been 11 percent lower when performance year risk scores were calculated using V28. These commenters discussed that maintaining the current risk adjustment methodology for ACOs in agreement periods that began prior to January 1, 2024, would unfairly harm such ACOs, especially those serving high-risk beneficiary populations. A few commenters also noted that while there is an option to early renew to begin a new agreement period on January 1, 2025, there are administrative costs associated with the early renewal application process which may be prohibitive for some ACOs. Several commenters also noted that if an ACO decides to early renew, their benchmark will be rebased for the new agreement period and some ACOs may be harmed by the 'ratchet effect' in which any savings generated in the current agreement period could lead to a lower benchmark in the new agreement period.

Response: The data analysis presented in the proposed rule (88 FR 52479 through 52481) examines the impact of adopting the full V28 CMS–HCC risk adjustment model which is not expected to occur until 2026. While the results of the data analysis suggest combined PY 2021 shared savings payments would have been about 11 percent lower than actual payments if V28 had been fully phased-in for the performance year, this 11 percent is larger in magnitude than the actual impact for PY 2024 for ACOs continuing in an existing agreement

[285] For more details, refer to Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 6, 2020), available at *https://www.cms.gov/files/document/2021-announcement.pdf.*

[286] For more details, refer to Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (January 15, 2021), available at *https://www.cms.gov/files/document/2022-announcement.pdf.*

[287] For more details, refer to Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 4, 2022), available at *https://www.cms.gov/files/document/2023-announcement.pdf.*

period under the current risk adjustment methodology. The impact will be significantly reduced since the risk adjustment model implemented for PY 2024 will be a blend of 67 percent V24 and 33 percent V28. The magnitude of the impact on ACOs for PY 2024 might only be one-third of what was estimated in the analyses included in the proposed rule, because those analyses looked at the fully implemented V28 risk model (88 FR 52480). Table 46 shows the estimated impacts of the PY 2024 blended CMS–HCC model on PY 2021 Shared Savings under both the current and proposed risk adjustment methodologies (where the current approach will be applied for PY 2024 calculations only for ACOs with agreement periods that started before January 1, 2024).

TABLE 46: Estimated Impacts on PY 2021 Shared Savings of the PY 2024 CMS-HCC Model blend of 67% V24 and 33% V28 under Current and Proposed Approaches to BY3 and PY 2024 Risk Score Calculation

	Current Approach BY3 V24, PY Blend	Proposed Approach BY3 Blend, PY Blend	Current minus Alternative
Minimum	-1.7%	-1.5%	-1.6%
10th percentile	-0.2%	0.0%	-0.3%
25th percentile	0.0%	0.0%	-0.1%
Median	0.0%	0.0%	0.0%
Mean	0.0%	0.1%	-0.1%
75th percentile	0.1%	0.1%	0.0%
90th percentile	0.3%	0.2%	0.1%
Maximum	1.5%	1.5%	1.5%

Further, the analyses in the proposed rule only examined the impact of ACO risk scores on the risk ratios used to update the benchmark at the time of financial reconciliation. These risk ratios are calculated as the performance year prospective CMS–HCC risk scores divided by BY3 prospective CMS–HCC risk scores. Under the current policy, which will only apply to ACOs in agreement periods that started before January 1, 2024, the BY3 prospective CMS–HCC risk scores will not be recalculated using the new V28 model. The V28 model is expected to, on average, lower ACO prospective CMS–HCC risk scores which caused a fall in the risk ratios. Under the current approach, this then led to lower updated benchmarks which resulted in worsened average ACO financial performance in our analysis. However, as mentioned previously, there are other ways in which an ACO's prospective CMS–HCC risk scores impact financial calculations. One important way is in the calculation of an ACO's regional adjustment to their historical benchmark. When determining the amount of an ACO's regional adjustment, the ACO's BY3 prospective CMS–HCC risk scores are used to multiply risk-adjusted regional expenditures. Under the proposed policy, all benchmark year risk scores will be calculated using the MA risk adjustment model applicable to the performance year. If the proposed policy were applied to ACOs in existing agreement periods, all BY3 risk scores for such ACOs would be recalculated using the PY 2024 blended model of 67 percent V24 and 33 percent V28. As the blended model, through the V28 component, is expected to lower average ACO prospective CMS–HCC risk scores, this would tend to decrease the amount of the regional adjustment. This would in turn offset some (or potentially all) of the reduction in benchmark that some ACOs would receive by not extending the proposed policy to ACOs in agreement periods that started before January 1, 2024. When we reviewed the ACOs that are most likely to see a decrease in their performance year risk scores, we also found these same ACOs would generally have the most favorable regional adjustments to their historical benchmarks, so the existing methodology would help them avoid negative impacts that would otherwise materialize from recalculation of those adjustments under the new risk model. Lastly, we note that risk scores continue to be renormalized across the assignable population in each eligibility group, which eliminates the risk that risk scores would be systematically biased against ACOs under either the current or proposed approaches described above. Due to these factors, we believe that the impact of the phased transition of V28 on financial performance for PY 2024 for ACOs in existing agreement periods will be lower than expressed by many commenters.

We also note that while the analysis in the proposed rule showed that on average ACOs would benefit from the proposed risk adjustment policy, this was not universal. In comparing the current and alternative approaches to calculating prospective CMS–HCC risk scores, the median value for the difference between the two approaches was 0.0 percent. While the mean impact on ACOs was negative, this was due to the larger impact on adversely affected ACOs rather than the number of ACOs that were adversely affected. In our analysis we found the proposed methodology would reduce benchmarks for at least 25 percent of ACOs in existing agreement periods. Due to this, applying the proposed policy to all ACOs in PY 2024 even those continuing in an existing agreement period, would slightly benefit some ACOs while marginally harming others. The Shared Savings Program's longstanding approach is to maintain a consistent benchmarking methodology for the duration of an ACO's agreement period because methodological changes can have varying impacts on ACO's benchmarks and performance.

Further, we do not believe it is desirable to implement an approach that would allow each ACO to select from a menu of options for customizing the benchmark methodology that would apply in any given performance year during an agreement period. Historically, we have not applied changes to the benchmark methodology during an agreement period, and as we have discussed in prior rulemaking (see, for example, 87 FR 69876), we have particular concern about allowing ACOs to ''opt in'' to certain benchmarking policies within an agreement period, as this creates an opportunity for selective behavior without the counterbalance of rebasing and introduces significant operational complexity. An approach

that allows an ACO to choose the more favorable of several methodologies for establishing its cost target would exacerbate our concerns about the potential for benchmarks to become overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings. We are concerned that this flexibility could lead to opportunities for arbitrage and may dull incentives for ACOs to improve their performance under the Shared Savings Program. Further, doing so would introduce considerable operational complexity into the program's benchmarking methodology.

During CY 2024, ACOs have the option to ''early renew'' for PY 2025, meaning to terminate their current participation agreement under § 425.220 and immediately enter a new agreement period to continue participation in the Shared Savings Program. (See paragraph (2) of the definition of ''renewing ACO'' in § 425.20, and 83 FR 67885 through 67890, and the application procedures set forth in § 425.224.) Early renewal would allow a currently participating ACO to be subject to the modified financial benchmarking methodology policies described in sections III.G.4.b–d and to the modified risk adjustment methodology sooner than if the ACO were to wait to renew to continue its participation in the Shared Savings Program after completing its current agreement period of at least 5 years. We believe that ACOs that elect to renew or early renew for PY 2025 would have sufficient time to decide whether to renew for a new agreement period under the Shared Savings Program, for providers/suppliers to consider the business case for forming or joining a Shared Savings Program ACO, and for CMS to prepare to implement these changes.

Comment: One commenter appeared to misunderstand what was being proposed, stating that they interpreted the proposed policy as introducing the MA risk adjustment models to the Shared Savings Program. They also interpreted the data analysis in section III.G.4.e.(3) of the proposed rule showing the impact of using V24 to calculate benchmark year prospective HCC risk scores and V28 to calculate performance year prospective HCC risk scores as measuring the impact of our proposed policy. They expressed concern that the use of different risk score models would lead to deviations in the uniformity of risk assessment which might diminish trust in the Shared Savings Program.

Response: We clarify that the current Shared Savings Program risk adjustment methodology calculates benchmark and performance year risk scores using the MA risk adjustment models that were applicable to the relevant calendar year. Under this approach, this may lead to situations in which benchmark and performance year risk scores are calculated under separate CMS–HCC risk score models. We proposed to revise the risk adjustment methodology to use the MA risk adjustment model that is applicable to the performance year to calculate both performance year and benchmark year prospective CMS–HCC risk scores. The proposed approach aims to ensure uniformity in risk assessment across multiple years by calculating prospective CMS–HCC risk scores using a consistent risk adjustment model.

After consideration of the public comments, we are finalizing our proposal to apply the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period, for ACOs in agreement periods beginning on or after January 1, 2024. We are finalizing our proposal to add a new section to our regulations at § 425.659 on calculating risk scores used in Shared Savings Program benchmark calculations, with minor modifications for grammar and clarity. We are also finalizing our proposal to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS–HCC risk adjustment methodology used to calculate prospective CMS–HCC risk scores under new § 425.659. Further, we are finalizing our proposal to add a new paragraph (a)(9)(vi) to § 425.652 to specify that we will redetermine factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1). We are finalizing as proposed a technical and conforming change to § 425.650(a), to revise the description of the benchmarking methodology applicable for agreement periods beginning before January 1, 2024, to include the new § 425.659 within the list of referenced sections.

5. Modifications to Advance Investment Payment Policies

a. Overview

In the CY 2023 PFS final rule (87 FR 69782 through 69805), we finalized a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, to receive advance shared savings payments. This payment option is referred to as advance investment payment (AIP) and the payments themselves are referred to as advance investment payments.

In that final rule, we explained that section 1899(i) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures (87 FR 69783 and 69784). In accordance with section 1899(i) of the Act, we determined that making advance investment payments to certain ACOs participating in the Shared Savings Program would improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program (*Id.*).

We established standards for an ACO's receipt and use of advance investment payments within the Shared Savings Program regulations at § 425.630 and specified requirements in connection with AIP in other sections within 42 CFR part 425. Such standards include: eligibility criteria to limit AIP to new, low revenue ACOs that are inexperienced with performance-based risk; application procedures and contents, including submission of a spend plan; policies governing use and management of payments; amount and frequency of payments, which are comprised of a one-time $250,000 upfront payment and up to 8 quarterly payments; the methodology for calculation of the quarterly payment amount based on the ACO's assigned population; termination of advance investment payments, as well as recoupment and recovery of advance investment payments; policies to monitor ACO eligibility for AIP; and ACO public reporting requirements regarding the use of advance investment payments.

In the CY 2024 PFS proposed rule (88 FR 52483), we proposed modifications to refine AIP policies to better prepare for initial implementation of AIP beginning with ACOs entering

agreement periods on January 1, 2024. In summary, we proposed to better support ACOs that are prepared to progress to performance-based risk by allowing ACOs to advance to two-sided model Levels within the BASIC track's glide path beginning in PY3 of the agreement period in which they receive advance investment payments (88 FR 52483). We also proposed to revise our policies for recoupment of advance investment payments from ACOs that wish to early renew and continue their participation in the Shared Savings Program (88 FR 52485). We proposed to specify that CMS would terminate quarterly advance investment payments in future quarters to ACOs that elect to terminate their participation in the Shared Savings Program (88 FR 52486). We proposed to require ACOs to report spend plan updates and actual spend information to CMS in addition to publicly reporting such information (88 FR 52484). Lastly, we proposed to codify that ACOs receiving advance investment payments may seek reconsideration review of all payment calculations (88 FR 52487). If finalized, we proposed that these policies would be effective beginning January 1, 2024 (88 FR 52488).

b. Modifications to AIP Eligibility Requirements to Allow ACOs to Advance to Performance-Based Risk During the 5-Year Agreement Period

(1) Background

The policies we finalized with the CY 2023 PFS final rule (87 FR 69404) require an ACO to remain under a one-sided risk model for the duration of its agreement period in which it receives advance investment payments to remain compliant with AIP requirements. The ACO would otherwise face potential compliance action and may be required to repay all advance investment payments within 90 days of receiving written notification from CMS. This limits an ACO's ability to select participation options that include progression along the BASIC track's glide path to a performance-based two-sided risk model. This policy arises from the interaction of numerous standards.

First, an ACO is eligible to receive advance investment payments if CMS determines that all of the following criteria are met: (1) the ACO is not a renewing or a re-entering ACO; (2) the ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program; (3) the ACO is inexperienced with performance-based risk Medicare ACO initiatives; and (4) the ACO is a low revenue ACO (§ 425.630(b)). An eligible ACO will receive a one-time upfront payment of $250,000 and quarterly payments each quarter for the first 2 performance years of the ACO's 5-year agreement period, totaling no more than 8 quarterly payments (§ 425.630(f)).

Second, under § 425.630(h), CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO is no longer inexperienced with performance-based risk Medicare ACO initiatives or is no longer a low revenue ACO. Section 425.316(e) specifies that if CMS determines during any performance year of the agreement period that an ACO receiving advance investment payments is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, and the ACO remains experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action, the ACO must repay all advance investment payments it received.

An eligible ACO that joins the Shared Savings Program in Level A of the BASIC track and opts to receive advance investment payments will be eligible for all 8 quarterly payments to be paid over PY1 and PY2, so long as the ACO remains in Level A (or progresses to Level B) in PY2 and remains inexperienced with performance-based risk Medicare ACO initiatives and a low revenue ACO. An ACO that joins the Shared Savings Program at Levels B through E of the BASIC track, however, will not be eligible to receive all 8 quarters of advance investment payments because current program regulations require that an ACO remain inexperienced with performance-based risk Medicare ACO initiatives while receiving advance investment payments (§ 425.630(h)(2)). More specifically, if an ACO receiving advance investment payments elects to participate at Level B of the BASIC track in PY1 progresses along the glide path to Level C for PY2, CMS would determine that the ACO is experienced with performance-based risk in PY2 and the ACO would no longer be eligible to receive advance investment payments during PY2.

In the CY 2023 final rule (87 FR 69787), we stated that advance investment payments were intended to assist smaller, community-based providers in forming high-performing ACO networks by providing much-needed startup capital that can be used to attract and maintain staffing, purchase healthcare delivery infrastructure and IT systems, and develop and implement a strategy to address the health needs of underserved communities. It is for this reason we restricted AIP eligibility to those ACOs that are inexperienced with performance-based risk. ACOs that are experienced with performance-based risk generally would not need advance investment payments to successfully participate in the Shared Savings Program as they have previously participated in the Shared Savings Program or certain Innovation Center models or CMS programs in which the ACO accepted risk for shared losses. In the CY 2024 PFS proposed rule, we proposed to modify program regulations to permit an ACO to progress to two-sided risk along the BASIC track's glide path within the agreement period while the ACO continues to benefit from advance investment payments.

(2) Revisions

We proposed to modify AIP eligibility requirements to allow an ACO receiving advance investment payments to transition to two-sided risk within its 5-year agreement period under the BASIC track's glide path. Specifically, we proposed to modify § 425.630(b)(2) and (3) to allow an eligible ACO receiving advance investment payments to advance to performance-based risk (by advancing from Level A or B to Level C, D, or E of the BASIC track's glide path) beginning in PY3 of the ACO's agreement period. We also proposed to modify § 425.316(e)(2) to specify that CMS will cease payment of advance investment payments if CMS determines that an ACO approved for AIP became experienced with performance-based risk Medicare ACO initiatives during the first or second performance year of its agreement period or became a high revenue ACO during any performance year of the agreement period in which it received advance investment payments. In accordance with § 425.316(e)(2)(ii), we may take compliance action against such ACOs. We also proposed to modify § 425.316(e)(2)(i) to specify that CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

Under the proposed approach, ACOs may choose to move into a two-sided risk participation option within the Shared Savings Program's BASIC track beginning in PY3 (and in subsequent performance years). These ACOs would still be required to repay advance investment payments through earned

shared savings over the remaining performance years of their agreement period as prescribed in § 425.630(g). We proposed that this policy would be effective January 1, 2024. Under this proposal, an ACO could not use advance investment payments to fund repayment mechanisms or repay shared losses. This limitation also reduces the risk that ACOs stretch themselves beyond their financial capacity while receiving advance investment payments by taking on large amounts of risk. Unlike other ACOs, ACOs receiving advance investment payments will have the additional financial obligation of repaying the advance investment payments if they misjudge their appetite for risk and leave the program mid performance period after incurring shared losses. These policies are intended to align with our goal to support the creation of new ACOs that need time and resource assistance to develop the infrastructure to operate an ACO that effectively manages patient care and lowers costs.

After 2 years of participation, new ACOs may have sufficient experience to be capable of taking on downside risk available in levels C–E of the BASIC track. As proposed, these modifications balance the risk of a new ACO taking on too much risk too quickly while allowing them to take on moderate risk as they develop more experience with the program.

Specifically, we proposed to amend the eligibility criteria specified in § 425.630(b) as follows. We proposed to revise the eligibility criterion at § 425.630(b)(2) to remove language stating that the ACO has applied to participate in the Shared Savings Program ''under any level of the BASIC track's glide path;'' the revised provision would simply state that ''CMS has determined that the ACO is eligible to participate in the Shared Savings Program.'' Further, we proposed to amend the criterion in § 425.630(b)(3) to specify that the ACO must be inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years but may participate in Levels of the BASIC track that would make it experienced with performance-based risk Medicare ACO initiatives starting with the third year of its first agreement period. Specifically, we proposed to specify in revisions to § 425.630(b)(3) that the ACO may participate in the Levels of the BASIC track's glide path as follows during the agreement period in which the ACO receives advance investment payments:

- For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.
- For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.
- For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

To illustrate the proposed policy, consider an ACO entering an agreement period beginning on January 1, 2024, that applies for and is determined to be eligible to receive advance investment payments. The ACO must participate in Level A for PY1. In PY2, the ACO may remain under Level A for all subsequent years of the agreement period in accordance with § 425.600(a)(4)(i)(C)(*3*) or may move to Level B. The ACO would receive advance investment payments for PY1 and PY2, receiving the one-time payment of $250,000 and the 8 quarterly payments. If the ACO remained at Level A for PY2, it could then transition to a higher level of risk and potential reward within the glide path for PY3 (that is, Levels B, C, D, or E) in accordance with § 425.600(a)(4)(i)(C)(*3*)(*iii*). If the ACO participated in Level B for PY2, it could automatically progress for PY3 to Level C (in accordance with § 425.600(a)(4)(i)(C)(*2*)) or elect to transition to Level D (in accordance with § 425.600(a)(4)(i)(C)(*2*)(*i*) and § 425.226(a)(2)(i)) or Level E (in accordance with § 425.600(a)(4)(i)(C)(*2*)(*i*) and § 425.226(a)(2)(i)) beginning with PY3.

Under this proposed modification, CMS will continue to recoup from future shared savings. In contrast to what is required under existing § 425.316(e)(3), the ACO will not be immediately obligated to repay all advance investment payments it received by virtue of its transition to a two-sided model in its third performance year or any subsequent performance year. We noted that under our proposal if an ACO opts to progress to a two-sided risk model (BASIC track's glide path Levels C through Level E) in PY2, CMS will terminate the ACO's advance investment payments, the ACO may be subject to compliance actions specified in §§ 425.216 and 425.218, and CMS may seek repayment of advance investment payments as set forth at § 425.316(e).

We solicited comments on our proposal to amend AIP policies and require that all ACOs receiving advance investment payments be inexperienced with performance-based risk Medicare ACO initiatives while the ACO receives advance investment payments—that is, during PY1 and PY2 of the agreement period—and to allow ACOs to progress to performance-based risk under the BASIC track's glide path beginning with PY3 of the same agreement period.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters largely supported CMS' proposal to allow ACOs receiving advance investment payments to progress along the glide path and move into a two-sided risk model beginning in PY 3 of the ACO's agreement period. Many commenters noted that this policy refinement will strengthen and enhance the Shared Savings Program and assist in meeting CMS' goal of having 100 percent of traditional Medicare beneficiaries in an accountable care relationship by 2030. Other commenters encouraged CMS to finalize this policy refinement, contending that advance investment payments will likely increase access to equitable care and reduce disparities in health outcomes in rural and underserved communities.

Response: We agree with commenters that this proposal will benefit the Shared Savings Program. Allowing ACOs receiving advance investment payments to move into a two-sided risk model beginning in PY 3 of their agreement period balances the risk of a new ACO taking on too much risk too quickly while allowing them to take on moderate risk as they develop more experience with the program, enabling ACOs receiving advance investment payments to progress along the BASIC track's glide path in a manner that works best for them. CMS expects this proposal will increase participation in the Shared Savings Program, especially among providers who practice in underserved communities, advance equitable access to quality care, and better health outcomes for ACOs' beneficiaries.

Comment: One commenter noted that allowing ACOs receiving advance investment payments to move into two-sided risk during the first agreement period provides greater flexibility for physician-led ACOs to participate in the Shared Savings Program. The commenter stated that this policy refinement will allow smaller practices to move into two-sided risk without the fear of having their advance investment payments immediately recouped.

Response: We agree with the commenter that this proposal will afford ACOs receiving advance investment payments the flexibility to move into a two-sided risk model later in their agreement period while continuing to

use advance investment payments in the remaining performance years of their initial agreement period without fear of immediate recoupment by CMS, which will support all ACOs, including physician-led ACOs and smaller practices that are part of ACOs.

Comment: One commenter shared that because ACOs receiving advance investment payments are required to repay all advance investment payments received in the first 2 years of their agreement period in their entirety, CMS should make the AIP payment option as expansive as possible. Other commenters encouraged CMS to consider expanding AIP eligibility to all ACOs regardless of their experience with performance-based risk Medicare ACO initiatives, whether they are a currently participating ACO or a renewing or re-entering ACO, or their status as a high revenue or low revenue ACO.

Response: We agree with the commenter that eligibility for advance investment payments should be expanded. This proposal supports that expansion and provides ACOs with increased flexibilities that should better support newly participating ACOs in their efforts to build and maintain a high-performing ACO. However, we disagree with commenters who suggest that all ACOs should be eligible for advance investment payments. As we stated in the CY 2023 PFS final rule (87 FR 69783 through 69785), expanding AIP eligibility to all ACOs or even all ACOs that can demonstrate need among their patient populations is not consistent with the purpose of AIP and would not be an appropriate use of the Trust Funds. AIP policy is based in part on the success of the ACO Investment Model, which primarily limited participation to ACOs who were (1) new to the Shared Savings Program; (2) did not include a hospital unless it was a critical access hospital or a small Inpatient Prospective Payment System (IPPS) hospital; and (3) were not owned or operated by a health plan. While these eligibility criteria do not exactly match the AIP eligibility criteria, the intent behind both sets of criteria is similar. In addition, advance investment payments are not intended to provide indefinite support to ACOs or to ACOs of all sizes, but to help provide start-up funding needed prior to earning shared savings for those ACOs that are most likely to face difficulty finding such funding.

As we previously explained, ACOs that are experienced with performance-based risk generally would not need advance investment payments to successfully participate in the Shared Savings Program as they have previously participated in the Shared Savings Program or certain Innovation Center models or CMS programs in which the ACO accepted risk for shared losses. Our experience administering the Shared Savings Program suggests that re-entering and renewing ACOs have alternative payment model experience and would not need, or benefit as significantly from, the start-up funds that advance investment payments provide because they have already invested in creating an ACO (see 87 FR 69784). They may also be able to leverage their experience to raise the necessary funds more easily than entities that are new and may primarily consist of ACO participants that are inexperienced with performance-based risk. Similarly, existing ACOs participating and earning shared savings have access to more resources to serve their aligned beneficiaries, and many existing ACOs already have health IT infrastructure in place to support and coordinate high quality care (87 FR 69786).

Advance investment payments are intended to advance shared savings to provide start-up funding for ACOs that are less well capitalized than a high revenue ACO, which should not need advance funding from CMS to increase staffing, improve healthcare infrastructure, and provide accountable care for underserved beneficiaries (87 FR 69786). By contrast, low revenue ACOs tend to be small, physician-led ACOs that are less well-capitalized organizations, and these ACOs may be encouraged to participate and remain in the program based on the availability of additional incentives, such as the opportunity to receive advance investment payments. For these reasons and the reasons stated elsewhere in this section, and to safeguard the Medicare Trust Funds, CMS will maintain more limited eligibility criteria at this time.

Comment: Other commenters requested that CMS further modify AIP eligibility requirements to include ACOs who have been designated as experienced with performance-based risk by participating in the ENHANCED track. The commenters noted that these ACOs may still lack the significant resources and infrastructure required to meaningfully address patients' health and social needs.

Response: We disagree with commenters that it would be appropriate to provide advance investment payments to an ACO that has been designated as experienced with performance-based risk Medicare ACO initiatives for the reasons stated previously in this section. We also disagree with commenters that it would be appropriate to provide advance investment payments to an ACO that is participating in the ENHANCED track. As we stated in the CY 2023 PFS final rule (87 FR 69786), ACOs in the BASIC track are typically less experienced with risk and are more likely to benefit from upfront funding or ongoing financial assistance, while ACOs in the ENHANCED track, given the level of risk involved in that track, are generally well established and confident in their ability to coordinate care for their beneficiary population. However, as described in section III.G.5.c of this final rule, in the event than an ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, and the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track, CMS will not seek to collect all advance investment payments received from an ACO in accordance with § 425.630(g)(4). CMS will carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period.

These ACOs also benefit from effective management and planning, and such ACOs would not need advance investment payments from CMS to increase staffing, improve healthcare infrastructure, and provide accountable care for underserved beneficiaries. We also note that we solicited comments as part of the RFI in the CY 2024 PFS proposed rule regarding how ACOs could better work with CBOs to address the unmet health and social needs of beneficiaries, and we will take the comments we received in response to that solicitation into consideration for future rulemaking. See section III.G.8.e of this final rule.

Comment: One commenter stated that all ACOs would benefit from AIP and would use the funds to invest in technology enhancements and account for resource expenditures resulting from the difficulty of keeping up with Shared Savings Program rules and guidance.

Response: We disagree with commenters who suggest that all ACOs should be eligible for advance investment payments for the reasons stated elsewhere in this section of this final rule. We also note that CMS furnishes annual program guidance based upon annual CMS rulemaking and updates those guidance materials with important and necessary program information for each upcoming performance year. These materials are

available to all ACOs. CMS guidance materials include proposed and final rule fact sheets, detailed explanations of program requirements and financial calculations, and a number of other materials found in the Application toolkit and the ACO Management System (ACO–MS) knowledge library. ACOs may also submit inquiries to the Shared Savings Program helpdesk. We also note that investments in new technologies, including those required to meet program standards, are generally necessary among all healthcare providers, including those not participating in the Shared Savings Program, to keep pace with the current standards of medicine and deliver high-quality, coordinated care to patients.

Comment: Other commenters suggested that CMS consider expanding AIP eligibility to existing ACOs that meet specific parameters. Specifically, commenters requested that CMS consider exceptions that would allow FQHCs, RHCs, and critical access hospitals (CAHs) to be eligible for AIP, even if they do not meet the current eligibility requirements regarding revenue and risk experience. Other commenters noted that the current eligibility criteria are overly limiting and exclude many safety net providers as a result. The commenters noted that these provider types still lack the significant resources and infrastructure required to meaningfully address patients' health-related and social needs, even if they are deemed high-revenue by CMS.

Response: We agree with commenters that FQHCs, RHCs, CAHs, and other safety net providers play an important role in addressing the healthcare and social needs of underserved communities. However, we disagree that revising the AIP eligibility criteria is necessary for FQHCs, RHCs, and CAHs to receive advance investment payments. AIP eligibility requirements are set forth at § 425.630(b). Section 425.630(b)(2) currently provides that an ACO must have applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and be eligible to participate in the Shared Savings Program to be eligible to receive advance investment payments. Section 425.102(a) states that CAHs that bill under Method II (as described in § 413.70(b)(3)), FQHCs, and RHCs are eligible to apply to participate in the Shared Savings Program. We remind commenters the Shared Savings Program currently includes these provider types among the 456 ACOs participating in CY 2023 (2023 Shared Savings Program Fast Facts: *https://www.cms.gov/files/document/2023-shared-savings-program-fast-facts.pdf*).

Moreover, as we explained in the CY 2023 PFS final rule (87 FR 69786), we disagree that the AIP eligibility criteria should include an exception for high revenue ACOs that include safety-net providers, such as CAHs, FQHCs, and RHCs, as ACO participants. This would result in many ACOs receiving advance investment payments that do not need access to start-up capital. The vast majority of FQHCs and RHCs participating in Shared Savings Program ACOs without a hospital are in low revenue ACOs, so the AIP eligibility criteria should not preclude them from receiving advance investment payments. We plan to monitor the impact of advance investment payments on ACO formation and program participation, including the impact on CAHs.

For the reasons explained in the previous discussion in this section of this final, we disagree with the commenters who suggested that CMS should revise the eligibility criteria to permit renewing or re-entering ACOs, currently participating ACOs, and ACOs that are experienced with performance-based risk Medicare ACO initiatives to receive advance investment payments.

Comment: Multiple commenters recommended that CMS allow new, high revenue ACOs to be eligible for AIP regardless of their geographic location or status as a safety net provider, contending that this approach is aligned with CMS' goal to increase participation in the program through AIP. A few commenters stated that the distinction between high and low revenue is ''artificial.'' Another commenter cited analysis that found there was no significant difference in high revenue and low revenue ACO performance. One commenter shared that current AIP eligibility requirements exclude Medicare beneficiaries who may experience negative health outcomes due to socioeconomic factors simply because they are attributed to a high revenue ACO. These commenters urged CMS to remove the requirement that an ACO be considered low revenue to be eligible for advance investment payments.

Response: We disagree with commenters about whether revenue status is an appropriate criterion to consider in determining AIP eligibility. As we explained previously in this section of this final rule, the intent of AIP is to advance shared savings to provide start-up funding for ACOs that are less well capitalized than a high revenue ACO. Low revenue ACOs tend to be small, physician-led ACOs that are less well capitalized than a high revenue ACO, and low revenue ACOs may be encouraged to participate and remain in the program based on the availability of additional incentives, such as the opportunity to receive advance investment payments.

In contrast to low revenue ACOs, high revenue ACOs should not need advance funding from CMS to increase staffing, improve healthcare infrastructure, and provide accountable care for underserved beneficiaries, including Medicare beneficiaries who may experience negative health outcomes due to socioeconomic factors, because they are more likely to be sophisticated organizations with access to additional funding through parent organizations or capital markets and are more likely to already have the resources needed to provide accountable care for underserved beneficiaries. In addition to having access to more capital, ACOs identified as high revenue have a higher degree of control over the healthcare of their assigned beneficiaries. Relative to low revenue ACOs, high revenue ACOs provide a larger proportion of the healthcare their beneficiaries receive. This is because the services high revenue ACOs provide to their beneficiaries account for a larger amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures (See § 425.20, ''High revenue ACO'' and ''Low revenue ACO''). They should therefore be in a better position to coordinate care for their beneficiaries. For further discussion of revenue status and other AIP eligibility criteria, we refer readers to our previous discussion in this section of this final rule and the CY 2023 PFS final rule (87 FR 69784 through 69786).

We also note that ACOs that meet the criteria set forth in § 425.630(b) are eligible to receive advance investment payments, regardless of their geographic location or status as a safety net provider. Separately, as we stated in the CY 2023 PFS final rule (87 FR 69803), we will continue to monitor and collect program data on advance investment payments and the AIP eligibility requirements. After data on how advance investment payments impact ACOs and their beneficiaries, including underserved beneficiaries, become available, CMS may revisit the AIP eligibility criteria in future rulemaking.

Comment: Some commenters noted that one barrier to increasing ACO participation in underserved communities is not including consideration of the level of need represented by their patient population in the AIP eligibility determination. Several commenters recommended CMS

consider other eligibility criteria which are more reflective of an ACO's level of capital and inclusive of the patient populations they serve. These commenters suggested that CMS consider the proportion of an ACO's assigned beneficiaries who meet the highest risk factors-based score when determining AIP eligibility (that is, those beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligibility for Medicare and Medicaid, or whose mailing addresses are matched to ADIs at or above the 85th percentile).

Response: We disagree with the comment that beneficiary need is not considered when we determine an ACO's eligibility for advance investment payments. As we explained in the CY 2023 PFS final rule (69785), re-entering and renewing ACOs are ineligible to receive advance investment payments partly because our experience administering the Shared Savings Program has shown us that these ACOs have already benefited from alternative payment model experience, and therefore, would be less likely to need financial support to develop programs targeting SDOH or to become operational. Similarly, as we explained previously in this section of this final rule, high revenue ACOs are ineligible to receive advance investment payments partly because, unlike low revenue ACOs, they are substantially better positioned to provide accountable care for underserved beneficiaries.

Comment: One commenter urged CMS to consider extending AIP eligibility to renewing or re-entering ACOs who have never achieved shared savings due to not having access to this type of up-front investment. Another commenter urged CMS to consider offering AIP opportunities for renewing, low revenue ACOs that require additional investment to sustain participation in the Shared Savings Program. The commenter noted this would be especially helpful for ACOs that have yet to earn shared savings and are caring for underserved populations.

Response: We remind commenters that advance investment payments are not intended to provide indefinite support to ACOs or to ACOs of all sizes, but to help provide start-up funding needed prior to earning shared savings for those ACOs that face difficulty finding such funding. Expanding AIP eligibility to all ACOs, including those that can demonstrate need among their beneficiary population, is not an appropriate use of the Medicare Trust Funds. For those reasons and the reasons explained previously in this section of this final rule, we disagree with the commenters who suggest we consider expanding AIP eligibility to certain renewing or re-entering ACOs.

For the reasons discussed above, we are finalizing the revisions we proposed at § 425.630(b) clarifying the AIP eligibility requirements and allowing the progression to performance-based risk for ACOs that receive advance investment payments beginning with PY 3 of the agreement period in which they received an advance investment payment. Under this finalized modification, CMS will continue to recoup from future shared savings. In contrast to what is required under existing § 425.316(e)(3), the ACO would not be immediately obligated to repay all advance investment payments it received by virtue of its transition to a two-sided model in its third performance year or any subsequent performance year. We note that under our proposal if an ACO opts to progress to a two-sided risk model (BASIC track's glide path Levels C through Level E) in PY2, CMS would terminate the ACO's advance investment payments, the ACO may be subject to compliance actions specified in §§ 425.216 and 425.218, and CMS may seek repayment of advance investment payments as set forth at § 425.316(e).

c. Modifications to AIP Recoupment and Recovery Policies for Early Renewing ACOs

(1) Background

In the CY 2023 PFS final rule (87 FR 69803 through 69805), CMS finalized program policies regarding recoupment and recovery of advance investment payments. In accordance with § 425.630(g)(4), if an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Paragraph (2) of the definition of ''renewing ACO'' at § 425.20 includes an ACO that continues its participation in the Shared Savings Program for a consecutive agreement period, without a break in participation, because it is an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. In prior rulemaking (see, for example, 83 FR 67885 through 67890), we have referred to this provision as allowing for an ''early renewal'' option. In developing the AIP policies in the PFS rulemaking for CY 2023, we did not address the potential interactions between the policy on recovery of advance investment payments specified in § 425.630(g) and a voluntary termination of the participation agreement by an ACO that is seeking to early renew.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52485), we proposed to amend § 425.630(g)(4) to create a limited exception to CMS's policy of recovering advance investment payments from an ACO that voluntarily terminates its participation agreement for the agreement period during which it received advance investment payments. Under this proposal, we would not seek to collect all advance investment payments received from an ACO in accordance with § 425.630(g)(4) if the ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, provided that the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track. Rather, we would carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period. ACOs who participate in the Shared Savings Program participate in either the Basic or Enhanced track for their entire agreement period. While all ACOs receiving advance investment payments must participate in the Basic track for their first agreement period, they have flexibility to begin a new agreement period and participate in either track while CMS recoups the payments from earned shared savings.

We proposed to allow an ACO approved for AIP to early renew its participation agreement before the expiration of its current agreement, as long as the ACO terminates its current participation agreement effective on or after December 31 of the ACO's second performance year. By requiring the ACO to maintain its current agreement period for the first 2 years, the ACO will receive all of its advance investment payments prior to renewing its participation agreement. We further proposed that in such circumstances, the early renewing ACO must continue to repay the advance investment payments through shared savings earned in the subsequent agreement period. If an ACO early renews prior to PY3, it will no longer comply with the eligibility requirements for receiving payments in § 425.630(b)(1) and may be

subject to compliance actions under §§ 425.216 and 425.218.

Section 425.630(e)(3) specifies that an ACO may spend advance investment payments over its entire agreement period and must repay to CMS any unspent funds remaining at the end of the ACO's agreement period. We proposed to amend § 425.630(e)(3) to permit an early renewing ACO to spend advance investment payments in its second agreement period so long as the advance investment payments are spent within 5 performance years of when it began to receive advance investment payments (that is, PY1 of its first agreement period). If the ACO does not spend all of the advance investment payments received by the end of the fifth performance year, the ACO must repay any unspent funds to CMS. The duration of spending advance investment payments was discussed in the CY 2023 PFS final rule (87 FR 69801).

As we stated in the CY 2024 PFS proposed rule (88 FR 52485), we anticipate these policy proposals would be most relevant to an ACO that is receiving advance investment payments and seeks to early renew to enter a new participation agreement to participate under modified Shared Savings Program policies that are not applicable to the ACO's current agreement period. For such an ACO, any remaining balance of advance investment payments owed would continue to be recouped from any shared savings the ACO earns in its new agreement period. Further, such an ACO would continue its participation in the Shared Savings Program without a lapse in participation and would be required to continue to adhere to all AIP requirements. Continued program participation aligns with our goals to improve the quality and efficiency of care. These policies provide ACOs the flexibility to participate in the Shared Savings Program in a manner that may work best for their structure and patient population without having to choose between immediately paying back the advance investment payments they received and being able to enter a new agreement with the Shared Savings Program. Some policy changes are applicable only to new agreement periods, and ACOs approved for AIP should have the opportunity to enter a new agreement to experience those changes. We are finalizing this proposal without modification, and it will be effective January 1, 2024.

We solicited comments on the proposed changes to § 425.630(e)(3) and (g)(4).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters were supportive of CMS' proposal to provide these additional flexibilities to ACOs that receive advance investment payments and wish to early renew their participation in the Shared Savings Program. One commenter shared that they appreciate CMS' proposal to allow ACOs receiving advance investment payments to early renew and not require immediate repayment of all advance investment payments received. The commenter contended that allowing ACOs to repay advance investment payments in the ACO's new agreement period allows the ACO to participate in the Shared Savings Program in the manner that works best for their structure and patient population. The commenter also supported CMS' proposal to allow an early renewing ACO that received advance investment payments to continue to spend advance investment payments in its second agreement period, provided that the funds are spent within 5 performance years of when it began to receive advance investment payments. One commenter noted that this policy refinement could ensure continued Shared Savings Program participation by ACOs in their initial agreement periods.

Response: We agree with commenters that allowing flexibility for early renewing ACOs that received advance investment payments in the agreement period they are terminating will provide incentives for continued participation in the Shared Savings Program. Allowing ACOs to carry advance investment payments over into a new agreement period will provide flexibility to these ACOs that they can use to maximize their shared savings potential and participate in the Shared Savings Program in a manner that may work best for their structure and patient population without having to choose between immediately paying back the advance investment payments they received and being able to enter a new agreement period.

Comment: Several commenters were supportive of CMS's proposals to allow ACOs that receive advance investment payments to early renew but made recommendations to CMS on refining our AIP recoupment policies. These commenters urged CMS to consider modifications to AIP recoupment and recovery policies, which currently dictate that CMS will recoup advance investment payments from all earned shared savings by an ACO until all advance investment payments are repaid. Several commenters urged CMS to consider a longer time period for recoupment of advance investment payments. One commenter noted that if an ACO that received advance investment payments was unable to achieve shared savings payments for a significant period, this existing policy may jeopardize the ACO's ability to maintain its infrastructure and investments to support care coordination and performance improvement efforts. This commenter recommended a more gradual repayment that allows the ACO to retain a portion of earned shared savings during the performance year, noting that ACOs often reinvest earned shared savings to improve care quality and efficiency of care delivery.

Response: As we explained in the CY 2023 PFS final rule (87 FR 69804 through 69805), AIP recoupment begins the first performance year of the agreement period in which the ACO achieves shared savings, and any advance investment payments that are not recouped in the first agreement period would continue into the ACO's next agreement period and subsequent agreement periods if an AIP balance persists. We disagree with commenters that a longer recoupment period would be appropriate. As we explained in the CY 2023 PFS final rule, we view our AIP recoupment policy as a critical measure necessary to ensure the adequate protection of the Medicare Trust Funds regardless of the characteristics of the ACO's provider composition, aligned beneficiary population, and financial or quality performance. Immediately recouping these funds from earned shared savings should not disadvantage any ACOs as they will be receiving quarterly payments for the first 2 years. Regarding the commenters who advocated that ACOs should be able to retain a portion of their advance investment payments, we note that the advance investment payments are not intended to supplement FFS payments, but rather provide start-up capital out of expected future shared savings to be used by new ACOs to provide sufficient resources for staffing, providing accountable care for underserved beneficiaries, and investing in healthcare delivery infrastructure.

After consideration of public comments, we are finalizing our proposed changes to AIP recoupment and recovery policies for early renewing ACOs. We are finalizing our proposed revisions to § 425.630(e)(3), with modifications for improved clarity. We are finalizing without modification our proposed revisions to § 425.630(g)(4).

In summary, we anticipate these finalized policy changes would be most

relevant to an ACO that is receiving advance investment payments and seeks to early renew to enter a new participation agreement to participate under modified Shared Savings Program policies that are not applicable to the ACO's current agreement period. For such an ACO, any remaining balance of advance investment payments owed would continue to be recouped from any shared savings the ACO earns in its new agreement period. Further, such an ACO would continue its participation in the Shared Savings Program without a lapse in participation and would be required to continue to adhere to all AIP requirements. These finalized policies will be effective January 1, 2024.

d. Amendments to Termination Policies To Allow CMS To Cease Distribution of Advance Investment Payments Following an ACO's Notification of Voluntary Termination

(1) Background

In the CY 2023 PFS final rule (87 FR 69803), we finalized policies for termination of advance investment payments at § 425.630(h). Section 425.630(h)(1) specifies that CMS may terminate an ACO's advance investment payments if the ACO fails to comply with the requirements of § 425.630 or meets any of the grounds for ACO termination set forth in § 425.218(b). However, we did not address the termination of advance investment payments if an ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). This created ambiguity regarding whether CMS would continue to make quarterly advance investment payments to an ACO that voluntarily terminates its participation agreement in accordance with § 425.220(a) and does not immediately enter a new agreement period. We are concerned that the continued payment of advance investment payments in such a case would not serve the purpose for which CMS is making such payments and would create unnecessary program integrity risks for the Shared Savings Program. In such a case, CMS would be knowingly paying funds to the ACO that will need to be repaid upon termination.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52485), we proposed to permit CMS to terminate advance investment payments for future quarters to an ACO that has provided CMS with notice of termination in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This avoids distributing advance investment payments to an ACO from which CMS would subsequently need to recover such payments. Specifically, we proposed to add § 425.630(h)(1)(iii), which allows CMS to terminate an ACO's advance investment payments when the ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). We also proposed conforming changes to the punctuation of the list of factors in paragraphs (h)(1)(i) and (ii) of § 425.630. These proposed changes would be effective January 1, 2024.

We solicited comments on this proposal. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed appreciation of CMS' proposed policy revisions to terminate advance investment payments made to an ACO in the case of voluntary termination. Commenters noted that this revision aligns with the policy for ceasing advance investment payments for other causes of termination and protects the Medicare Trust Funds. One commenter suggested that CMS consider the reasons for termination and investments made by the ACO when requiring terminated ACOs to pay back all advance investment payments received.

Response: We agree with commenters that ceasing advance investment payments to ACOs that inform CMS of their intent to terminate their participation agreement is necessary to safeguard the Medicare Trust Funds. We disagree with the commenter who suggested that CMS consider the reasons for the ACO's termination before requiring the repayment of all advance investment payments received. As we stated previously in this section of this final rule, recoupment of advance investment payments is a critical measure necessary to ensure the adequate protection of the Medicare Trust Funds regardless of the characteristics of the ACO's provider composition, aligned beneficiary population, and financial or quality performance. By requiring immediate repayment of advance investment payments upon early termination, we also reduce the risk that ACOs will voluntarily terminate their participation agreements to avoid repayment of advance investment payments.

After consideration of public comments, we are finalizing this proposal without modification. Beginning January 1, 2024, CMS will cease paying advance investment quarterly payments to any ACO that voluntarily terminates its participation agreement in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This policy revision is consistent with § 425.630(g)(4), which requires such an ACO to repay all advance investment payments within the 90 days after receiving notice of the amount due to CMS.

e. Requirements for ACOs To Report to CMS Spend Plan Updates and Use of Advance Investment Payments

In the CY 2023 PFS final rule (87 FR 69786 through 69788), CMS finalized program policies to require ACOs that receive advance investment payments to submit a spend plan to CMS as a part of their Shared Savings Program application (§ 425.630(d)(1)). In accordance with § 425.630(d)(3), CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the spend plan requirements specified at § 425.630(d)(2) and the requirements for use and management of advance investment payments at § 425.630(e).

In the CY 2023 PFS final rule (87 FR 69801 and 69802), we also finalized requirements at § 425.308(b)(8) that an ACO receiving advance investment payments must publicly report information, updated annually, about the ACO's use of advance investment payments for each performance year, including the following:

- The ACO's spend plan.
- The total amount of any advance investment payments received from CMS.
- An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under § 425.630(d), and such other information as may be specified by CMS.

These provisions do not require an ACO to submit this same information to CMS. To support CMS's ability to monitor AIP efficiently, in the CY 2024 PFS proposed rule (88 FR 52486), we proposed that an ACO must report to CMS the same information about its use of advance investment payments that it is required to publicly report under § 425.308(b)(8).

To ensure that § 425.630 sets forth the complete requirements applicable to an ACO's obligation to report information on its receipt and use of advance investment payments, we proposed to add a new provision at § 425.630(i) specifying that an ACO must (1) publicly report information about the ACO's use of advance investment

payments for each performance year in accordance with § 425.308(b)(8); and (2) in a form and manner and by a deadline specified by CMS, report to CMS the same information it is required to publicly report in accordance with § 425.308(b)(8).

We expect that these proposed changes would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use of advance investment payments. We anticipate that these proposed changes will impose little to no administrative burden on participating ACOs, which are already required to publicly report this information by § 425.308(b)(8). Further, we expect to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden for ACOs. These proposed changes would be effective January 1, 2024.

We solicited comments on this proposal. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposal to require ACOs receiving advance investment payments to report the same information to CMS as is reported publicly on the ACOs public reporting website page. Another commenter noted that AIP reporting will require additional steps for the ACOs who have elected to receive advance investment payments. The commenter cautioned CMS to consider ways to reduce any extra reporting steps and instead allow for increased flexibility for reporting on advance investment payments and AIP spend plans.

Response: We agree with commenters that the information ACOs publicly report about their use of advance investment payments must be consistent with the information the ACOs provide to CMS. This proposal ensures that CMS receives the same information ACOs publicly account for advance investment payments received and their actual advance investment payment spending by category (that is, increased staffing, healthcare infrastructure and provisions of accountable care by underserved beneficiaries) and thereby supports CMS's monitoring of ACOs' use of advance investment payments. While CMS is mindful of reporting burden, this proposal supports our program integrity and monitoring efforts, and the administrative burden on participating ACOs should be minimal because they are already required to publicly report this information by § 425.308(b)(8). We remind the commenters that we expect to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden on ACOs. In the future, CMS will consider ways to further ease the reporting burden on ACOs receiving advance investment payments.

Comment: One commenter shared that AIP could be leveraged by ACOs to enhance sociodemographic data collection, create targeted initiatives to reduce health disparities, and develop relationships with community-based organizations (CBOs) to address social needs. In short, the commenter suggested that advance investment payments could accelerate the investments and infrastructure for existing ACOs to build health equity programs, including data collection on the social determinants of health of beneficiaries.

Response: We agree with the commenter that AIP could provide an opportunity to collect sociodemographic data on beneficiaries in the Shared Savings Program if necessary to implement initiatives focused on increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health as required in § 425.630(e)(1). We note that advance investment payments must be used consistent with all applicable laws and regulations, including applicable anti-discrimination laws. We also agree with the commenter that advance investment payments could assist in providing coordinated care to underserved populations, and we agree that advance investment payments could be valuable in enabling clinical practices to partner with CBOs when identifying and providing care to underserved beneficiaries, which we note may include those who are impacted by SDOH factors that contribute to poor health outcomes. In the future, after advance investment payments are implemented in PY 2024, we will monitor how advance investment payments impact ACOs and their beneficiaries, including how ACOs use the funds. We intend to expand access to accountable care in underserved communities and will continue to refine and improve the Shared Savings Program to encourage ACO participation.

After consideration of public comments, we are finalizing as proposed the addition of a new provision at § 425.630(i). This finalized change will help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use of advance investment payments.

f. Permitting Reconsideration Review of Quarterly Payment Calculations

(1) Background

In the CY 2023 PFS final rule (87 FR 69795 and 69796), we specified that an ACO can request a reconsideration review if CMS does not make an advance investment payment to the ACO under subpart I of part 425 (§ 425.630(f)). However, we did not specify that an ACO could request reconsideration of the amount of the advance investment payments.

(2) Revisions

In the CY 2024 PFS proposed rule (88 FR 52487), we proposed to permit an ACO to request a reconsideration review for all AIP quarterly payment calculations, not just instances where no payments are distributed. We proposed to revise § 425.630(f) to provide that CMS would notify in writing each ACO of its determination of the amount of the advance investment payments it will receive and that such notice would inform the ACO of its right to request reconsideration review in accordance with the procedures specified under 42 CFR part 425, subpart I. We solicited comments on this proposal.

We received several public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: All commenters supported CMS' proposed policy refinement. Commenters also suggested that CMS provide payment details far enough in advance to allow sufficient time to resolve reconsideration reviews and avoid delayed payments to ACOs.

Response: We appreciate the commenter's support of our proposed policy. CMS intends to provide payment details as quickly as operationally possible to avoid delays in payment of advance investment payments.

After consideration of public comments, we are finalizing as proposed the revision of § 425.630(f) without modification.

6. Shared Savings Program Eligibility Requirements

a. Overview

We proposed two modifications to the Shared Savings Program eligibility

requirements that will be implemented on January 1, 2024. Specifically, we proposed the following, which are discussed in more detail in sections (b) and (c) below:

- Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.
- Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the 5 most recent performance years.

b. Shared Governance Requirement

(1) Background

In the November 2011 final rule (76 FR 67819), we finalized policies that require an ACO to establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO, and we codified the governing body policies at § 425.106. Specifically, § 425.106(c)(3) mandates that at least 75 percent control of an ACO's governing body must be held by ACO participants. An ACO's governing body is responsible for providing ACO leadership, strategic direction, and oversight for operational management towards meeting the goals of the ACO, including better care, healthy communities, and reduced spending. This responsibility incorporates not only the delivery of improved healthcare, but also the promotion of evidence-based healthcare practices, improved engagement of patients and caregivers, reporting on quality and cost, provision of high-quality care to beneficiaries, and the distribution of shared savings, among other functions. In the November 2011 final rule (76 FR 67819), we indicated our belief that this requirement allowed for Medicare-enrolled entities that directly provide health care services to beneficiaries to drive decision-making, while recognizing that partnerships with non-Medicare enrolled entities outside this 75 percent composition allow these participants access to capital and infrastructure needed for an ACO. This physician-driven leadership is balanced by the remaining percentage of the governing body that is made up of patient advocates, accounting, legal and other professionals that support administrative duties and other functions of the ACO.

We affirmed in the November 2011 final rule (76 FR 67820) our belief that the 75 percent participant control requirement is necessary to ensure that ACOs are provider-driven, innovative in care delivery and strike an appropriate balance to incentivize and empower ACO participants to be accountable for the success of the ACO's operations and improve the health outcomes of their beneficiaries. Previously, commenters expressed concern that the 75 percent participant control threshold is overly prescriptive and may hinder operations, conflict with IRS and State tax laws, and restrict access to capital for the ACO. ACOs requested flexibility to develop their own governing body composition to meet the unique leadership needs of the ACO. In response to these comments, CMS granted an exception process for an ACO that wishes to structure its governing body in a manner that does not meet the 75 percent participant control threshold as required under § 425.106(c)(3). Under the exception process defined at paragraph (c)(5), an ACO must describe why it seeks to differ from the 75 percent participant control threshold and how the ACO will involve ACO participants in innovative ways in ACO governance. If the exception is granted by CMS, an ACO can form a governing body with less than 75 percent participant control.

In the December 2014 Medicare Shared Savings Program proposed rule (79 FR 72776) we proposed to revise § 425.106(c)(5) to remove the flexibility for ACOs to deviate from the requirement that at least 75 percent control of an ACO's governing body must be held by ACO participants. We stated that, through program implementation, we learned that ACO applicants do not have difficulty meeting the requirements under § 425.106(c)(3) that ACO participants maintain 75 percent control of the governing body. We also noted that since CY 2012, we had not denied participation to any ACO applicants solely based on failure to comply with this requirement and no exceptions have been granted by CMS under § 425.106(c)(5). Furthermore, we affirmed the 75 percent participant control requirement to be ''necessary and protective of the ACO participant's interests'' and thus, that there was no reason to continue to offer an exception to the rule.

During the public comment period for the December 2014 Medicare Shared Savings Program proposed rule, several commenters advocated for retaining the flexibility offered at § 425.106(c)(5), stating that an ACO may elect to utilize the exception in the future. In our response, we noted that our program experience thus far had not suggested that commenters' concerns that laws concerning the composition of tax-exempt or State-licensed entities would interfere with their ability to meet the 75 percent participant control threshold would impact their compliance with this requirement. However, since implementation of the requirement remained in the early stages and we had limited applicability with ACOs in two-sided risk tracks, we declined to finalize the proposal in the June 2015 final rule (80 FR 32719) and elected to retain the flexibility at § 425.106(c)(5). In the final rule, we noted that we anticipated granting such exceptions only in limited circumstances (that is, an ACO being unable to meet the 75 percent participant control requirement because it conflicts with other laws) and might revisit this issue in future rulemaking.

(2) Revisions

We continue to believe that ACO participants should drive ACO leadership to move toward improved quality of care and patient outcomes, and that this is a key component of ACO success and ability to earn shared savings. The 75 percent participant control threshold is critical to ensuring that governing bodies are participant-led and best positioned to meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and infrastructure for ACO formation and administration.

Over the years, a few ACOs have requested an exception to form a governing body with less than 75 percent participant control. CMS discussed the exemption requests with the interested ACOs and ultimately most ACOs adjusted to comply with the 75 percent participant control requirement. As noted in the proposed rule, we believed that no ACO had been granted an ACO an exception to this requirement, despite the flexibility provided in current regulation. Accordingly, we believed that there was no reason to continue to offer an exception to the requirement. Thus, we proposed to remove the option under § 425.106(c)(5) for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants. Additionally, we proposed a corresponding revision to § 425.204(c)(3) to remove the option for ACOs to request an exception to the 75 percent control requirement under § 425.106(c)(3) as part of their Shared Savings Program applications.

We solicited comments on the appropriateness of our proposed policy refinement and elimination of the exception process. As stated in the CY 2024 PFS proposed rule, the proposed modification to § 425.106(c) would make no changes to paragraphs(c)(2), (3) and (4). We also proposed to amend § 425.106(c)(5) to remove reference to paragraph (c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. Specifically, in our proposal the revised regulation text would state that in cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries. Additionally, we proposed to amend § 425.204(c)(3) to remove references to § 425.106(c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. We proposed that these amendments would become effective on January 1, 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters largely supported our proposal to remove the option for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants. Commenters noted they believe the threshold was appropriate, attainable, and important to ACO care delivery. Other commenters also noted that they believe that it is important to ACO participant involvement and supported centering practitioners in ACO governance.

Response: We agree with the majority of commenters who stated that it was appropriate to remove the exception to meeting the requirement that 75 percent control of the ACO's governing body must be held by ACO participants. We agree with commenters about the importance of ACO participant governance and that it is attainable. We believe that this requirement is necessary and protective of the ACO participants' interests and does not believe that it is necessary to grant exceptions to this requirement.

Comment: One commenter did not support removing the exception and wanted ACOs to retain the ability to make this request. Another commenter contested the statement that CMS has never issued an exception to the 75 percent control threshold, as they had worked with ACOs who believe they have received such an exception.

Response: We disagree with the commenter who wants to retain the exception for the meeting the 75 percent participant control threshold as we do not believe it is necessary for ACO participation as noted above. However, in response to the comment regarding previously issued exceptions, we reviewed all previous application data and discovered 3 ACOs operating with an exception to the 75 percent threshold and 2 that had an exception at the start of their agreement period but are currently meeting the threshold. While CMS failed to identify these ACOs in the proposed rule and the assertion that approvals had never occurred was cited by several supporting comments, these previously issued exceptions do not change our belief that exceptions to this requirement should no longer be permitted. To reduce disruption for the few ACOs who do not currently meet the requirement, we are finalizing this policy with the modification that the exception will be permitted only for agreement periods beginning before January 1, 2024.

After consideration of the public comments, we are finalizing our proposal with modification, to specify that the option under § 425.106(c)(5) for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants is applicable only to agreement periods beginning before January 1, 2024.

Additionally, we are finalizing with modification the proposed changes to § 425.204(c)(3). We are finalizing revisions to § 425.204(c)(3)(iii) to limit the option for ACOs to request an exception to the 75 percent control requirement under § 425.106(c)(3), as part of their Shared Savings Program applications, to agreement periods beginning before January 1, 2024. Further, we are finalizing a technical change to § 425.204(c)(3)(ii), to provide a more complete cross-reference to § 425.106(c)(2), for clarity and consistency.

c. Identifying ACOs Experienced With Risk Based on TINs' Prior Participation

(1) Background

In the December 2018 final rule, we added a new paragraph (d) under § 425.600 to set forth the participation options for ACOs that are experienced or inexperienced with ''performance-based risk Medicare ACO initiatives'' (which is defined at § 425.20 to include certain Innovation Center ACO models, as well as two-sided risk tracks of the Shared Savings Program). We also finalized the definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' (83 FR 68062). These definitions classify ACOs by experience level based on the percentage of ACO participant TINs that participated in performance-based risk Medicare ACO initiatives during a 5-year lookback period. However, current regulation text does not specify how CMS determines whether an ACO participant TIN has ''participated'' in a performance-based risk Medicare ACO initiative. To improve clarity of the regulations, we proposed to codify our existing program policy under which an ACO participant TIN is considered to have participated in a performance-based risk Medicare ACO initiative if it was or will be included in financial reconciliation for a performance year under such initiative during any of the 5 most recent performance years.

Under the December 2018 final rule, an ACO is ''inexperienced with performance-based risk Medicare ACO initiatives'' (and therefore, eligible to enter an agreement period under the BASIC track's glide path), if less than 40 percent of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''each'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date, and the ACO legal entity has not participated in any performance-based risk Medicare ACO initiative (83 FR 67895). Similarly, an ACO is ''experienced with performance-based risk Medicare ACO initiatives'' if 40 percent or more of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''any'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date (83 FR 67895). Thus, if 40 percent or more of the entities on an ACO participant list participated in a performance-based risk Medicare ACO initiative in a single performance year within the 5 most recent performance years, we would determine that the ACO meets the definition of ''experienced with performance-based risk Medicare ACO initiatives.'' Conversely, we would determine that an ACO satisfies the definition of ''inexperienced with performance-based risk Medicare ACO initiatives'' only if it is below the 40 percent threshold in all of the 5 most recent performance years prior to the ACO's agreement start date. In other words, an ACO is

inexperienced with performance-based risk Medicare ACO initiatives as long as it does not meet the definition of ''experienced with performance-based risk Medicare ACO initiatives'' in any of the five most recent performance years prior to the ACO's agreement start date. We chose to use a 5-year lookback period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives for a number of reasons, including that it could reduce the incentive for organizations to wait out the period in an effort to establish a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies.

We recognized that some ACOs or TINs in performance-based risk Medicare ACO initiatives participate for only part of a performance year, but our current regulation text does not specify the duration of participation required for CMS to determine that an ACO participant TIN has participated in a performance-based risk Medicare ACO initiative.

(2) Revisions

We proposed to codify the current operational approach for determining whether an ACO participant has participated in a performance-based risk Medicare ACO initiative. Under our current operational approach, an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if its TIN was or will be used to calculate financial reconciliation for the entity participating in such ACO initiative (''Initiative ACO''). In general, if an ACO participant was included on an Initiative ACO's participant list for a performance year during the 5 most recent performance years before the ACO's agreement start date, and the Initiative ACO is, or will be, financially reconciled for that performance year, the ACO participant will be considered to have participated in the Initiative ACO. This will generally be true regardless of whether the entity leaves the Initiative ACO mid-performance year because its claims experience would still be used in the Initiative ACO's alignment and financial reconciliation for that performance year. If the ACO participant was included on an Initiative ACO's participant list for a performance year during the lookback period, but the ACO voluntarily terminates before the deadline for reconciliation or is otherwise not eligible for reconciliation, the ACO participant will not be considered to have experience with risk because its claims experience would not be used for financial reconciliation.

Except for determinations made regarding AIP ACOs for purposes of § 425.316(e)(2), we determine whether an ACO is experienced with performance-based risk Medicare ACO initiatives prior to the start of an ACO's agreement start date. At the time we make these determinations, the ACO may be in the middle of a PY for which reconciliation has not yet occurred. Nevertheless, we believe that at the time we make these determinations, we have the information necessary to determine whether an ACO or ACO participant TIN will be included in financial reconciliation for a PY in the relevant Medicare ACO initiative because this issue is addressed in the terms of each Medicare ACO initiative. For example, as outlined in § 425.221(b)(2)(ii)(A), if an ACO in a two-sided model terminates from the Shared Savings Program after June 30th of a PY, they will be held responsible for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. Any ACO participant TIN that was included on the participant list for that performance year will have been included in beneficiary alignment and their claims experience used to calculate the benchmark and performance year expenditures. For other Medicare ACO initiatives, the terms of the participation agreement specify when the ACO is subject to reconciliation and which TINs will be included in reconciliation.

We proposed to modify the existing definitions for ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' at § 425.20 to include the following new sentence at the end of each definition: An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years. We also proposed a technical correction to remove the language ''as defined under this section'' from both definitions. We proposed that these amendments would become effective on January 1, 2024.

We solicited comments on the proposed regulation text.

The following is a summary of the comments received on the proposal to codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the 5 most recent performance years and our responses:

Comment: Commenters supported the proposal to codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the 5 most recent performance years. Multiple commenters appreciated CMS' transparency regarding program operations.

Response: We thank the commenters for their support and agree that aligning the definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' with current operational methodologies will bring increased clarity and transparency around the determination of experience level.

Comment: While multiple commenters appreciated the additional detail this proposal provides regarding TIN risk experience determination, they requested further clarification on the methodology described. One commenter asked how a determination of experience would be made if a portion of a TIN has participated in performance-based risk Medicare ACO initiatives during the 5 most recent performance years. In particular, they asked if a TIN would be classified as experienced if one participant in the TIN previously participated in ACO REACH, where participation is determined at the TIN/NPI level. Other commenters advocated for a process where ACOs could submit a reconsideration review if an ACO participant TIN has been determined to have participated in an Innovation Center ACO Model based on a small percentage of NPIs billing under the TIN for a split-TIN model. Both sets of commenters providing these additional suggestions advocated for CMS to align the experience thresholds at the ACO and TIN levels, meaning a TIN would only be considered experienced if 40 percent or more of the NPIs billing under the TIN participated in any performance-based risk Medicare ACO initiatives.

Response: We thank the commenters for their support to codify the existing operational approach around TIN

experience determination. As the commenters stated, the Shared Savings Program identifies participants using full TINs, which requires all individuals and entities that have reassigned their right to receive Medicare payment to the TIN of an ACO participant to participate in the ACO and comply with program requirements (82 FR 53689). As stated in the December 2018 final rule, we believe that defining ACO participants to include all NPIs that have reassigned their billing rights to the TIN is a means to allowing the ACO's redesigned care processes to more broadly reach all Medicare FFS beneficiaries that may receive care from ACO participants, including those that may not meet the program's assignment criteria, and provides incentives for lower performing providers within an ACO participant TIN to improve (83 FR 67874). Additionally, NPIs who have participated in a risk-based arrangement can help facilitate care redesign within their TIN, better preparing the TIN to join a ACO taking on risk. The impact of ACO participant experience can be seen in the shared savings results. Of the ACOs that newly joined the Shared Savings Program in 2022, 88 percent of the ACOs considered experienced with performance-based risk earned shared savings in the first performance year in comparison to 46 percent of the ACOs that were considered inexperienced with performance-based risk.

After consideration of public comments, we are finalizing without modification the proposed changes to the definitions for ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' at § 425.20. We believe these changes will improve ACO understanding of our current operational policies.

7. Technical Changes to References in Shared Savings Program Regulations

a. References to an ACO's Assignment Methodology Selection

Section 1899(c)(2)(A) of the Act, as amended by the Bipartisan Budget Act of 2018, provides all ACOs with a choice of prospective assignment for agreement periods beginning on or after January 1, 2020. In the December 2018 final rule (83 FR 67859 through 67863), we finalized modifications to the Shared Savings Program's regulations, to separate the choice of beneficiary assignment methodology from the choice of participation track (financial model). We also added a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections (see 83 FR 67857 through 67859). In accordance with § 425.226, before the start of a performance year an ACO may make elections related to its participation in the Shared Savings Program, including selection of its beneficiary assignment methodology, which will be effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election. Section 425.226(a)(1) specifies that an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of the Shared Savings Program regulations. An ACO may select either of the following: (i) preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2); or (ii) prospective assignment, as described in § 425.400(a)(3).

For consistency, in the December 2018 final rule (83 FR 67859 through 67863), we also finalized conforming changes to regulations that previously identified assignment methodologies according to participation track. Among other changes to the Shared Savings Program regulations, we added § 425.400(a)(4)(ii) to establish that for agreement periods beginning on July 1, 2019, and in subsequent years, the ACO may select the assignment methodology CMS employs for the assignment of beneficiaries. As specified in § 425.400(a)(4)(ii)(B), this selection of assignment methodology is made prior to the start of each agreement period and may be modified prior to the start of each performance year as specified in § 425.226 (83 FR 67863).

Although §§ 425.226(a)(1) and 425.400(a)(4)(ii) both reference assignment methodology selection, there are key differences in the purpose each section serves in directing action from the ACO versus action that CMS initiates. Section 425.226 states that the initial selection of, and any annual selection for a change in, beneficiary assignment methodology by an ACO must be made in the form and manner and according to the timeframe, that we establish. Therefore, § 425.226(a)(1) is the relevant regulation for referencing the ACO's option to select and to change its selection of assignment methodology. That is, § 425.226 describes actions for which the ACO is responsible because the ACO is selecting the assignment methodology that will be effective at the beginning of the ACO's agreement period or making a change to the ACO's prior assignment methodology selection that will become effective at the beginning of the next performance year.

In comparison, § 425.400 outlines how we employ the assignment methodology described in §§ 425.402 and 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment. Therefore, § 425.400(a)(4)(ii) is the relevant regulation for referencing how we determine the assignment methodology to be used in the referenced program operations or program calculations. That is, § 425.400(a)(4)(ii) governs actions undertaken by us because we are applying the ACO's selected assignment methodology when determining benchmarking, preliminary prospective assignment, retrospective reconciliation, and prospective assignment.

Throughout the current Shared Savings Program regulations text, there are various references to § 425.226(a)(1) or § 425.400(a)(4)(ii). We conducted a review of the Shared Savings Program regulations text to determine whether the existing 12 references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) align with provisions' intended purposes. We also considered the intended purposes of the provisions in identifying the appropriate cross-reference to include in the proposed new regulation at § 425.655, which is described in section III.G.4.b. of this final rule.

We believe the following five references to § 425.400(a)(4)(ii) are consistent with the intended purpose of § 425.400(a)(4)(ii) because they refer to how we determine the ACO's chosen assignment methodology for purposes of determining beneficiary assignment or performing certain program calculations: § 425.609(c)(1); § 425.652(a)(5)(v)(A) and (b)(2)(iv)(A); § 425.654(a)(1)(i); and § 425.656(b)(3).

We believe the following two references to § 425.226(a)(1) are consistent with the intended purpose of § 425.226(a)(1) because the references are used when referring to the ACO's option to change its selection of assignment methodology: § 425.601(a)(9) introductory text; and § 425.652(a)(9) introductory text.

We identified five inconsistencies in references to §§ 425.226(a)(1) and 425.400(a)(4)(ii) that we proposed to revise in the CY 2024 PFS proposed rule (see 88 FR 52490). To follow is a description of the five references that we proposed to revise in 42 CFR part 425, subpart G to ensure that the appropriate assignment selection reference is being cited, for clarity and consistency.

For performance years starting on January 1, 2019, and subsequent

performance years, we add beneficiaries to an ACO's list of assigned beneficiaries based on a beneficiary's designation of an ACO professional as the provider or supplier they consider responsible for coordinating their overall care, if certain conditions are satisfied, including the conditions specified in § 425.402(e)(2)(ii)(A). In accordance with § 425.402(e)(2)(ii)(A), the beneficiary must meet the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). Further, § 425.402(e)(2)(ii)(A) specifies that the exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under § 425.402(e), regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii). The citation to § 425.400(a)(4)(ii) in § 425.402(e)(2)(ii)(A) is not consistent with the intended purpose of the reference, which is to refer to the ACO's option to change its assignment methodology selection. Therefore, in the CY 2024 PFS proposed rule (88 FR 52490), we proposed to amend § 425.402(e)(2)(ii)(A) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

The introductory text of § 425.601(a) (applicable to agreement periods beginning on or after July 1, 2019, and before January 1, 2024) and of § 425.652(a) (applicable to agreement periods beginning on January 1, 2024, and in subsequent years) specify that in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, we determine the per capita Parts A and B FFS expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). Accordingly, the introductory text in § 425.601(a) and in § 425.652(a) is describing how we will compute expenditures for beneficiaries that would have been assigned to the ACO based on the assignment methodology selected by the ACO. These provisions are referring to how we determine the assignment methodology to be used to identify the beneficiary population that would have been assigned in the three benchmark years, not to the ACO's act of selecting the assignment methodology. Therefore, in the CY 2024 PFS proposed rule (see 88 FR 52490), we proposed to amend the introductory text of § 425.601(a) and of § 425.652(a) by removing the references to § 425.226(a)(1) and adding in their place references to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(ii) specifies that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.226(a)(1). In § 425.652(a)(9)(ii), the reference to § 425.226(a)(1) is not consistent with the intended purpose of the reference, which is to specify how we determine the assignment methodology that will be used to identify the assigned beneficiary and assignable beneficiary populations for purposes of redetermining the regional adjustment amount in the event the ACO changes its selected assignment methodology for a performance year. Therefore, in the CY 2024 PFS proposed rule (88 FR 52490), we proposed to amend § 425.652(a)(9)(ii) by removing the reference to § 425.226(a)(1) and adding in its place the reference to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(iv) describes that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology under 42 CFR part 425, subpart E. In § 425.652(a)(9)(iv), the reference to § 425.400(a)(4)(ii), is not consistent with the intended purpose of the reference, which is to specify that we will redetermine the proration factor used in calculating the prior savings adjustment if the ACO changes its beneficiary assignment methodology selection. Therefore, we proposed to amend § 425.652(a)(9)(iv) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

We solicited comments on these proposed technical changes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported these proposals and provided no further elaboration or suggestions, stating that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text:

Response: We agree with commenters that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

We are finalizing the proposal to amend five inconsistencies in references to §§ 425.226(a)(1) and 425.400(a)(4)(ii). Specifically, we are finalizing the following:

- Amend § 425.402(e)(2)(ii)(A) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1).
- Amend the introductory text of § 425.601(a) and of § 425.652(a) by removing the reference to § 425.226(a)(1) and adding in its place a reference to § 425.400(a)(4)(ii).
- Revise § 425.652(a)(9)(ii) to remove the reference to § 425.226(a)(1) and include a reference to § 425.400(a)(4)(ii), among other revisions to this paragraph that we are finalizing with this final rule (see section III.G.3.a. of this final rule).
- Amend § 425.652(a)(9)(iv) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1).

b. Definition of Rural Health Clinic

In the November 2011 final rule, we established a definition for the term ''Rural health center (RHC)'' for the Shared Savings Program at § 425.20.[288] The definition of ''Rural health center (RHC)'' at § 425.20 states that this term has the same meaning given to this term under § 405.2401(b). The term ''Rural health clinic (RHC)'' is defined at

[288] See, for example, 76 FR 67930 through 67932 (discussion of our proposal to define FQHCs and RHCs as these terms are defined in § 405.2401(b)), and 76 FR 67974 and 67975 (finalized regulations text for § 425.20).

§ 405.2401(b) to mean a facility that has—

- Been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and 42 CFR part 491 concerning RHC services and conditions for approval; and
- Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

In the CY 2024 PFS proposed rule (88 FR 52490 and 52491), we explained that the inconsistency between § 425.20, which inaccurately uses the word ''center,'' and § 405.2401(b), which accurately uses the word ''clinic,'' had recently came to our attention. We noted that the term ''rural health clinic'' was in use and defined at § 405.2401(b) when we established the term and definition for ''Rural health center (RHC)'' under part 425 with the November 2011 final rule. Furthermore, we noted that in the November 2011 final rule (76 FR 67803), we separately established an acronym ''RHCs'' for ''Rural Health Clinics'' in the acronyms list reflecting the accurate term.

To ensure clarity and accuracy, we proposed to correct the error in the definition for ''Rural health center (RHC)'' at § 425.20 by replacing the word ''center'' with the word ''clinic''. We also clarified that all uses of the acronym ''RHC'' or ''RHCs'' throughout part 425—including in the definition of ''primary care physician'' in § 425.20, as well as in §§ 425.102 and 425.304 and throughout 42 CFR part 425, subpart E—have been interpreted to refer to ''rural health clinic'' or ''rural health clinics'' as defined at § 405.2401(b). Further, we proposed to revise the definition of rural health center in § 425.20 to specify that the referenced provision at § 405.2401(b) is within 42 CFR Chapter IV. We solicited comments on these proposed technical changes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported these proposals and provided no further elaboration or suggestions, stating that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

Response: We agree with commenters that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

After consideration of public comments, we are finalizing as proposed.

c. Definition of At-Risk Beneficiary

In the November 2011 final rule (see 76 FR 67974), we established the definition of ''At-risk beneficiary'' at § 425.20, the meaning of which includes, but is not limited to, a beneficiary who—

- Has a high-risk score on the CMS–HCC risk adjustment model;
- Is considered high cost due to having two or more hospitalizations or emergency room visits each year;
- Is dually eligible for Medicare and Medicaid;
- Has a high utilization pattern;
- Has one or more chronic conditions;
- Has had a recent diagnosis that is expected to result in increased cost;
- Is entitled to Medicaid because of disability; or
- Is diagnosed with a mental health or substance abuse disorder.

In the November 2011 final rule, we explained that we agreed with commenters that our proposed definition of at-risk beneficiary should be expanded to include patients who are entitled to *Medicare* (emphasis added) because of disability (see 76 FR 67950). However, in codifying the relevant regulation text at § 425.20, we inadvertently referred to patients who are entitled to *Medicaid* because of disability (emphasis added). In the CY 2024 PFS proposed rule (88 FR 52491), we noted that an individual who is entitled to Medicare because of disability and who is also entitled to Medicaid, would be included under the category ''Is dually eligible for Medicare and Medicaid.''

We proposed to correct the typographical error in the definition for ''At-risk beneficiary'' at § 425.20 by replacing the word ''Medicaid'' in paragraph (7) with the word ''Medicare''. We also proposed to adjust inaccurate punctuation in the list of paragraphs within this definition by replacing the period at the end of paragraphs (5) and (6) with a semi-colon. We solicited comments on these proposed changes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported these proposals and provided no further elaboration or suggestions, stating that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

Response: We agree with commenters that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

After consideration of public comments, we are finalizing as proposed.

d. Updating Terminology in Regulations on Data Sharing with ACOs

In the CY 2024 PFS proposed rule (88 FR 52491), we explained that it had come to our attention that certain terminology that is used in the data sharing regulations for the Shared Savings Program in 42 CFR part 425, subpart H is outdated or inconsistent with the terminology used elsewhere in the Medicare program and in the HIPAA regulations in 45 CFR part 164. We proposed technical and conforming changes to § 425.702(c)(1)(ii)(A)(*3*) and § 425.702(c)(1)(ii) for clarity and consistency.

In accordance with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS discontinued the use of Social Security Number-based Health Insurance Claim Numbers (HICNs) as the beneficiary identifier on Medicare cards and replaced that identifier type with Medicare Beneficiary Identifiers (MBIs) by April 2019. MBIs are now used for Medicare transactions like billing, eligibility status, and claim status. All claims with a date of service on or after January 1, 2020, must use the beneficiary's MBI, rather than the HICN.[289] [290] To accommodate this change from HICN to MBI, starting in PY 2018 we revised Shared Savings Program reports that provide beneficiary-identifiable information under § 425.702, and claim and claim line feed files with beneficiary identifiable claims data provided under § 425.704, to include a field for the beneficiary's MBI. By the end of PY 2019, we discontinued populating data in the HICN fields. However, when we made this operational update, we did not make conforming changes to the regulations text at § 425.702(c)(1)(ii)(A) to revise the list of the four data elements we provide to ACOs on their FFS beneficiary population: (1) beneficiary name; (2) date of birth; (3) HICN; and (4) sex. Therefore, because we have discontinued use of the HICN, we proposed to revise § 425.702(c)(1)(ii)(A)(*3*) to refer to ''Beneficiary identifier'' instead of ''Health Insurance Claim Number (HICN).'' We explained that this change to the regulations text would not change

[289] CMS, MLN Matters, ''New Medicare Beneficiary Identifier (MBI) Get It, Use It''. Article number SE18006, revised March 19, 2020. Available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se18006.pdf.*

[290] CMS.gov website, Medicare Beneficiary Identifiers (MBIs), at *https://www.cms.gov/Medicare/New-Medicare-Card.*

the information that is provided to ACOs pursuant to § 425.702(c)(1)(ii).

Further, we proposed to revise the list of purposes in § 425.702(c)(1)(ii) for which an ACO may request certain beneficiary-identifiable data for purposes of population-based activities to better align with the terminology used in the first paragraph of the definition of health care operations at 45 CFR 164.501. Specifically, we proposed to remove the reference to ''process development'' and to add in its place a reference to ''protocol development.'' In prior rulemaking, we indicated that ACOs could request beneficiary-identifiable data under § 425.702(c)(1)(ii) for purposes of carrying out population-based activities, including process development, and we referred to care coordination processes and required process development under § 425.112 (see 80 FR 32734 and 32735). In the proposed rule, we stated that we did not believe the proposed revision would impact ACOs' ability to request data for these types of process development. Rather, activities related to care coordination processes and the development of required processes under § 425.112 would continue to fall within the population-based activities listed in § 425.702(c)(1)(ii) for which an ACO may request data, including protocol development (as added by this proposed revision) and care coordination. We also noted that this proposed revision would ensure that the terminology used in § 425.702(c)(1)(ii) is consistent with the language of the proposed new provision at § 425.702(c)(1)(iii) (see section III.G.2.b.(2) of this final rule for a discussion of this proposal).

We solicited comments on these proposed changes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported these proposals and provided no further elaboration or suggestions, stating that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

Response: We agree with commenters that these technical changes will eliminate errors and inconsistencies and improve clarity in the regulatory text.

After consideration of public comments, we are finalizing as proposed.

8. Comment Solicitation on Potential Future Developments to Shared Savings Program Policies

a. Background

As we described in the CY 2024 PFS proposed rule (88 FR 52492), in an article published on the New England Journal of Medicine's website on April 27, 2022,[291] CMS articulated a vision for how ACOs participating in the Shared Savings Program and in Innovation Center models can help CMS achieve its goal of having all beneficiaries in Original Medicare cared for by health care providers who are accountable for the cost and quality of care by 2030. This article describes a vision for the Shared Savings Program and new Innovation Center models to expand participation in ACOs, strengthen incentives for savings for participants and for Medicare, and make access to ACOs more equitable, including: (1) aligning features of new Innovation Center models and features in the Shared Savings Program; (2) adopting lessons from the ACO Investment Model to help provide upfront investments for small ACOs that lack experience with performance-based risk; (3) examining benchmarking approaches that could support increased participation, including among organizations serving patients with high costs of care, and addressing the effects of rebasing and regional benchmark adjustments; and (4) examining the use of incentives to recruit health care providers that care for underserved populations to join ACOs, with the goal of closing gaps in outcomes, and asking health care providers to consider beneficiaries' social needs in care plans.

In the CY 2023 PFS final rule (87 FR 69777 through 69968), we adopted several policies to advance these goals, including providing advance shared savings payments in the form of AIPs to certain new, low revenue ACOs that they can use to build the infrastructure needed to succeed in the Shared Savings Program and promote equity by holistically addressing beneficiary needs, including social needs; reinstating a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs and shared losses for ENHANCED track ACOs; modifying the benchmarking methodology to strengthen financial incentives for long-term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks; supporting the business case for ACOs serving high-risk and a high proportion of dually eligible populations to participate; mitigating bias in regional expenditure calculations for ACOs electing prospective assignment; and expanding opportunities for certain low revenue ACOs participating in the BASIC track to share in savings.

In the CY 2024 PFS proposed rule (88 FR 52492), we explained that we have also continued to receive significant input from interested parties regarding opportunities to increase participation in ACO initiatives. One such option would be to identify ways that the Shared Savings Program can support ACOs' efforts to strengthen primary care, such as by providing prospective payments for primary care that would reduce reliance on FFS payments and support innovations in care delivery that better meet beneficiary needs and increase access to primary care in underserved communities. Empirical data support the notion that primary care serves as the foundation of high-performing ACOs. ACO performance results have indicated that ACOs comprised of 75 percent or more of primary care clinicians share in savings at almost twice the rate of those ACOs comprised of less than 75 percent primary care clinicians.[292] Another option would be to offer a higher risk track in the Shared Savings Program.

We solicited public comments on potential future developments to Shared Savings Program policies (88 FR 52492 through 52497).

b. Incorporating a Higher Risk Track Than the ENHANCED Track

As described in the CY 2024 PFS proposed rule (88 FR 52492), CMS, over time, has considered a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent (that is, a rate higher than that currently offered under the ENHANCED track) that builds on the experience of the Next Generation ACO (NGACO) and ACO Realizing Equity, Access, and Community Health (ACO REACH) Models. ''Higher risk'' sharing provides a higher level of potential reward which may encourage ACOs that would not otherwise have participated in the Shared Savings

[291] Jacobs D, Rawal P, Fowler L, Seshamani M. Expanding Accountable Care's Reach among Medicare Beneficiaries. *NEJM.org,* April 27, 2022, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2202991.*

[292] Refer to CMS, Press Release, ''Medicare Shared Savings Program Saves Medicare More Than $1.6 Billion in 2021 and Continues to Deliver High-quality Care'' (August 30, 2022), available at—As of August 30, 2022, available at *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-16-billion-2021-and-continues-deliver-high.*

Program because of current limitations on potential upside to consider participating. Also, a higher risk sharing model may incentivize participating ACOs to take on more risk (and potential reward) and incentivize ACOs to improve performance in the program, which may result in reduced healthcare costs for Medicare, and more effective, efficient care for beneficiaries. In addition, higher risk sharing may incentivize ACOs to develop new care delivery strategies, such as a focus on specialty care integration and reduced care fragmentation. Offering a higher risk sharing track may also help CMS reach our goal of having all beneficiaries in Original Medicare in a care relationship with a health care provider who is accountable for the costs and quality of their care by 2030 by encouraging efficient ACOs to continue participation in the Shared Savings Program.

Currently, under the Shared Savings Program, ACOs may enter participation agreements under one of two tracks—the BASIC track or the ENHANCED track. The BASIC track allows eligible ACOs to begin under a one-sided model and incrementally transition to higher levels of risk and potential reward through the BASIC track's glide path. The ENHANCED track is a two-sided model that represents the highest level of risk and potential reward currently offered under the Shared Savings Program. The rules governing the participation options available to ACOs and the progression from lower to higher risk for ACOs entering the program are described in § 425.600 of the regulations.

Under the BASIC track, eligible ACOs operate under either a one-sided model or a two-sided model, either sharing savings only or sharing both savings and losses with the Medicare program. Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of an agreement period with the ACO beginning participation under a one-sided model and progressing to incrementally higher levels of risk and potential reward, unless the ACO chooses to begin under a two-sided model and/or progresses more quickly than the glide path would require.[293] The glide path includes five levels (Levels A through E). Levels A and B are one-sided models (shared savings only); [294] and Levels C, D, and E are two-sided models (shared savings and shared losses) that provide for incrementally higher performance-based risk.[295] An ACO in the ENHANCED track operates under a two-sided model, sharing both savings and losses with the Medicare program, for all five performance years of the agreement period.

To qualify for a shared savings payment, an ACO must meet a minimum savings rate (MSR) requirement, meet the quality performance standard or alternative quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under 42 CFR part 425.[296] For ACOs meeting the applicable quality performance standard established under § 425.512(a)(2), (4)(i) (for PY 2022 and PY 2023), or (5)(i) (for PY 2024 and subsequent performance years), the final shared savings rate is equal to the maximum sharing rate specific to the ACO's track/level of participation as follows: 40 percent for ACOs participating in Level A or Level B of the BASIC track; [297] 50 percent for ACOs participating in Levels C, D, or E of the BASIC track; [298] and 75 percent for ACOs participating in the ENHANCED track.[299] Beginning in PY 2023, ACOs meeting the MSR requirement that do not meet the applicable quality performance standard established under § 425.512(a)(2), (4)(i) or (5)(i), as applicable, but meet the alternative quality performance standard described in § 425.512(a)(4)(ii) (for PY 2023) or (5)(ii) (for PY 2024 and subsequent performance years) will have the opportunity to share in savings at a lower rate that is scaled by the ACO's quality performance. Additionally, beginning in PY 2024, certain ACOs participating in the BASIC track that do not meet the MSR have the opportunity to share in savings at a rate that is equal to half of the rate to which they would have otherwise been entitled had they met the MSR.[300] CMS computes an ACO's shared savings payment by applying the final sharing rate to the ACO's savings on a first dollar basis (meaning the final sharing rate is applied to the ACO's full total savings amount), with the payment subject to a cap that is equal to 10 percent of the updated benchmark for an ACO in the BASIC track or 20 percent of the updated benchmark for an ACO in the ENHANCED track.[301]

ACOs that operate under a two-sided model and have losses that meet or exceed a minimum loss rate (MLR) must share losses with the Medicare program.[302] Once this MLR is met or exceeded, the ACO will share in losses at a rate determined according to the ACO's track/level of participation, up to a loss recoupment limit (also referred to as the loss sharing limit).[303] In determining shared losses, ACOs participating in Level C, D, or E of the BASIC track are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent.[304] ENHANCED track ACOs are subject to a loss rate that is scaled by the ACO's quality performance, subject to a minimum of 40 percent and a maximum of 75 percent.[305]

For agreement periods beginning before January 1, 2024, certain ACOs were only allowed to enter the program in the ENHANCED track, and ACOs entering the program in the BASIC track were limited in how many agreement periods they could participate in the BASIC track before being required to transition to the ENHANCED track. Based on changes finalized in the CY 2023 PFS final rule (87 FR 69818 through 69821), for agreement periods starting on January 1, 2024, and in subsequent years, participation in the ENHANCED track will be optional.

In the NGACO Model, NGACOs were offered the choice between two risk arrangements, partial risk or full risk. Under both arrangements, the NGACO was responsible for 100 percent of performance year expenditures, for services rendered to the NGACO's aligned beneficiaries.[306] Under the

[293] Refer to § 425.600(a)(4)(i).

[294] Refer to §§ 425.600(a)(4)(i)(A)(*1*), 425.605(d)(1)(i) (Level A); §§ 425.600(a)(4)(i)(A)(*2*), 425.605(d)(1)(ii) (Level B).

[295] Refer to §§ 425.600(a)(4)(i)(A)(*3*), 425.605(d)(1)(iii) (Level C); §§ 425.600(a)(4)(i)(A)(*4*), 425.605(d)(1)(iv) (Level D); §§ 425.600(a)(4)(i)(A)(*5*), 425.605(d)(1)(v) (Level E).

[296] Refer to §§ 425.100(b), 425.604(c), 425.605(c), 425.606(c), 425.610(c).

[297] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[298] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[299] Refer to § 425.610(d).

[300] Refer to § 425.605(h).

[301] Refer to § 425.605(d); § 425.610(e).

[302] Refer to § 425.100(c).

[303] Refer to § 425.605(d); § 425.610(f), (g).

[304] Refer to § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C).

[305] Refer to § 425.610(f).

[306] In 2020, due to the impacts of the COVID–19 pandemic, NGACOs were offered an optional amendment to the Participation Agreement (PA) for 2020 (PY5). For NGACOs that signed the amendment, CMS removed all beneficiary experience associated with COVID–19 related admissions and retrospectively updated the prospective trend with a regional observed trend. For 2021, CMS modified the NGACO financial methodology to provide financial protection to all NGACOs continuing in the model for PY6. PY6 financial protections included: adoption of an extreme and uncontrollable circumstances policy, under which any shared losses were prorated based on the number of months during the PHE and the number of beneficiaries residing in an impacted area, and all expenses associated with COVID–19 related admissions were removed from both PY expenditures and retrospective trend.

partial risk arrangement, the NGACO could receive or owe up to 80 percent of savings/losses, whereas under the full risk arrangement, the NGACO could receive or owe up to 100 percent of savings/losses. To mitigate the ACO's risk of large shared losses, as well as to protect the Medicare Trust Funds against paying out excessive shared savings, NGACOs were required to choose a cap on gross savings/losses. The cap, expressed as a percentage of the benchmark, ranged from 5 percent to 15 percent. The risk arrangement chosen by the NGACO (80 or 100 percent) was applied to gross savings or losses after the application of the cap. In PYs 1–3, a discount was applied to the NGACO's benchmark that was set at a standard 3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent. In PYs 4–6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement. The purpose of the discount was to ensure that CMS received a financial benefit from any savings achieved by the NGACOs participating in the model.

Under the ACO REACH Model, REACH ACOs are offered the choice of participating under the Global or the Professional Risk Sharing Options. As in the NGACO Model, under both risk sharing options, the REACH ACO is responsible for 100 percent of performance year expenditures for services rendered to aligned beneficiaries. Because ACOs electing the Global Risk Sharing Option retain up to 100 percent of the savings/losses, a discount is applied to the benchmark to ensure savings are also generated for CMS. Consequently, for ACOs in the Global Risk Sharing Option, the benchmark is reduced by a fixed percentage based on the performance year.[307] The benchmark for ACOs participating in the Professional Risk Sharing Option does not include this discount, and these ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.

As we explained in the CY 2024 PFS proposed rule (see 88 FR 52493 through 52494), when considering including a higher risk track in the Shared Savings Program, we must balance several factors to protect beneficiaries, ACOs, and the Medicare Trust Funds. One factor to consider is that there may be selective participation with regard to which ACOs would choose to participate in a higher risk track, if offered. For example, Shared Savings Program ACOs that have a history of high levels of shared savings or have received a favorable high regional adjustment to their benchmark may be more likely than other ACOs to switch to the higher risk track upon renewing or early renewing their participation in the program so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Medicare, and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model under section 1899(d) of the Act. In the proposed rule, we expressed concerns that introducing a higher risk track would lead to only select ACOs participating, creating benefits limited almost entirely to those ACOs and limited to no benefits for beneficiaries or CMS.

Another consideration we explained in the proposed rule is that ACOs in a higher risk track could have an increased incentive (relative to existing Shared Savings Program risk models) to avoid high-cost beneficiaries in the performance year in order to maximize their potential shared savings payment or avoid or reduce potential shared losses. The Shared Savings Program truncates individual beneficiary expenditures at the 99th percentile of national Medicare FFS expenditures by enrollment type, which can help to protect ACOs from the impact of expenditure outliers (that is, to prevent a small number of extremely costly beneficiaries from significantly affecting the ACO's per capita expenditures) and reduce the incentive for ACOs to avoid high-cost beneficiaries. As described earlier in this section of this final rule, the Shared Savings Program also caps the amount of shared savings an ACO may receive or the amount of shared losses it may owe, which can further discourage beneficiary selection. If introducing a higher risk track to the program, we would need to consider whether the program's existing approach to expenditure truncation and capping shared savings and shared losses would be sufficient in curbing incentives for ACOs to engage in beneficiary selection in light of the higher potential risk and reward, while ensuring that the new risk model will still be attractive to ACOs and improve the quality and efficiency of the care their assigned beneficiaries receive.

When considering a higher risk track, we would need to balance the incentives for ACOs to transition to higher levels of risk and potential reward only when they are very confident it is in their financial interest to do so, with the benefits of increasing ACO participation in the Shared Savings Program and in two-sided accountable care tracks, all while ensuring sufficient financial safeguards against inappropriately large shared losses for ACOs coordinating and improving quality of care for high-cost beneficiaries.

In the proposed rule (88 FR 52492 through 52494), we sought comment on the following: (1) policies/model design elements that could be implemented so that a higher risk track could be offered without increasing program expenditures; (2) ways to protect ACOs serving high-risk beneficiaries from expenditure outliers and reduce incentives for ACOs to avoid high-risk beneficiaries; and (3) the impact that higher sharing rates could have on care delivery redesign, specialty integration, and ACO investment in health care providers and practices.

The following is a summary of the public comments we received in response to the comment solicitation on incorporating a higher risk track than the ENHANCED track and our response:

Comment: Many commenters supported a higher risk track option in the Shared Savings Program. Commenters offered a variety of reasons for their support of a higher risk track, including that it would encourage more participation in the Shared Savings Program, bring more beneficiaries into an accountable care arrangement, improve care delivery, and could serve as a track for ACO REACH Model participants to transition into the Shared Savings Program, if the track is designed somewhat similarly to ACO REACH Model (for example, by offering options regarding the shared savings rate, options for waivers, and an option for paper-based voluntary alignment), after the ACO REACH Model expires at the end of 2026. Some commenters suggested that if CMS adopted certain design features, such as waivers to permit a home visit program and a tool that allows providers to receive advance payment for non-primary care services, those design features could lead ACOs to generate more savings and spur innovation. Multiple commenters requested that the higher risk track be

[307] For more details, refer to CMS, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Settlement Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-fncl-settlement* (see Table 4: Schedule of Discounts by Risk Arrangement).

optional. Several commenters requested that CMS use lessons learned from the NGACO Model and the ACO REACH Model when designing a higher risk track, specifically lessons relating to benefit enhancements and beneficiary engagement incentives, such as the post-discharge home visit waiver, care management home visit waiver, tailored Part B cost sharing support, SNF 3-day waiver, and telehealth waiver. One commenter recommended the higher risk track be offered within the Shared Savings Program, as opposed to being within a new ACO model offered by the Innovation Center.

Many commenters provided input on financial model design elements for a higher risk track. One key design element discussed was the shared savings/shared losses rate. Several commenters supported a full risk model; that is, a model with a 100 percent shared savings/shared losses rate. Many of these commenters paired their support for a full risk model with other financial model design elements such as risk corridors, stop-loss insurance, caps on shared savings and shared losses, or discounts to the benchmark. Several commenters suggested that CMS should offer a choice between a full-risk model with a discount, or a shared savings rate of 85 or 90 percent, with some of these commenters specifically citing the ACO REACH Model and NGACO Model as precedent for these arrangements.

A couple of commenters requested design elements that would result in asymmetrical upside versus downside financial risk. One commenter suggested a shared savings rate of at least 85 percent, with a cap on gross shared savings not to exceed 20 percent of the ACO's updated benchmark, along with a shared loss rate that is between 55 percent and 75 percent, with a cap on gross shared losses not to exceed 15 percent of the ACO's updated benchmark. Another commenter suggested that CMS offer an asymmetric shared savings rate and shared loss rate, where the rates would start off as symmetrical but would be ''offset. . .in opposite directions based on an ACO's proportion of underserved beneficiaries,'' and explained their belief that this option could offer a higher shared savings rate while safeguarding ACOs from inappropriately large shared losses. As another option, the commenter suggested CMS explore an ''asymmetric MSR/MLR option, where the offset factor is based on the ACO's proportion of underserved beneficiaries,'' and explained their belief that such an option would protect ACOs with high proportion of underserved beneficiaries from being accountable for unforeseen losses, while increasing the likelihood of becoming eligible to share in savings.

Multiple comments included input on the level of any discount to benchmark. A couple of commenters recommended the discount be capped at 50 percent of the average shared savings rate among all ACOs participating in the Shared Savings Program. Several commenters expressed concerns that the level of the discount may end up being set too high for them to want to participate. One commenter stated that a discount of 3 percent would be a dealbreaker for many ACOs. Another commenter recommended that the discount be no more than 2 percent. A couple of commenters expressed concern that in the ACO REACH Model, ACOs had average net savings of less than 1 percent after the discount was incorporated. Several commenters stated that, for a full risk model with a 3 percent discount, they would need to generate savings of at least 12 percent to earn more than they would earn in the ENHANCED track.

A few commenters recommended changing the benchmarking methodology for a higher-risk track. Suggestions included using regional-based benchmarks, using a fully administratively-set benchmark, removing the cap on regional adjustments, and applying an offset factor creating asymmetry between the MSR and MLR for an ACO based on its proportion of underserved beneficiaries. Some of these commenters stated that a track with higher risk should have more innovative benchmarking policies, and others stated that benchmark setting should reward risk-taking by ACOs whose assigned beneficiaries include high-needs populations.

Many commenters recommended that providers participating in the higher risk track be paid using a payment methodology other than Medicare FFS payment, including ''prospective payments for primary care,'' ''prospective payments,'' primary care or total cost of care ''capitation payments,'' ''population-based payments,'' payments for ''team-based care,'' ''advanced payment option,'' ''bundled payments,'' and a ''hybrid payment option that includes primary care capitation.'' Some commenters suggested that payments under these alternative payment methods should be available as of January 1, 2025, so that primary care practices do not feel compelled to leave ACOs for the sole purpose of accessing prospective primary care payments in the Making Care Primary model. One commenter stated that a total cost of care capitation option would support ACOs interested in better engaging specialists through mechanisms such as shadow bundles.[308] One commenter requested that flexibility be offered in selecting the level of capitation, including the selection of the specific services subject to capitation. The commenter stated that this flexibility would allow more small, independent, and new entrant practices to participate in a new higher risk track. A few commenters suggested that an alternative payment method be treated like any other Medicare Part B expenditure for purposes of benchmark and shared savings calculations.

Commenters had differing views as to whether the new payments under a higher risk track should be made to ACOs or directly to providers and suppliers. A couple of commenters suggested that the ACO should have a choice of whether CMS makes prospective payments to the ACO or directly to the primary care practices, stating that ''ACOs composed of independent practices who have joined together to participate in the Shared Savings Program typically need to share services through the ACO'' and, in these cases, ''paying the prospective payment directly to the ACO makes the most sense.'' A few commenters suggested there be ''safeguards to ensure investments,'' which we understand to mean prospective payments, reach primary care practices. One commenter stated that prospective payments to physicians are important so that physicians have the resources they need to proactively manage patients' care. Several commenters suggested that we establish clear guidelines for what portion of a capitated payment an ACO itself may retain, rather than share with its ACO participants. Commenters also requested that we ''require ACOs receiving capitated payments to help participating practices build the capacity to independently receive and effectively use prospective payments to support the provision of comprehensive primary care.'' One commenter mentioned that ACOs have varying organizational structures which will require CMS to take a very thoughtful approach to ensure payments intended to support primary care, including capitated or per patient per month payments, reach the primary care practices where physicians and care teams are delivering the care. Another

[308] Shadow bundles are data that provide information on specialists' care patterns and clinical episodes of care. They are developed using existing assignment and claims data, and they assign services and associated payments to clinical episodes and provide additional information on procedural or condition-specific care.

commenter preferred an approach under which CMS would make capitated payments directly to primary care practices, but also stated that another option would be to make capitated payments to ACOs with stipulations that establish the maximum level of retention of those payments by ACOs and to establish a strong audit mechanism and financial penalties for non-compliance.

Several commenters provided input on the amount of payments for primary care services under a higher risk track. Some of these commenters requested that the ACO receive prospective primary care payments in an amount greater than Medicare's historical payments to the ACO's primary care providers to provide funds for innovative care delivery strategies. Another commenter suggested that monthly primary care capitation payments be set equal to 100 percent of an ACO's historical primary care spending, stating that this would provide important cash flow opportunities for ACOs looking to make proactive investments in primary care capacity to better manage patient care. One of the commenters requested CMS provide ACOs with the ability to gradually increase to higher levels of capitation payments, like Comprehensive Primary Care Plus Track 2.

Many commenters suggested ways to protect ACOs serving high-risk beneficiaries from expenditure outliers and reduce incentives for ACOs to avoid high-risk beneficiaries. Several commenters suggested that CMS incorporate risk corridors or risk adjustment to account for treatment of complex and high-cost beneficiaries. A few commenters encouraged CMS to evaluate the applicability of some of the safeguards and policies in place under the ACO REACH Model that aim to reduce the potential for cherry-picking of beneficiaries, mitigate the potential of ''bad actors,'' and ensure appropriate resources for higher cost beneficiaries. A few commenters stated that there are already sufficient protections in place because there are several policies in place to identify and mitigate practices related to avoiding higher risk beneficiaries.

Response: We appreciate the feedback we received in response to this comment solicitation. We will consider this information to inform future rulemaking.

c. Increasing the Amount of the Prior Savings Adjustment

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for eligible ACOs entering an agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for re-entering and renewing ACOs. In the final rule, we explained that reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule (87 FR 69899), we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. In the CY 2024 PFS proposed rule, we also noted that we proposed to further mitigate the impacts of the negative regional adjustment when the overall adjustment to an ACO's historical benchmark is negative; however, the negative regional adjustments by enrollment type would continue to be factored in when the overall regional adjustment is positive. (Refer to 88 FR 52494, and 88 FR 52465 through 52472.)

In the CY 2023 PFS final rule (87 FR 69914 through 69915), we finalized a policy to apply a 50 percent scaling factor to the pro-rated positive average per capita prior savings, because we believed it would be important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under its prior agreement period(s). In response to discussion of this policy in the CY 2023 PFS proposed rule (87 FR 69910), ACOs and other interested parties commented that we should consider using a higher scaling factor that may more closely match the maximum shared savings rate from an ACO's prior agreement period. However, in the CY 2023 PFS final rule, we reiterated our belief that a 50 percent scaling factor would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track (for example, 40 percent). Additionally, we noted that if we were to finalize a scaling factor that would more closely match the average shared savings rate from an ACO's prior agreement period, many ACOs would have a scaling factor below 50 percent, which would be less advantageous than the policy that we finalized (see 87 FR 69910 through 69911).

In the CY 2023 PFS final rule (see 87 FR 69902), we also finalized a policy to calculate the final adjustment to the benchmark by adding the pro-rated average per capita prior savings to the ACO's negative regional adjustment for ACOs that are higher spending relative to their regional service area. Under this policy, we apply the 50 percent scaling factor after offsetting the negative regional adjustment to maximize the portion of the pro-rated average per capita savings that would be added to the negative regional adjustment in determining the final adjustment to the benchmark and strengthen incentives for ACOs to remain in the program.

MedPAC commented on the CY 2023 PFS proposed rule that while the prior savings adjustment is a reasonable policy for mitigating ratcheting effects, implementing both the prior savings adjustment and the regional adjustment policies together would be duplicative. MedPAC also expressed concern that the prior savings adjustment and the regional adjustment could interact in a way that would perpetuate a

programmatic bias towards ACOs receiving a positive regional adjustment. In MedPAC's view, many ACOs would receive an inflated prior savings adjustment because the prior savings adjustment would be based on savings achieved using benchmarks already inflated by the regional adjustment. However, we explained in the CY 2023 PFS final rule (87 FR 69913) that because for most ACOs, the positive regional adjustment would exceed the prior savings adjustment, our policy of applying the larger of the regional adjustment and the prior savings adjustment potentially mitigates this concern.

In the CY 2024 PFS proposed rule (88 FR 52494 through 52495), we solicited comments on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment. such as using an average of the ACO's shared savings rates from the 3 years prior to the start of its agreement period, increasing to 75 percent of shared savings achieved if the ACO participated in the ENHANCED track in the 3 years prior to the start of the agreement period, or another value corresponding to the maximum shared savings rate the ACO was eligible to earn in the 3 years prior to the start of the agreement period. We also solicited comments on potential changes to the positive regional adjustment to reduce the possibility of inflating the benchmark, while still mitigating potential ratchet effects on ACO benchmarks.

The following is a summary of the public comments we received in response to the comment solicitation on increasing the amount of the prior savings adjustment and our response:

Comment: In response to the RFI regarding implementing changes to the prior savings adjustment and related changes to the positive regional adjustment to mitigate potential ratchet effects on ACOs' benchmarks, the majority of comments were supportive of increasing the prior savings adjustment in at least one of the ways described in the proposed rule, with several commenters specifically recommending using the maximum shared savings rate the ACO was eligible to receive during the benchmark years. We also received several comments regarding potential changes to the positive regional adjustment to reduce the possibility of inflating ACOs' benchmarks, while still mitigating potential ratchet effects on those benchmarks. Of those, most commenters favored increasing the cap on the positive regional adjustment to provide an additional incentive to ACOs that are already efficient relative to their region. One commenter noted that beneficiaries assigned based on primary care services furnished by specialists tend to have higher costs and suggested adjusting the cap on the positive regional adjustment based on the share of the ACO's assigned beneficiary population that is assigned based on step 2 of the step-wise beneficiary assignment methodology. One commenter recommended capping the positive regional adjustment using risk adjusted regional per-capita FFS expenditures in BY3 instead of national per-capita FFS expenditures, and also suggested incorporating an offset factor for the regional adjustment for ACOs that serve an unusually high proportion of underserved beneficiaries relative to other ACOs in their region.

Two commenters, including MedPAC, were opposed to increasing the amount of the prior savings adjustment to align with the higher shared savings rate available under the ENHANCED track. MedPAC noted that using the sharing rate available under the ENHANCED track to increase the scaling factor of the prior savings adjustment would exacerbate the inflation of benchmarks due to the regional adjustment. As an alternative, MedPAC suggested that the prior savings adjustment should serve as a mechanism for phasing out the regional adjustment entirely. MedPAC also suggested that the prior savings adjustment could be scaled based on an ACO's own efficiency within its region, which would mitigate both the ratchet effect and benchmark inflation because the regional adjustment would be removed both from performance year benchmarks and the prior savings adjustment. Another commenter opined that the current 50 percent scaling factor is appropriate because it aligns with the weight used to determine positive regional adjustments for ACOs receiving a regional adjustment for their second or subsequent agreement periods.

Several commenters recommended increasing the cap on the prior savings adjustment beyond 5 percent of national per-capita FFS expenditures. Several also recommended risk adjusting the capped amount to reflect differences in the health status of ACOs' beneficiary populations. A number of commenters also recommended allowing ACOs to receive the greater of the 50 percent factor and 5 percent of national per-capita FFS expenditures, and one commenter suggested allowing ACOs to retain 75 percent of the average savings achieved by the ACO over the three benchmark years. One commenter was opposed to increasing the 5 percent cap, suggesting instead that the cap be based on a weighted average of national and risk-adjusted regional per-capita FFS expenditures as described in § 425.652(a)(5)(iv).

A few commenters recommended implementing a quartile-based benchmark system similar to Medicare Advantage, adjusting benchmarks relative to regional spending. Additionally, a few commenters suggested that ACOs transitioning from total cost of care models such as the ACO REACH Model be eligible for a prior savings adjustment based on savings achieved under those models. One commenter also suggested calculating the prior savings adjustment at the TIN level instead of the ACO level.

Response: We appreciate the feedback we received in response to this comment solicitation. We will consider this information to inform future rulemaking.

d. Expanding the ACPT Over Time and Addressing Overall Market-wide Ratchet Effects

As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates. In accordance with § 425.601(b), for agreement periods beginning on July 1, 2019, and before January 1, 2024, we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year.

In the CY 2023 PFS final rule (87 FR 69881 through 69898), we finalized a policy for agreement periods beginning on January 1, 2024, and in subsequent years, to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) that we refer to as the Accountable Care Prospective Trend (ACPT), into a ''three-way'' blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. The three-way blend is calculated as the weighted average of the ACPT (one-third weight) and the existing national-regional ''two-way'' blend (two-thirds weight). The ACPT will be projected for an ACO's entire agreement period near the start of that agreement period, providing a degree of certainty to ACOs.

We explained in the CY 2023 PFS final rule that the ACPT will insulate a portion of the annual benchmark update from any savings occurring as a result of

the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor. Because the ACPT is prospectively set at the outset of an agreement period, any savings generated by ACOs during the agreement period would not be reflected in the ACPT component of the three-way blend. Accordingly, the incorporation of the ACPT may allow benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. By limiting ACOs' ability to slow spending growth for purposes of their own benchmarks, we noted that we believed the use of this three-way blend to update ACOs' benchmarks would incentivize greater savings by ACOs and greater program participation. Additionally, because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, we also stated our belief that this change to the update methodology would help to address concerns raised by ACOs and other interested parties regarding the disproportionate impact of an ACO's savings on the benchmark update for ACOs with high market share.

In the CY 2023 PFS final rule, we noted that it was possible that incorporating the ACPT into a three-way blended update factor would have the potential for mixed effects. For example, it might also lower an ACO's benchmark relative to the two-way blend if external factors lead to higher program spending growth than originally projected at the start of an ACO's agreement period. Consequently, we finalized that if an ACO generates losses for a performance year that meet or exceed its MLR (for two-sided model ACOs) or negative MSR (for one-sided model ACOs) under the three-way blend, we would recalculate the ACO's updated benchmark using the two-way blend and the ACO would receive whichever benchmark update minimizes shared losses. However, the ACO would not be eligible to share in savings resulting from use of the two-way blend in updating the benchmark. We also finalized that if unforeseen circumstances such as an economic recession, pandemic, or other factors cause actual expenditure trends to significantly deviate from projections, we would retain discretion to decrease the weight applied to the ACPT in the three-way blend.

In their comments on the proposal to adopt the three-way blend in the CY 2023 PFS proposed rule (see 87 FR 69890), ACOs and other interested parties expressed concern that the three-way blend effectively increases the proportion of the benchmark update that is based upon national trends, as opposed to regional trends, noting that the blend may not adequately account for geographic variation in spending growth that is outside of an ACO's control. Over a 5-year agreement period, we recognize some ACOs may be disadvantaged or advantaged in the short term by benchmark updates that give greater weight to a national update factor. However, as we stated in the CY 2023 PFS final rule (87 FR 69891), we expect that the net impact of these deviations will be modest in the context of offsetting considerations. For example, the three-way blend only incorporates the ACPT at a one-third weight and maintains the current two-way blend for the majority weight of the benchmark trend calculation, allowing for a significant proportion of the benchmark update to reflect expenditure growth in an ACO's regional service area. The ACPT itself is also expected to project spending above realized spending as ACOs generate savings, thereby providing a stable, predictable component of the update factor that will be beneficial for ACOs.

Interested parties who commented on the proposal in the CY 2023 PFS proposed rule to incorporate the ACPT as part of a three-way blend suggested modifications to the three-way blend to further mitigate potential ratchet effects and to better reflect regional variation in spending. These included modifications such as: (1) keeping a two-way national-regional blend and substituting the national component of the two-way blend with the ACPT (see 87 FR 69890); and (2) adjusting the weight of the ACPT in the three-way blend to reflect each ACO's market penetration, as is done with the national component of the two-way blend (see 87 FR 69893). We declined to implement these suggestions in the CY 2023 PFS final rule.

In the CY 2024 PFS proposed rule (88 FR 52495 through 52496), we sought comment on the following potential refinements to the ACPT and the three-way blended benchmark update factor as CMS works toward broad implementation of administrative benchmarks: (1) replacing the national component of the two-way blend with the ACPT; and (2) scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area.

The following is a summary of the public comments we received in response to the comment solicitation on expanding the ACPT over time and addressing overall market-wide ratchet effects, and our response:

Comment: Many commenters supported replacing the national component of the two-way blend with the ACPT over use of the three-way blend finalized in the PY 2023 PFS final rule. MedPAC also supported the concept of scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area. However, MedPAC also expressed a preference for phasing out the regional component of the update factor in favor of an administrative growth factor. Another commenter also supported scaling the weight of the ACPT in a blended update factor based on each ACO's market share, but only above a minimum threshold for market share.

Several commenters were opposed to moving to a two-way blended update factor with the ACPT replacing the national component of the current two-way blend and favored keeping the three-way blend as finalized in the CY 2023 PFS final rule. Recommendations from these commenters included: (a) focusing on the longer-term goal of moving to an administrative benchmark; (b) providing additional details on how the three-way blend will be operationalized before making any changes; and (c) evaluating the impact of the three-way blend before making changes. A few commenters were also opposed to scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area.

Several commenters recommended that CMS remove an ACO's assigned beneficiaries from the assignable population for the region when calculating the update factor (the commenter did not specify if they were referencing the two-way or three-way blended update factor). Most of these commenters were also supportive of substituting the ACPT for the national component of the two-way blend, but commenters varied on whether removing assigned beneficiaries from the assignable population should be done in conjunction with, or as an alternative to, that approach.

Several commenters favored calculating a two-way blended and three-way blended update factor for each ACO and using the more advantageous factor when updating the benchmark in each performance year.

Some of these commenters favored using the national and regional two-way blend, while others preferred an updated two-way blend including the ACPT in place of the national component.

A number of commenters were concerned that the 5-year projection used in the ACPT, as finalized in the CY 2023 PFS final rule, would potentially be less accurate in later years of an ACO's agreement period and recommended only projecting the ACPT out for 3 years instead of 5. A few commenters also expressed general support for a longer-term move toward administrative benchmarks to address the ratchet effect experienced by renewing ACOs.

Response: We appreciate the feedback we received in response to this comment solicitation. We will consider this information to inform future rulemaking.

e. Promoting ACO and CBO Collaboration

Section 1899(b)(2)(G) of the Act requires an ACO participating in the Shared Savings Program to define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies. In the November 2011 final rule (76 FR 67827), we finalized policies to require that a participating Shared Savings Program ACO provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We emphasized our belief that ACOs should retain the flexibility to establish processes that are best suited to their practice and patient population. As part of these required processes, we explained that ACOs should adopt a focus on patient-centeredness, which could include such activities as: a process for evaluating the needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of this population, including how the ACO intends to partner with other interested parties in the community to improve the health of its population; a plan to engage in shared decision-making with beneficiaries; and a plan to implement individualized care plans, including taking into account the community resources available to the individual beneficiary.

When establishing these required processes and patient centeredness criteria in the November 2011 final rule (76 FR 67826), we stated that as we learn more about successful strategies in these areas, and as we gain more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements under section 1899(b)(2)(G) of the Act may be revised. For example, in subsequent rules we underscored the importance of health information technology development and infrastructure within care coordination. In the June 2015 final rule (80 FR 32725), we finalized two modifications to the care coordination processes required of ACOs under § 425.112(b)(4): (1) adding a new eligibility requirement under § 425.112(b)(4)(ii)(C), which required an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries, and (2) adding a new provision at § 425.112(b)(4)(ii)(D), which required the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries. In the CY 2018 PFS final rule (82 FR 53222), we shifted from requiring an ACO to submit documents detailing how it would meet the requirements of § 425.112 as a narrative in its Shared Savings Program application to instead requiring it to certify at the time of application that it has defined the required processes and patient centeredness criteria consistent with the requirements specified in § 425.112 and to furnish such documentation upon request—thereby reducing ACO burden while maintaining CMS's flexibility to obtain additional documentation when necessary (see § 425.204(c)(ii)).

Additionally, in our June 2015 final rule (80 FR 32722), we specified that the care coordination processes under § 425.112 could include coordination with CBOs that provide services that address social determinants of health. This coordination could include a plan to partner with interested parties in the community, a plan to engage in shared decision making with beneficiaries, and a plan to implement individualized care plans. In that rulemaking (80 FR 32722 and 32723), we also confirmed our understanding that ACOs differ in their ability to adopt the appropriate health information exchange technologies, but we continued to underscore the importance of robust health information exchange tools in effective care coordination.

In the CY 2024 PFS proposed rule (88 FR 52496 through 52497), we solicited comments on ways to improve and incentivize collaboration between ACOs and interested parties in the community or CBOs. As explained in the CY 2023 PFS final rule (87 FR 69790), where we refer to CBOs, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), or the Centers for Disease Control, or from State-funded grants to provide social services. Generally, we believe such organizations are trusted entities that know the populations they serve and their communities, want to be engaged, and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a trusted source to share information.[309] We recognize that ACOs wishing to address social needs may want to make investments in goods or social services that would enable their ACO participants and ACO providers/suppliers to work with CBOs that have expertise in identifying and providing the types of social services that the ACO's beneficiary population requires.

It is important to note that the Shared Savings Program does not prohibit ACOs from partnering with CBOs. Currently, if a CBO is enrolled in Medicare, it may already be an ACO participant or an ACO provider/supplier. We believe CBOs could play an important role in identifying and addressing gaps in health equity. As we stated in the CY 2023 PFS final rule, we hope to encourage more ACOs to partner with CBOs whether they provide items and services reimbursed by Medicare or not. We recognized, however, that Federal and other sources of grant funding for social services may be insufficient to fully address the demand for services within a community or broader geography. As we noted in that final rule, contractual arrangements between the health care

[309] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response, Community-Based Organizations during COVID–19, available at *https://www.phe.gov/emergency/events/COVID19/atrisk/returning-to-work/Pages/default.aspx*.

sector and CBOs providing social services have increased in recent years to meet this demand.

In the CY 2024 PFS proposed rule (88 FR 52496 through 52497), we solicited comments on approaches, generally, for encouraging or incentivizing increased collaboration between ACOs and CBOs, including any policies specifically designed to encourage ACOs to partner with CBOs and address unmet health-related social needs. We also solicited comments on potential changes CMS could make to the patient-centered care requirements in § 425.112 to strengthen partnerships between ACOs and interested parties in the community, including CBOs, to address unmet health-related social needs.

The following is a summary of the public comments we received in response to the comment solicitation on promoting ACO and CBO collaboration, and our response:

Comment: Commenters generally supported increasing collaboration between ACOs and CBOs. Commenters noted that they appreciate the opportunity to highlight ways ACOs could increase collaboration with CBOs and strengthen partnerships between ACOs and interested parties in the community to address health equity and SDOH. Commenters stated that some ACOs are actively working with community partners to address SDOH and are working to close the loop between referrals to social services and follow-up interventions.

Several commenters encouraged CMS to consider increased financial support to sustain ACO–CBO collaboration. The commenters stated that many CBOs are underfunded and lack connections to the health care system or the ability to share data effectively. Some commenters stated that they use shared savings to support partnerships with CBOs, but that more stable and predictable funding mechanisms that would support the long-term collaboration needed to improve care for beneficiaries may be needed. Some commenters suggested that CMS consider new and innovative payment methods for encouraging relationships between ACOs and CBOs, including advance payments to ACOs that agree to invest in CBO capacity to align with ACO providers to deliver targeted interventions to priority populations or a capitated payment methodology that would better support the capacity of CBOs, including systems and other infrastructure they can use to improve coordination of care.

Commenters shared further suggestions with CMS (listed below) and stressed the need for non-financial support in increasing ACO–CBO collaborations.

- Commenters encouraged CMS to provide additional ''technical assistance,'' as well as additional program guidance and resources to ACOs that they can use when establishing or expanding partnerships with CBOs in the community.
- Commenters encouraged CMS to conduct outreach and provide support to CBOs that may be interested in collaborating with ACOs.
- Commenters suggested that CMS expand payment mechanisms using a similar approach embedded in the Maryland Total Cost of Care (TCOC) Model for supporting collaboration with CBOs.
- Commenters suggested that CMS add an ACO quality measure to assess the percentage of the ACO population screened for health-related social needs, and the percentage of the population that had an intervention delivered by a CBO.
- Commenters suggested that CMS improve SDOH data collection and expand and refine the use of payment methodologies that appropriately address the health, social, and equity goals of the community.

Several commenters recommended changes to the Shared Savings Program's financial methodology to support ACO collaboration with CBOs. Specifically, they noted that increasing the financial benchmark to reflect assigned beneficiaries with social risk factors would provide resources for ACOs to develop robust community partnerships and allow flexibility for ACOs to provide supplemental benefits to those beneficiaries. Other commenters recommended that CMS leverage technology by providing ACOs with quality data reported via MIPS for purposes of identifying beneficiaries who have been screened for SDOH. One commenter encouraged CMS to consider a ''tiered level of ACO participation'' in the Shared Savings Program based on the degree to which the ACO collaborates with CBOs and integrates them into its governance structure and/or its ACO participant/ACO provider/supplier structure.

In addition to the suggestions for increasing and incentivizing ACO–CBO collaboration as summarized above, commenters also shared a few potential program risks from advancing ACO–CBO collaboration. Commenters expressed concern regarding the capacity of CBOs to furnish care and shared that increasing collaboration between ACOs and CBOs would also increase referrals to the CBO, possibly straining the CBO's resources and increasing the demand on those resources. However, a few commenters noted that CMS could better evaluate the needs of communities to assist ACOs in meeting those needs. Lastly, commenters cautioned against any new regulations intended to increase ACO–CBO collaboration, noting that ACOs would benefit from the continued flexibility to form relationships that best meet the ACO's goals and the needs of the beneficiaries that they serve.

Response: We thank commenters for their suggestions and appreciate the feedback we received for this solicitation. We will consider this information in future rulemaking.

f. Out of Scope Comments

The following is a summary of the public comments that we received that went beyond the scope of the four RFIs in the CY 2024 PFS proposed rule (88 FR 52492 through 52497) and our response.

Comment: A few commenters requested certain waivers of Medicare requirements for Shared Savings Program ACOs. One commenter requested that CMS allow wider use of telehealth by allowing all Shared Savings Program ACOs access to telehealth waivers, and expand what telehealth waivers cover (for example, to include patient cost-sharing, modalities, and covered services). Another commenter asked CMS to ''waive the initiating face-to-face relationship requirement for the proposed and existing care management codes for partner organizations that have been designated by an ACO that accepts downside risk.'' This commenter also requested that ACOs be able to waive beneficiary co-pays and cost sharing requirements. One commenter requested that CMS change the ''eligibility requirements for beneficiaries for the Skilled Nursing Facility (SNF) 3-Day Rule Waiver which currently precludes the beneficiary from residing in a SNF or other long term care setting.'' Another commenter encouraged CMS to allow SNFs to be added to the ACO's SNF Affiliate List on a quarterly basis as well as ''reconsider the timing and star rating criteria so SNFs have an opportunity to correct'' their processes following an ''incident'' that reduced their star rating to ensure that the SNF would have an opportunity to attain their minimum star rating status in time for the following Shared Savings Program performance year. Other commenters suggested modifications to the Shared Savings Program's financial methodology unrelated to the RFIs or proposals in the CY 2024 PFS proposed rule, such as:

• Eliminating the distinction between low revenue ACOs and high revenue ACOs (refer to the definitions of ''High revenue ACO'' and ''Low revenue ACO'' at § 425.20);
• Setting regional-only benchmarks;
• Making equity adjustments in financial benchmarking;
• Removing the ACO's own assigned beneficiaries from regional expenditure calculations when adjusting and updating the ACO's benchmark;
• Retroactively applying the policy described at § 425.605(h) (Calculation of shared savings for certain BASIC track ACOs not meeting MSR requirement) to expand opportunities for certain ACOs to share in savings so that it will apply to PY 2023 and all prior years.
• Developing a pediatric risk algorithm; and
• Developing ''value-based arrangements'' (such as a nested bundled payment for skilled nursing facility, home health, or palliative care/serious illness management services) that ''are embedded within the ACO for non-physician participating providers or organizations.''

Another commenter suggested CMS provide ''projected or year-to-date shared savings levels that include a single dollar amount without requiring template population.'' The commenter also requested that CMS allow an ACO to exclude a beneficiary from the ACO's assigned beneficiary population if the beneficiary declines data sharing. One commenter requested that CMS require ACOs to include geriatric expertise on their governing bodies or incentivize health systems to become ''Age-Friendly Health Systems.''

Response: We appreciate the commenters' input but note that these suggestions go beyond the scope of the RFIs in the CY 2024 PFS proposed rule.

H. Medicare Part B Payment for Preventive Vaccine Administration Services (§§ 410.10, 410.57, 410.152)

1. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and vaccine administration for the specified preventive vaccines—the pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under sections 1833(a)(1)(B) and (b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccines or the services to administer them. Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except when furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC). Some other preventive vaccines, such as the zoster vaccine for the prevention of shingles, are not specified for Medicare Part B coverage under section 1861(s)(10) of the Act and are instead covered and paid for under Medicare Part D.

2. Medicare Part B Payment for the Administration of Preventive Vaccines

a. Pneumococcal, Influenza and Hepatitis B Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65186), we finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit. We explained that since payment policies for the administration of the preventive vaccines described under section 1861(s)(10) of the Act are independent of the PFS, these payment rates will be updated as necessary, independent of the valuation of any specific codes under the PFS. (Please see COVID–19 vaccine administration payment information in the next section.) The CY 2022 PFS final rule (86 FR 65180 through 65182) provides a detailed discussion on the history of the valuation of the three Level II Healthcare Common Procedure Coding System (HCPCS) codes, G0008, G0009, and G0010, which describe the services to administer an influenza, pneumococcal, and hepatitis B vaccine, respectively.

In the CY 2023 PFS final rule (87 FR 69984), we finalized a policy to annually update the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the Medicare Economic Index (MEI). Additionally, we finalized the use of the PFS Geographical Adjustment Factor (GAF) to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. These adjustments and updates apply to HCPCS codes G0008, G0009, G0010, and to the Level I Current Procedural Terminology (CPT) codes that describe the service to administer COVID–19 vaccines, which we discuss in the next section.[310]

The current payment rates for G0008, G0009, and G0010, as finalized in the CY 2023 PFS final rule, can be found on the CMS Vaccine Pricing website under ''Seasonal Flu Vaccines''.[311] The payment rates for these services, with the annual update applied for CY 2024, are available in Tables 46A and 46B in section III.H.3.d. of this final rule.

b. COVID–19 Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65181 and 65182), we provided a detailed history regarding the determinations of initial payment rates for the administration of COVID–19 vaccines, and an explanation of how the payment policy evolved to a rate of $40 per dose. We noted that in the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that identifies the resource costs and inputs that should be considered when determining payment rates for preventive vaccine administration. As part of the comment solicitation, we requested feedback specifically related to the circumstances and costs associated with furnishing COVID–19 vaccines, to ensure that we took these into consideration when determining our payment policy. In the CY 2022 PFS final rule (86 FR 65185), we stated that, after consideration of all the comments received, it was appropriate to establish a single, consistent payment rate for the administration of all four Part B preventive vaccines in the long term, but to pay a higher, $40 payment rate for administration of COVID–19 vaccines in the short term, while pandemic conditions persisted (86 FR 65185).

In the CY 2023 PFS final rule (87 FR 69988 through 69993), we stated that due to timing distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), we reconsidered the policies finalized in the CY 2022 PFS final rule in light of our goal to promote broad and timely access to COVID–19 vaccines. We explained that our goal would be better served if our policies with respect to payment for

[310] COVID–19 vaccine coding is available at *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies''.

[311] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''Seasonal Flu Vaccines''.

administration of these products, as addressed in the November 2020 IFC and CY 2022 PFS final rule, continue until the EUA declaration for drugs and biological products with respect to COVID–19 (see 85 FR 18250) is terminated. Therefore, we finalized that we would maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, approximately $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered.

The current payment rates for the CPT codes that describe the service to administer COVID–19 vaccines, as finalized in the CY 2023 PFS final rule, are available on the CMS COVID–19 Vaccine Pricing website, under ''COVID–19 Vaccines & Monoclonal Antibodies''.[312] The payment rates for these services, with the annual update applied for CY 2024, are available in Tables 46A and 46B in section III.H.3.d. of this final rule.

Comment: Some commenters requested CMS to clarify the Part B preventive vaccine administration payment amounts for CY 2024. Commenters specifically asked that, due to the uncertainty surrounding the ''commercialization'' of COVID–19 vaccines, and due to the additional expenses and operational complexity that COVID–19 vaccines still present in relation to other vaccines, CMS maintain the existing higher COVID–19 vaccine administration payment through CY 2024. These commenters expressed that they would appreciate additional clarification about the transition date for the COVID–19 vaccine administration payment amount from $40 to the $30. One commenter asked CMS to clarify payment amounts for both COVID–19 vaccine products and their administration, and the commenter also specifically requested a chart similar to Tables 85 and 86 published in the CY 2023 PFS final rule (87 FR 69993).

Response: We acknowledge the commenters' requests for clarification regarding the transition date for the vaccine administration payment amount for COVID–19 vaccines. In the CY 2023 PFS final rule (87 FR 69988 through 69993), we set this transition to occur on January 1 of the year following the year in which the Secretary ends the March 27, 2020, EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products. In the CY 2023 PFS final rule (87 FR 70224), we also codified this policy in regulations at § 410.152(h)(2) and (3).

As discussed in the CY 2023 PFS final rule (87 FR 69987), an emergency declaration pursuant to section 564 of the FD&C Act (an ''EUA declaration'') continues until specifically terminated.[313] When an EUA declaration is to be terminated, notice of termination will be published in the **Federal Register** to provide advance notice to the public that the EUA declaration is being terminated and provide for a transition period. This will permit manufacturers, health care facilities, providers, patients, and other interested parties time to transition from EUA products and the policies that support them. An EUA declaration under section 564 of the FD&C Act is distinct from, and not dependent on, an HHS PHE declaration under section 319 of the PHS Act. While the HHS PHE declaration under section 319 of the PHS Act for COVID–19 expired on May 11, 2023, the EUAs issued under the section 564 EUA declarations for drugs and biological products with respect to COVID–19 continue to remain in effect.[314]

Per commenters' suggestions, we have included Tables 46A and 46B, at the end of section III.H.3 of this final rule, that reflect the potential alternative payment amounts for Part B preventive vaccine administration for CY 2024. Table 47 displays the CY 2024 Part B payment rates for preventive vaccine administration if the EUA declaration continues into CY 2024, and Table 48 displays the CY 2024 Part B payment rates for preventive vaccine administration if the EUA declaration ends on or before December 31, 2023.

For more information on Part B payment for COVID–19 vaccines and their administration, please see the CMS COVID–19 Vaccine Pricing website at *https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies.'' The website includes Medicare Part B payment amounts for COVID–19 vaccine products. For more information on the end of the Centers for Disease Control and Prevention's (CDC) COVID–19 Vaccination Program and the transition to private purchasing of COVID–19 vaccines in the commercial marketplace, please see *https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html*.

Comment: Several commenters requested that CMS evaluate how the current Part B preventive vaccine administration payment amounts impact vaccination rates, and that CMS work with vaccine providers to ensure the in-home add-on payment is adequate, given the additional costs associated with at-home administration. Other commenters suggested CMS to continue the $40 payment amount for COVID–19 vaccine administration beyond the end of CY 2023, and extend that payment amount to the administration of all Medicare preventive vaccines. Some commenters noted that, while COVID–19 vaccines are somewhat easier for physician practices to manage than in previous years, the vaccines will still require unique practice considerations and additional expenses for those administering the vaccines.

Response: The CY 2022 PFS final rule (87 FR 65184 through 65186) contains an extensive discussion on our rationale for initially setting the $40 COVID–19 vaccine administration rate, and for eventually aligning the COVID–19 vaccine administration rate with the rate for administration of the other Part B preventive vaccines, that is, $30 per vaccine administered. In the CY 2023 final rule (87 FR 69988 through 69993), we set this transition to occur on January 1 of the year following the year in which the Secretary ends the March 27, 2020, EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products.

We acknowledged the unique circumstances that still surround the COVID–19 vaccine landscape, even now that the COVID–19 public health

[312] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies''.

[313] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends*, viewed September 19, 2023.

[314] Ibid.; *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html*, viewed September 19, 2023.

emergency (PHE) has expired.[315] We believe that our proposal to continue the higher COVID–19 vaccine administration rate through the end of the year in which the EUA declaration ends, rather than immediately aligning the COVID–19 vaccine administration payment amount with that of the other Part B preventive vaccines upon the expiration of the PHE, provides an appropriate transition period to recognize continued higher resource needs. We will continue to review payment policies for Part B preventive vaccines and their administration, as circumstances continue to evolve regarding COVID–19 specifically, and regarding public health in general. When the transition to a calendar year post-EUA declaration does arrive, we plan to provide both vaccine providers and Medicare enrollees with sufficient notice and thorough guidance regarding the transition.

3. In-Home Additional Payment for Administration of COVID–19 Vaccines

a. Background

In the CY 2022 PFS final rule (86 FR 65187 and 65190), we provide a detailed discussion on the payment policy for COVID–19 vaccine administration in the home. In summary, providers and suppliers that administer a COVID–19 vaccine in the home, under certain circumstances, can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*).[316] In CY 2022, the Medicare Part B payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home was $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home). These payment amounts were then geographically adjusted using PFS GPCIs (as discussed in the CY 2023 PFS final rule at 87 FR 69980 through 69983). We note that when a preventive vaccine that is covered and paid under section 1861(s)(10) of the Act, is furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC), the in-home additional payment mechanism is not applicable, since vaccine administration in those settings is based on reasonable cost, and is paid through the cost report process.

Since announcing the add-on payment for in-home COVID–19 vaccine administration in June 2021, we have noted that we established these policies on a preliminary basis to ensure access to COVID–19 vaccines during the public health emergency, and that we would continue to evaluate the needs of Medicare patients and these policies. In the CY 2022 PFS proposed rule (86 FR 39224 through 39226), we included a comment solicitation to collect feedback on these policies and potential future changes. As part of the comment solicitation, we requested feedback related to our definition of ''home,'' program integrity concerns, changes that we should consider, costs associated with administering COVID–19 vaccines in the home, and whether outside of a PHE there is a need to vaccinate people in the home rather than going to a health care provider or supplier. In the CY 2022 PFS final rule (86 FR 65188 through 65190), we discussed the feedback received, and we noted that commenters overwhelmingly recommended that we continue making the additional payment for COVID–19 vaccines administered in the home beyond the end of the PHE. Many commenters also supported extending the payment to other preventive vaccines, either permanently or until the end of the PHE. Commenters emphasized the importance of increasing vaccination rates and making vaccines available to underserved homebound beneficiaries who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources. We agreed with commenters that the added costs and compelling needs required CMS to adopt the in-home add-on payment rate for COVID–19 vaccine administration. In addition, we stated that since we did not expect those needs or costs to diminish immediately with the end of the PHE, we believed it would be appropriate to leave the in-home add-on payment rate in place through the end of the calendar year in which the PHE ends. We explained that this extension of payment past the end of the PHE would also afford CMS the opportunity to monitor vaccine uptake data (86 FR 65189).

In the CY 2023 PFS final rule (87 FR 69984 through 69986), we discussed that we had received many comments and requests from interested parties that the in-home add-on payment be applied more broadly to all preventive vaccines. Commenters also expressed concerns that discontinuation of the in-home additional payment would negatively impact access to the COVID–19 vaccine for underserved homebound beneficiaries. We noted that while we agreed with these concerns, we also believed that we needed to learn more about the populations served through the current in-home add-on payment, and other potential populations that may not have been able to access a COVID–19 vaccine despite the availability of the in-home add-on payment, in order to understand the barriers experienced when receiving vaccinations in a home versus in the community. We also noted the need to consider potential program integrity concerns. Therefore, we finalized that we would continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home, under the certain circumstances, only for the duration of CY 2023. We explained that we were continuing the additional payment for at-home COVID–19 vaccinations for another year to provide us time to track utilization and trends associated with its use, so to inform the Part B preventive vaccine policy on payments for in-home vaccine administration for CY 2024.

We also finalized the policy to adjust this payment amount for geographic cost differences as we do the payment for the preventive vaccine administration service, that is, based upon the fee schedule area where the COVID–19 vaccine is administered, by using the PFS GAF. In addition, we finalized an update to the $35.50 payment amount by the CY 2023 MEI percentage increase, consistent with the policy finalized for the other preventive vaccine administration services. We noted that in the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Therefore, we finalized (87 FR 69986) that for CY 2023, the in-home additional payment amount for COVID–19 vaccine administration described by HCPCS code M0201 was $36.85 ($35.50 × 1.038 = $36.85), and we established that payment for these services is adjusted for geographic cost differences using the relevant PFS GAF.

We note that in section III.H.3 of this final rule, we are finalizing revisions to § 410.152 that relate to these policies.

b. Conditions for Billing HCPCS Code M0201 Through CY 2023

In establishing the additional payment for COVID–19 vaccine

[315] *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html*, viewed on September 19, 2023.

[316] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies''.

administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. In the CY 2022 PFS final rule, we provided a detailed discussion on how we established the certain conditions under which the code can be used, and the situations we contemplated to arrive at our final payment policy (86 FR 65187 and 65188).

For purposes of this add-on payment for in-home COVID–19 vaccine administration, the following requirements have applied when billing for HCPCS code M0201: [317] [318]

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

++ They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

++ They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

++ They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID–19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be:

++ A private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter);

++ An apartment in an apartment complex or a unit in an assisted living facility or group home (including assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program);

++ A patient's home that is made provider-based to a hospital during the PHE for COVID–19; or

++ Communal spaces of a multi-unit or communal living arrangement.

- A home cannot be:

++ An institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[319]

To meet requirements for billing HCPCS code M0201, a COVID–19 vaccine must be administered inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. HCPCS code M0201, as noted in the code descriptor, can be billed only once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.

c. Policies for CY 2024 and Subsequent Years

As discussed in the CY 2024 PFS proposed rule (88 FR 52499 through 52500), we have engaged in an in-depth analysis of the use of HCPCS billing code M0201, which specifically indicates that a COVID–19 vaccine was furnished in the home on a Medicare claim. The analysis found that data for in-home COVID–19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 show the payment code was used at a disproportionately high rate by underserved populations, including persons who are dual eligible for both Medicare and Medicaid and those of advanced age. The data reflect that, between June 2021-June 2022, those 85 years of age and older were over 3 times more likely than younger beneficiaries to have received an in-home COVID–19 vaccination, and persons who are dual eligible for both Medicare and Medicaid were over 2 times more likely than those who are not dual eligible to have received a COVID–19 vaccine provided in their home. The data also showed higher usage of the in-home payment code among those with some common chronic conditions.[320]

Considering the results of our study, we concluded that the in-home additional payment improved healthcare access to vaccines for these often-underserved Medicare populations. From an analysis of the data, the in-home additional payment is billed significantly more frequently for beneficiaries that are harder to reach and that may be less likely to otherwise receive these preventive benefits. Therefore, we proposed to maintain the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit. In addition, since our statutory authority at section 1861(s)(10) of the Act to regulate Part B preventive vaccine administration is identical for all four preventive vaccines, and since the payment has been shown to positively impact health equity and healthcare access, we proposed to extend the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. We proposed to provide the additional payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine administrations in the home when the conditions described in section III.H.3.b of the CY2024 PFS proposed rule are met. We noted that several of the conditions we established for the in-home additional payment refer specifically to COVID–19. We also stated in the CY 2024 PFS proposed rule, that if we finalize the proposal to expand the in-home additional payment to the other preventive vaccines, we would broaden the conditions for the payment to reflect preventive vaccines for the other diseases.

In the CY 2024 PFS proposed rule (88 FR 52500), we explained that, for CY 2024, the proposed growth rate of the 2017-based MEI was estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through fourth quarter 2022. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the CY 2024 PFS final rule; we would apply that new MEI percentage increase to update last year's $36.85 CY 2023 in-home additional payment amount for Part B preventive vaccine administration.

Since expanding this policy could mean that multiple vaccines are administered during the same visit to the home, we proposed to limit the additional payment to one payment per

[317] *https://www.cms.gov/medicare/payment/covid-19/medicare-covid-19-vaccine-shot-payment.*

[318] *https://www.cms.gov/files/document/vaccine-home.pdf.*

[319] 42 CFR 409.42(a).

[320] Common chronic conditions as identified by the CMS Chronic Conditions Data Warehouse, *https://www2.ccwdata.org/web/guest/home/.*

home visit, even if multiple vaccines are administered during the same home visit. We emphasized that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. We stated our intent of continuing to monitor utilization of the M0201 billing code for the in-home additional payment, and that we plan to revisit the policy should we observe inappropriate use or abuse of the code. We proposed to modify the regulations at § 410.152(h) to reflect these policies.

We solicited comments on the policy condition regarding Medicare payment of the in-home additional payment amount for up to a maximum of five vaccine administration services per home unit or communal space within a single group living location, but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location. We invited feedback on the applicability of this policy to the proposed policy to make the in-home additional payment available for the administration of all four Part B preventive vaccines.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of our proposals to maintain the in-home additional payment for the administration of COVID–19 vaccine, and to extend the in-home additional payment to the administration of the other three Part B preventive vaccines. Many commenters remarked that this proposal, if finalized, would greatly improve access to vaccines for vulnerable, hard to reach and medically underserved populations. Commenters referenced increased access for the those with chronic illness, financial and social precarity, and for those who lack access to digital resources; those who face difficulty accessing transportation or who have limitations to mobility; minority and marginalized patients; older Americans; dually-eligible individuals; and generally, all those with barriers who rely on in-home care. Similarly, several commenters pointed to the positive impact the proposal would have on health equity. Other commenters voiced their belief that the policy will improve utilization of preventive vaccines, and therefore, help beneficiaries avoid serious illness. One commenter noted that the proposal would support primary care providers in their effort to combat vaccine hesitancy.

Several comments voiced their support for our continued payment amount updates based on inflationary factors via the MEI, and for our geographic adjustments of payment amounts based on the PFS GAF.

Many of the supportive commenters discussed the importance of vaccination in general. One commenter stated that the COVID–19 pandemic emphasized the need for an effective vaccine delivery infrastructure. The commenter also emphasized the importance of vaccination in pediatric and primary care. Another commenter discussed the barriers that Medicare enrollees face in obtaining vaccinations, and noted, with reference to an article published by the Assistant Secretary for Planning and Evaluation, that homebound older adults are more likely to be members of racial and ethnic minorities.[321] Another commenter mentioned that, in addition to vaccines' contributions to the prevention of disease and lowering of healthcare costs, vaccines also contribute to treatment plans for certain conditions. Commenters encouraged CMS to continue incentivizing vaccination using every tool available, and to continue to believe creatively about ways to support vaccine access all parts of Medicare.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to improve health access and equity. We agree that finalizing this proposal would improve access to preventive vaccines for all of the aforementioned groups of Medicare enrollees, including vulnerable, hard to reach and medically underserved populations, and those with chronic conditions and mobility challenges. We look forward to continuing our work with all of our partners in order to continue facilitating increased access to vaccinations for both Medicare enrollees and all Americans.

Comment: Some commenters requested that CMS consider a wide expansion of the proposals regarding in-home additional payments for Part B vaccine administration. While virtually all commenters supported our proposals, some commenters requested that the Part B vaccine benefit cover all Medicare-covered vaccines, including those currently covered under Part D, such as the new respiratory syncytial virus (RSV) vaccine. One commenter specified that this move would likely minimize cost-sharing for patients. Others stated that the proposed in-home additional payment should apply to all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). One commenter stated that they believe that all vaccines should be available in all settings of care.

A few commenters requested that CMS clarify that those furnishing vaccines in the home be permitted to bill for any additional unexpected services at the time of the visit.

Another commenter voiced support for legislation that would allow pharmacists to bill for vaccine administration under Medicare Part B, as they believe that would help relieve constraints on primary care providers and other healthcare professionals. Similarly, another commenter requested that CMS address the types of health care providers that are permitted to bill for furnishing preventive vaccines, and this commenter specifically noted that CMS should consider allowing Emergency Medical Services (EMS) Providers, Nursing Technicians, Pharmacy Technicians, and other provider types to be paid for administering vaccines, in order to increase access to preventive care.

One commenter requested that CMS use COVID–19 vaccine reporting requirements that were put in place during the pandemic to continue to prioritize vaccine reporting and suggested that this policy would support CMS' efforts to promote interoperability.

Response: We thank commenters for their interest in and support of our policies. We note that, in accordance with the statute, Part B payment can be made only for the preventive vaccines specified at section 1861(s)(10) of the Act. Please see sections III.H.1 and III.H.2 of this final rule for more information.

We will not address each of these comments specifically, as they are outside of the scope of our proposals in the CY 2024 PFS proposed rule. We did not make any proposals regarding expanding the Part B preventive vaccine benefit to additional vaccines. We did not make any proposals regarding payment for vaccines covered under Part D, and we did not address vaccine administration in other health care settings. We also note that our proposals were limited to payment for in-home vaccine administration. We did not make any proposals regarding the scope of practice for those who would administer the vaccines, and we did not

[321] Characteristics of Homebound Older Adults: Potential Barriers to Accessing the COVID–19 Vaccine Issue Brief. Office of the Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. April 5, 2021. *https://aspe.hhs.gov/reports/characteristics-homebound-older-adults-potential-barriers-accessing-covid-19-vaccineissue-brief.*

address COVID–19 vaccination reporting.

However, as noted above, CMS is dedicated to the goal of increasing vaccine access for Medicare enrollees. We appreciate that these commenters share CMS' priorities in this area. We are actively taking these comments into consideration for the future, as appropriate under our statutory authority.

Comment: Some commenters requested specific expansions of our proposed policies. One commenter requested that we remove the requirement that a patient have difficulty leaving the home, or that patient must face barriers to getting a vaccine in settings other than their home, for the additional payment for in-home vaccine administration to apply. This commenter and others also suggested that we allow ''home'' to be defined to include skilled nursing facilities. Other commenters requested that CMS consider lifting the limit on the additional in-home payment to one payment per home visit, given the costs and operations associated with administering vaccines. A commenter explained that each vaccine administration involves unique work, time, and risk, and each vaccine administration has its own associated products.

One commenter requested CMS to consider further incentivizing access to home-based care by revising the additional in-home vaccine administration payment to address travel-related expenses, including various factors such transportation options, transportation costs, geographic distance and traffic conditions. Similarly, other commenters requested CMS to consider an additional payment for an extended visit with a patient or an extended commute to a patient.

Response: The proposals we included in the CY 2024 PFS proposed rule for the add-on payment for in-home administration of preventive vaccines are the first to establish payment for in-home vaccination under Part B outside the circumstances of the PHE for COVID–19. Our proposed regulations regarding the Part B preventive vaccine in-home additional payment are based on the payment conditions for the COVID–19 in-home additional payment, and they allow beneficiaries to receive Part B preventive vaccines in a variety of circumstances. As stated earlier in this section, we intend to continue to monitor utilization of the HCPCS M0201 billing code for the in-home additional payment, and we plan to revisit the policy should we observe inappropriate use or abuse of the code. We are also carefully reviewing all the comments discussed above and will take them into consideration for potential future rulemaking regarding in-home vaccine administration payments.

After consideration of public comments, we are finalizing these policies as proposed. The in-home additional payment for the administration of pneumococcal, influenza, and hepatitis B vaccines will be effective January 1, 2024, together with the current additional payment for the in-home administration of COVID–19 vaccines that is being extended. That is, providers and suppliers would continue to bill Medicare Part B for the additional payment for the in-home administration of COVID–19 vaccines, and beginning January 1, 2024, they would also be able to bill Medicare Part B for the in-home administration of pneumococcal, influenza, and hepatitis B vaccines. In addition, like the current in-home additional payment for COVID–19 vaccine administration, the in-home additional payment for the administration of Part B preventive vaccines will be geographically adjusted based on the PFS GAF, and annually updated by the CY 2024 MEI percentage increase.

We proposed in the CY 2024 PFS proposed rule (88 FR 52500) that if more recent data become available (for example, a more recent estimate of the CY 2024 MEI percentage increase), we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the CY 2024 PFS final rule, and would then apply that new MEI percentage increase to update last year's $36.85 CY 2023 in-home additional payment amount for Part B preventive vaccine administration. More recent data are now available, and we believe it is appropriate to use the updated data to update the in-home additional payment amount for CY 2024. The MEI percentage increase for this CY 2024 final rule is 4.6 percent, based on the most recent historical data through second quarter 2023. The CY 2024 in-home additional payment for Part B preventive vaccine administration is therefore $38.55 ($36.85 × 1.046 = $38.55).

Thus, in this final rule, we are amending the Part B payment for preventive vaccine administration regulations at § 410.152(h) to reflect the following:

- Effective January 1, 2022, the Medicare Part B additional payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home, under certain circumstances, is $35.50. For COVID–19 vaccines administered in the home January 1, 2022, through December 31, 2022, the additional payment amount under Medicare Part B is adjusted to reflect geographic cost variations using the PFS GPCIs.
- Effective January 1, 2023, the additional payment amount for the administration of a COVID–19 vaccine in the home is updated annually based upon the percentage change in the MEI. For COVID–19 vaccines administered in the home January 1, 2023, through December 31, 2023, the in-home vaccine administration payment amount is adjusted to reflect geographic cost variations using the PFS GAF.
- Effective January 1, 2024, the payment policy allowing for additional payment for the administration of a COVID–19 vaccine in the home is extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit, and the in-home vaccine administration payment amount is the same for all four vaccines (though only one payment is made per home visit regardless of how many vaccines are administered). That is, beginning January 1, 2024, Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home, under certain circumstances. This additional payment amount will be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF.

d. Summary of Payment Amounts for CY 2024 and Subsequent Years

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, we are including Tables 46A and 46B that summarize Medicare Part B the potential alternative preventive vaccine administration payment amounts at the time of the publication of this final rule. If the EUA declaration continues in effect on January 1, 2024, the payment rates in Table 47 will apply. If the EUA declaration is terminated before January 1, 2024, the payment rates in Table 48 will apply.

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TABLE 47: CY 2024 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$32.57	MEI	GAF
COVID-19 Vaccine[2,4]	$43.43	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,4,5]			
Infusion: Health Care Setting	TBD	N/A	GAF
Infusion: Home	TBD	N/A	GAF
Intravenous Injection: Health Care Setting	TBD	N/A	GAF
Intravenous Injection: Home	TBD	N/A	GAF
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.

[2] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*.

[3] *https://www.cms.gov/monoclonal*. As of the issuance of the CY2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] To be determined (TBD). As of the issuance of the CY 2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

[6] The CY 2024 MEI percentage increase is 4.6 percent based on the most recent historical data through the 2nd quarter of 2023.

TABLE 48: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2024, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[7]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1,4]	$32.57	MEI	GAF
COVID-19[2,4]	$32.57	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,5]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD [5,6]	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.

[2] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*.

[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered. Beneficiary coinsurance and deductible are applicable.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] As of the issuance of the CY2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

[6] Please see section III.H.4 of this final rule.

[7] The CY 2024 MEI percentage increase is 4.6 percent based on the most recent historical data through the 2nd quarter of 2023.

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4. Other Amendments to Regulation Text

In CY 2023 PFS final rule (87 FR 69987 through 69993), we finalized changes to our policies regarding Part B coverage and payment for COVID–19 monoclonal antibody products and their administration. In that final rule (87 FR 69987), we discussed that all COVID–19 monoclonal antibody products and their administration are covered and paid for under the Part B preventive vaccine benefit through the end of year in which the Secretary terminates the EUA declaration for drugs and biological products with respect to COVID–19. In addition, we explained that, under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine, as well COVID–19 monoclonal antibodies and their administration, through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website (87 FR 69987). In Tables 46A and 46B, we do not list the unique payments rates for the administration of COVID–19 monoclonal antibodies since at the time of the publication of this final rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States.

In the CY 2023 PFS final rule, we also established a policy to continue coverage and payment for monoclonal antibodies that are used for pre-exposure prophylaxis (PrEP) of COVID–19 under the Part B preventive vaccine benefit, if they meet applicable coverage requirements (87 FR 69992). We explained that we will continue to pay for these products and their administration even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we established that payments for the administration of monoclonal antibodies that are used for PrEP of COVID–19 would be adjusted for geographic cost variations using the PFS GAF. However, we did not codify these policies in our regulations. In the CY 2024 PFS proposed rule (88 FR 52500), proposed revisions to the relevant regulations to include monoclonal antibodies that are used for PrEP of COVID–19 under the Part B preventive vaccine benefit. Specifically, we proposed to revise the following regulations to reflect policies for monoclonal antibodies for PrEP of COVID–19 that we finalized in the CY 2023 PFS final rule:

- At § 410.10, in paragraph (l), we proposed to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.
- At § 410.57, in paragraph (c), we proposed to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.

We note again that at the time of the publication of this final rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. Therefore, we did not finalize any payment regulations regarding monoclonal antibodies for PrEP of COVID–19 at this time. If and when a new monoclonal antibody for PrEP of COVID–19 becomes authorized for use, we will use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS final rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. We will subsequently proposed coding and payment rates for the administration of that product via rulemaking.

We also note that, for the purposes of the in-home additional payment discussed above in section III.H.3 of this final rule, that additional payment is not applicable to the administration of monoclonal antibodies for PrEP of COVID–19. For monoclonal antibodies for PrEP of COVID–19, as displayed in Tables 46A and 46B, we set the coding and payment rates for the administration of COVID–19 monoclonal antibodies in the home to be higher than those in other health care settings, and therefore such amounts already account for the higher costs of administering the product in the home. More information on our coding and payment policies for COVID–19 monoclonal antibodies is available at *https://www.cms.gov/monoclonal*.

Also, in the CY 2023 PFS final rule, we codified our payment rates for all four Part B preventive vaccines, and we finalized that the vaccine administration payment rates for all four Part B preventive vaccines would be annually updated by the MEI and geographically adjusted by the PFS GAF. We included these policies in regulation text at § 410.152(h). However, we neglected to include the effective date for the MEI policy in the regulation text. Therefore, in the CY 2024 PFS proposed rule (88 FR 52501), we proposed the following correction, and we reorganized other elements of the regulation text at § 410.152(h) as we proposed to codify the in-home additional payment:

- At § 410.152, at paragraph (h)(5), we proposed to add that the paragraph is effective beginning January 1, 2023.
- At § 410.152, we proposed to combine the existing paragraphs (h)(2) and (3) into a new paragraph (h)(2), with paragraphs (h)(2)(i) and (h)(2)(ii).
- At § 410.152, at a revised paragraph (h)(3), we proposed new regulations regarding the in-home additional payment for preventive vaccine administration, as described in section in section III.H.3.c of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed amendments to regulation text detailed above. Commenters reiterated their support for CMS' policy regarding monoclonal antibodies for PrEP of COVID–19, since these products provide certain patients, including immune-compromised patients, additional options for preventive care for COVID–19.

Response: We thank commenters for their support of our proposals.

Comment: One commenter requested CMS clarify guidance regarding payment for potential monoclonal antibodies that are indicated for both PrEP and treatment of COVID–19.

Response: As previously stated, at the time of the publication of this final rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. If and when a new monoclonal antibody for either PrEP or treatment of COVID–19 becomes authorized for use, we would use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS final rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. In the case of a monoclonal antibody for PrEP of COVID–19, we would subsequently propose coding and payment rates for the administration of that product via rulemaking.

After consideration of public comments, we are finalizing these amendments to regulation text as proposed.

I. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016). MDPP was established in 2017 as an ''additional preventive service'' covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model test), CMS created a new MDPP supplier type through rulemaking in the CY 2017 PFS final rule (81 FR 80471),[322] in addition to requiring organizations that wish to participate in MDPP enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions using a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum. Sessions are furnished over 12 months by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. Suppliers may use the CDC-developed PreventT2 curriculum [323] or an alternate CDC-approved curriculum when delivering MDPP. The primary goal of the expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss.

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP on April 1, 2018. Through the National Diabetes Prevention Recognition Program (DPRP), the CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards,[324] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test,[325] the CDC's National DPP,[326] and DPRP Standards,[327] please refer to the CY 2017 [328] (81 FR 80471) and CY 2018

[322] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. 81 FR 80471. Accessed March 12, 2023. *https://www.govinfo.gov/content/pkg/FR-2016-11-15/pdf/2016-26668.pdf.*

[323] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[324] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[325] Health Care Innovation Awards. *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[326] *https://www.cdc.gov/diabetes/prevention/index.html.*

[327] *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[328] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. 81 FR 80471.

PFS [329] (82 FR 52976) final rules and related websites.

We proposed to amend § 410.79(b),[330] Conditions of coverage, to remove the definition for the core maintenance session interval while adding definitions for the following terms: Combination delivery, Distance learning, Extended flexibilities, Extended flexibilities period, Full-Plus CDC DPRP recognition, Online delivery, and Virtual sessions. In addition, we proposed to amend § 410.79(c)(2)(i)(A) and (B) [331] to update the maximum number of payable sessions during the MDPP core services period. We also proposed to amend § 410.79(e)(3) to extend certain flexibilities established through rulemaking as a result of the recent COVID–19 public health emergency (PHE) for a period of 4 years.[332] Furthermore, we proposed to amend § 414.84 Payment for MDPP Services [333] to streamline the MDPP payment structure by adding service-based attendance payments while still retaining the diabetes risk reduction performance payments for 5 percent and 9 percent weight loss. We also proposed to amend § 424.205(a) and (c) to remove ''MDPP interim preliminary recognition'' and replace it with ''CDC preliminary recognition''.[334]

1. Changes to § 410.79 by Amending Paragraphs (b), (c)(2)(i) and (e)(3)

MDPP is a comprehensive behavior change intervention for people with pre-diabetes with the goal of preventing them from becoming diabetic. CMMI expanded this model in 2018 based on a Health Care Innovation Award (HCIA) to the National Young Men's Christian Association (YMCA) of the USA (Y–USA), who tested the Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (National DPP) in the Medicare population through their network of YMCAs in multiple US markets (DPP model test).[335] The DPP model test successfully met statutory criteria for model expansion,[336] demonstrating five percent weight loss by participants (a key metric of the program's success) along with statistically significant reductions in Medicare spending, ED visits and inpatient stays.[337]

The MDPP expanded model was implemented through the rulemaking process in two phases in the CY 2017 PFS final rule [338] and in the CY 2018 PFS final rule.[339] In the CY 2017 PFS, we established MDPP to expand the duration and scope of the DPP model test, created a new supplier class, finalized the MDPP framework for expansion, and finalized details about the benefit such as beneficiary eligibility criteria, MDPP supplier eligibility criteria, enrollment policies, and the MDPP benefit period. In the CY 2018 PFS, we finalized additional policies necessary for suppliers to begin furnishing MDPP services nationally in 2018, including established the MDPP payment structure and amounts, provided additional supplier enrollment requirements and supplier compliance standards. In addition, we updated CY 2017 policies regarding MDPP services and beneficiary eligibility, established an MDPP-specific supplier enrollment application and an effective date for MDPP billing privileges.

Although MDPP was established through the 2017 PFS, it went into effect in 2018, with supplier enrollment starting January 1, 2018, and beneficiary enrollment starting April 1, 2018. After nearly 6 years of implementation, we are finalizing updates to MDPP based on lessons learned since the expanded model's launch, including updates to definitions and the core services period as well as extending the flexibilities allowed under the COVID–19 Public Health Emergency for a period of 4 years.

The core maintenance session interval, as defined in the CY 2018 PFS, means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.[340] The core maintenance session interval represents a performance interval for attendance-based payments in the current payment structure. Because we proposed that beneficiary attendance be paid on a fee-for-service basis, we proposed removing the core maintenance session interval to make the payment structure less confusing.

Accessed March 12, 2023. *https://www.govinfo.gov/content/pkg/FR-2016-11-15/pdf/2016-26668.pdf.*

[329] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 52976. *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

[330] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52738. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[331] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52739. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[332] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52739. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[333] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52740. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[334] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52750. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[335] L Hinnant, S Razi, R Lewis, A Sun, M Alva, T Hoerger et al. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. RTI International. March 2016; *https://www.cms.gov/priorities/innovation/files/reports/hcia-ymcadpp-evalrpt.pdf.*

[336] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

[337] Rojas Smith. L., Amico, P., Hoerger, T. J., Jacobs, S., Payne. J., & Renaud, J.: Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report Addendum — August 2017 (*https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf* (pp. 858–914).

[338] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. 81 FR 80170. *https://www.govinfo.gov/content/pkg/FR-2016-11-15/pdf/2016-26668.pdf.*

[339] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 52976. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[340] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53359. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

In prior rulemaking, we did not formally define the MDPP delivery modalities that are considered virtual. In this final rule, we proposed adding definitions for distance learning and online delivery modalities in § 410.79(b) to better clarify which virtual modalities can be used in the proposed Extended flexibilities period.[341]

We also proposed to modify the definitions for Make-up session, MDPP services period, and MDPP session as defined in § 410.79(b) to remove most references to ongoing maintenance sessions.[342] In the finalized CY 2022 PFS, we removed eligibility for the ongoing maintenance sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022.[343] Given that the 2-year MDPP services period for those beneficiaries who started MDPP on or before December 31, 2021, will end on or before December 30, 2023, eligibility for ongoing maintenance services will end December 31, 2023 for all beneficiaries.

The core services period, as defined in § 410.79(c)(2)(i)(A) and (B), consists of at least 16 core sessions offered at least one week apart during the months 1 through 6 of the MDPP services period, and two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. In order to conform to the proposed revisions to the payment structure in § 414.84, we proposed to amend the expanded model regulations to allow for fee-for-service payments for beneficiary attendance during the core services period.

MDPP's performance-based payment structure was established in the CY 2018 PFS final rule[344] to pay for the Set of MDPP services that makes up the periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all MDPP performance payments constitutes the total performance-based payment amount for the Set of MDPP services. Although beneficiaries may currently attend at least 16 weekly sessions in months 1-6 and at least 6 monthly sessions in months 7–12, MDPP suppliers are only paid five times for beneficiary attendance: after a beneficiary attends the 1st, 4th and 9th sessions in months 1–6, and after attending the second core maintenance session in months 7–9 and in months 10–12.[345]

Since this payment structure went into effect in 2018, feedback was received from suppliers and interested parties that the MDPP performance-based payment structure is confusing to suppliers, including those new to Medicare and existing Medicare-enrolled suppliers. Confusion with claims submission has been due in part to the MDPP payment structure, which pays for attendance and diabetes risk-reduction performance-based milestones instead of paying for an individual service. Paying for an individual service delivery is typical in Medicare.[346] Public comments in response to the CY 2018 PFS proposed rule have indicated that CMS should modify its payment structure such that it allows for an adequate and predictable payment stream to cover the cost of providing services as long as beneficiaries attend sessions.

After 5 years of testing the current performance-based payment structure, we have determined that the structure is inadequate to meet MDPP supplier needs and beneficiary retention. For example, there are currently five attendance-based performance payments over the 12-month MDPP service period, with a potential 4- to 5-month lag between the third payment and the fourth payment. We believe that our current payment structure does not incentivize beneficiary retention. As a result, we proposed fee-for-service payments for beneficiary attendance in this final rule, allowing for up to 22 attendance-based payments versus the five that are currently in place. Thus, we proposed allowing beneficiaries to attend a maximum of 22 sessions during the core services period, including up to 16 sessions in months 1-6 and up to 6 sessions in months 7–12.[347]

We proposed to amend the MDPP expanded model to revise certain MDPP policies finalized in the CY 2021 PFS final rule.[348] We proposed to extend the flexibilities allowed under the COVID-19 PHE for a period of 4 years until December 31, 2027. These Extended flexibilities are described in § 410.79(e)(3)(iii), and (iv) of this final rule. The MDPP regulations provide for the following flexibilities during the PHE or an applicable 1135 waiver event:

- *Alternatives to the requirement for in-person weight measurement (§ 410.79(e)(3)(iii)).* Section 410.79(e)(3)(iii) permits an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary.

[341] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52738. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[342] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52738. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[343] Centers for Medicare & Medicaid Services. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 FR 64996. *https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf.*

[344] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 52976. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[345] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53280. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[346] What Part B Covers. *https://www.medicare.gov/what-medicare-covers/what-part-b-covers.*

[347] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52739. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[348] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19. 85 FR 85027. *https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf.*

We stated that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility allows suppliers to bill for participants achieving weight loss performance goals.

• *Elimination of the maximum number of virtual services (§ 410.79(e)(3)(iv):* The virtual session limits described in § 410.79(d)(2), and (d)(3)(i) and (ii) do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. MDPP suppliers were permitted to provide the Set of MDPP services virtually during the PHE for COVID-19, as long as the virtual services were furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, follow the CDC-approved National DPP curriculum requirements, and the supplier has an in-person DPRP organizational code.

We proposed that during the Extended flexibilities period, MDPP suppliers may provide virtual services as long as they are provided in a manner consistent with the CDC DPRP standards for distance learning.[349] The extension of these flexibilities under § 410.79I(3)(v) will allow beneficiaries to obtain the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning for a period of 4 years.

In the May 2, 2023, **Federal Register** (88 FR 27413), we published a notice extending PHE flexibilities for MDPP suppliers, providing them the opportunity to deliver the Set of MDPP services either virtually or in-person (or a combination of both) from May 12, 2023, through December 31, 2023. As a result, MDPP suppliers can continue delivering the Set of MDPP services on a virtual basis during this period to allow MDPP suppliers additional time to resume in-person services. For more information on the **Federal Register** Notice, please see *https://www.federalregister.gov/d/2023-09188*. For more information on the flexibilities that MDPP suppliers were permitted to implement during the PHE, please see *https://www.ms.gov/files/document/participants-medicare-diabetes-prevention-program-cms-flexibilities-fight-covid-19.pdf*. The CDC's 2021 DPRP Standards allow two types of virtual delivery modalities: ''Distance learning'' and ''online'' delivery.[350] According to CDC, *Distance learning* involves ''a yearlong National DPP lifestyle change program delivered 100 percent by trained Lifestyle Coaches via remote classroom or telehealth. The Lifestyle Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.''[29] Although ''telehealth'' is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 52976) that MDPP services delivered via a telecommunications system or other remote technologies do not qualify as telehealth services.[351]

Additionally, CDC defines *online* delivery as a yearlong National DPP lifestyle change program delivered 100 percent online for all participants. [29] The program is experienced through the internet via smart phone, tablet, or laptop in an asynchronous classroom where participants are experiencing the content on their own time without a live Lifestyle Coach teaching the content. However, live Lifestyle Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.[352]

In the CY 2021 PFS final rule (85 FR 84472),[353] we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by suppliers who offered in-person services. For the proposed Extended flexibilities period,[354] we proposed to limit virtual delivery to the CDC DPRP definition of ''distance learning.'' This proposal was based on internal data from the PHE for COVID–19, including anecdotal, monitoring, evaluation, claims, and CDC DPRP data, suggesting that the majority of the MDPP virtual sessions delivered during the PHE for COVID–19 1135 waiver event were distance learning sessions.

Although the MDPP was certified and established as an in-person service, in response to the PHE for COVID–19, we established and implemented policies that allowed MDPP suppliers to provide MDPP services virtually during the PHE for COVID–19, as long as the virtual services: were furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, the curriculum furnished during the virtual sessions addressed the same curriculum topics as the CDC-approved National DPP curriculum, the supplier had an in-person DPRP organizational code, and other requirements specified at

[349] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52739. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[350] Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[351] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[352] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[353] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84472), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.*

[354] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52503. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

§ 410.79(e)(3)(iv) were satisfied.[355] We believe that distance learning allows for a similar live group experience for beneficiaries but only when delivered in a synchronous virtual manner through telephonic or video conference. Through utilizing distance learning, participants may still interact with their Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike online delivery which is delivered asynchronously. Therefore, the proposed Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''online'' modality, including virtual make-up sessions.

We previously stated that the MDPP expanded model was certified for expansion by the Chief Actuary of CMS, based on a model test that used in-person delivery.[356] Given the 3-year duration of the PHE for COVID–19 and the feedback received from MDPP suppliers, beneficiaries, MA plans, interested parties, and comments submitted during the CY 2022 rulemaking, there is interest in extending the flexibilities offered during the PHE for COVID–19 to reduce the burden of traveling to an in-person class on a weekly basis, as beneficiaries experienced transportation as well as child/elder care challenges with in-person delivery. Additionally, we have heard interest in a hybrid or combination delivery option where participants could attend some in-person classes as well as virtual classes. As a result of this feedback, we proposed to extend the flexibilities allowed under § 410.79(e)(3)(iii) (regarding use of alternative methods for obtaining weight measurements during virtual services) and § 410.79(e)(3)(iv) (regarding elimination of the maximum number of virtual services) for 4 years, to give us time to test and evaluate the distance learning delivery of MDPP.

Since MDPP was established in the CY 2017 PFS final rule, CMS and interested parties have considered whether fully virtual services could be included as part of the expanded model. For example, in the CY 2017 PFS proposed rule, we proposed that MDPP suppliers be allowed to provide MDPP services via remote technologies, even though the majority of CDC DPRP organizations provided in-person delivery at that time.[357] However, we also recognized that the virtual delivery of the Set of MDPP services may introduce additional risk of fraud and abuse. CMS stated that if that provision was to be finalized, we will propose specific policies in future rulemaking to mitigate these risks. In the CY 2017 PFS final rule (81 FR 80459), we deferred establishing policies related to organizations delivering the Set of MDPP services virtually.

In the subsequent CY 2018 PFS proposed rule, we explained our rationale for proposing not to allow fully virtual delivery of MDPP, but did propose to allow, consistent with CDC DPRP Standards, a limited number of virtual make-up sessions for participants who missed a regularly scheduled session.[36] ''Virtual make-up session'' was defined in § 410.79(d)(2) as a make-up session that is not furnished in-person and that is furnished in a manner consistent with the requirements in paragraph § 410.79(d)(1). In the CY 2018 PFS final rule,[358] we finalized that the Set of MDPP services would be primarily delivered in-person, in a classroom-based setting, and within an established timeline.

We prioritized establishing a service that, when delivered within this framework, would create the least risk of fraud, waste, and abuse; increase the likelihood of success for beneficiaries; and maintain the integrity of data. Furthermore, we believed at that time that in-person administration of beneficiaries' weight measurements was the most reliable and appropriate approach to monitoring beneficiary-level progress toward the 5 percent weight loss programmatic goal.

However, circumstances have changed since the start of the expanded model. We have received comments from interested parties in response to the CY 2018 PFS proposed rule and thereafter regarding increasing the limited virtual delivery of MDPP. Commenters noted that increased virtual options could expand access to MDPP for beneficiaries in rural areas, those who lack access to healthcare providers, specifically minority beneficiaries living within underserved communities, beneficiaries who are homebound or who lack transportation options, as well as increase beneficiary choice of delivery modality and flexibility of location. Commenters also noted that virtual National DPP delivery has been successful in reaching beneficiaries in certain locations. Ultimately, we finalized our policy that suppliers could offer no more than four virtual makeup sessions during months 1–6 and two virtual makeup sessions during months 7–12.

On March 13, 2020, less than 2 years after MDPP went into effect, COVID–19 was declared a national emergency by Proclamation 9994.[359] By mid-March 2020, MDPP suppliers were largely

[355] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 85027), December 28, 2020. *https://www.federalregister.gov/d/2020-26815*.

[356] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84833), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.pdf*.

[357] Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 81 FR 46417. July 15, 2016. *https://www.govinfo.gov/content/pkg/FR-2016-07-15/pdf/2016-16097.pdf*.

[358] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 53359, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf*.

[359] *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/10/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic-3/#:~:text=On%20March%2013%2C%202020%2C%20by,(COVID%2D19)%20pandemic*.

unable to deliver in-person classes due to national and local restrictions resulting from the national emergency. On April 6, 2020, CMS established MDPP PHE-related flexibilities in the first interim final rule with comment (IFC–1),[360] to allow for temporary flexibilities that prioritized availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by extreme and uncontrollable circumstances during the PHE for COVID–19. These flexibilities allowed an unlimited number of virtual sessions, waived the once-per-lifetime limit for those participating in MDPP when the PHE for COVID–19 started, and waived the 5 percent weight loss requirement to continue with ongoing maintenance sessions.

However, we did not waive the requirement for in-person weigh-ins at that time, leaving suppliers unable to obtain the 5 percent weight loss performance payment given the local and State restrictions that may have kept individuals at home during the initial months of the PHE for COVID–19. This prevented suppliers from collecting an in-person weight from beneficiaries at each MDPP session as described in § 424.205(g)(2)(v) to document the 5 percent weight loss.

In the CY 2021 PFS final rule,[361] we finalized the MDPP Emergency Policy and updated the PHE flexibilities established in the IFC–1 in the following ways: allowing for virtual weigh-ins and new cohorts to begin virtually; reinstating the 5 percent weight loss requirement during an 1135 waiver event; and reinstating the once-per-lifetime limit during an 1135 waiver event starting with beneficiaries who started the Set of MDPP services in 2021 or thereafter. These changes sought to address interruptions in services caused by CMS not waiving the in-person weigh-in in IFC–1, which prevented MDPP suppliers from starting new cohorts and getting reimbursed for participants who achieved and maintained the 5 percent weight loss goals. Additionally, beneficiaries who began sessions on or before December 31, 2020, were able to re-start MDPP sessions at a later date. Similarly, we allowed suppliers to pause, then resume MDPP sessions at a later date.

During the PHE for COVID–19, we allowed full virtual delivery of MDPP. In making that policy change in the CY 2021 PFS final rule, we stated that ''Because MDPP services are covered under Medicare only when they are furnished at least in-part in-person, a supplier that does not have an organizational code authorizing in-person services (''virtual-only suppliers'') may not provide MDPP services, either virtually or in-person.''[362] We indicated that it is not appropriate to permit virtual-only suppliers, such as suppliers with CDC DPRP recognition in the distance learning, online, or combination only modalities, to furnish MDPP services when the Emergency Policy is in effect. This is due to the requirement that MDPP suppliers remain prepared to resume in-person delivery of the Set of MDPP services to start new cohorts and to serve beneficiaries who wish to return to in-person services when the Emergency Policy is no longer in effect.

As stated earlier, we proposed in the CY 2024 PFS proposed rule to extend the flexibilities allowed during the PHE for COVID–19 under § 410.79(e)(3)(iii), and (iv) for 4 years, or through December 31, 2027.[363] Next, we proposed that the Extended flexibilities under § 410.79(e)(3)(iii) and (iv) continue to apply only to MDPP suppliers that have and maintain CDC DPRP in-person recognition.[364] We recognized that organizations and interested parties may be disappointed that we did not propose to allow organizations with CDC recognition in distance learning delivery modalities to participate in MDPP unless they also have and maintain their in-person CDC recognition. In the CY 2021 PFS final rule,[365] we stated that virtual only suppliers are not permitted to provide the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services after the PHE for COVID–19 or other applicable 1135 waiver event ends, and MDPP suppliers need to be able to accommodate their request.

During the PHE for COVID–19, we allowed greater flexibility with the use of virtual sessions, but the virtual delivery was primarily furnished as a virtual classroom or through distance

[360] Centers for Medicare & Medicaid Services, HHS. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. (85 FR 19230, Monday, April 6, 2020) *https://www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.*

[361] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84831), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.pdf.*

[362] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84830), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.pdf.*

[363] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52503. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[364] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52504. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[365] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84831), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.pdf.*

learning. In the CY 2024 PFS proposed rule,[366] we proposed that suppliers may offer a combination delivery of MDPP, including both in-person and distance learning. After almost 4 years of having the option to deliver the Set of MDPP services through distance learning, between the PHE for COVID–19 and the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, allowing MDPP suppliers to have the option to continue delivering the Set of MDPP services in the same manner will be the least disruptive to both suppliers and beneficiaries. We also proposed that MDPP suppliers may no longer suspend the Set of MDPP services as described in paragraph (e)(3)(v) in this section on or after January 1, 2024.[45] We believe we have given MDPP suppliers ample time, through the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, to adequately prepare to resume MDPP services from an operational perspective.

Furthermore, we also believe that our proposal to extend the PHE flexibilities for 4 years, or through December 31, 2027, will make MDPP more equitable and accessible for all eligible beneficiaries by providing both suppliers and beneficiaries more flexibility in how the Set of MDPP services are delivered, including in-person, distance learning, or a combination of in-person and distance learning. For example, allowing virtual sessions will make MDPP more accessible to beneficiaries who reside in rural or urban communities or urban underserved communities, and who may have transportation and other barriers to attending in-person classes. We anticipate that the combination of a simplified payment structure in addition to more flexibilities regarding how MDPP is delivered will encourage more organizations to engage in and deliver MDPP, making MDPP more accessible to more beneficiaries.

Additionally, extending the PHE flexibilities for 4 years would provide CMS an opportunity to evaluate the impact of the Extended flexibilities over a longer period of time. To better track the use of distance learning through claims, we proposed the creation of a new HCPCS G-code specific to ''distance learning,[367]'' that will more accurately track sites from which distance learning occurs, the number of MDPP sessions delivered by distance learning, monitor the expanded model for fraud, waste, or abuse, and evaluate the impact of distance learning and in-person delivery modalities of MDPP relative to cost-savings and diabetes risk reduction among participants.

In previous rulemaking, we received comments about how to best monitor the use of virtual make-up sessions, and whether CMS would use an additional HCPCS code or modifier to indicate virtual sessions since there was a limit to the number of virtual make-up sessions a beneficiary can attend.[368] In response, we finalized the use of the virtual make-up sessions in § 410.79(d)(2) and stated that MDPP suppliers must include the virtual modifier (VM) on claims to indicate the use of the virtual make-up session.[369] As part of the MDPP flexibilities established in response to the PHE for COVID–19, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2) and (d)(3)(i) and (ii), but still required MDPP suppliers to use the VM to indicate when a beneficiary received MDPP virtually.

Given the inconsistent use of the VM as it was described in the CY 2018 PFS final rule to document the virtual make-up sessions allowed during the PHE for COVID–19 as described in § 410.79(e)(2)(iii), we proposed to add a HCPCS code for distance learning to better track the synchronous virtual delivery of the Set of MDPP services to be used instead of the VM when submitting MDPP claims, including claims for make-up sessions since we are not permitting online (asynchronous virtual) delivery of the Set of MDPP services.[370] At this time, we did not propose to remove use of the VM entirely in-case we need it in future rulemaking, for example, should we allow online make-up sessions in future rulemaking.

MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities.[371] Given that the MDPP curriculum consists of no fewer than 16 weekly sessions in months 1–6, and 6 monthly sessions in months 7–12 months, the participation commitment may pose significant challenges to beneficiaries with limited mobility or access to reliable transportation. Based on findings from the 2nd evaluation report of the MDPP expanded model,[372] we believe that in-person requirements have contributed to significant MDPP underutilization, not only for those who reside in rural communities, but also populations that experience excessive diabetes-related disparities, including populations of color, low-income beneficiaries, those living in Tribal and rural communities, and the disabled.

To date, beneficiary uptake of MDPP has been low, with 4,848 beneficiaries participating as of December 31, 2021, and approximately half of those participants were Medicare FFS beneficiaries, and the remaining MA beneficiaries. White women account for the majority of MDPP participants to date, with the both the National DPP and MDPP having enrolled a similar high proportion of non-Hispanic white women. The evaluator estimated that 97 percent of participants travel less than 25 miles to attend in-person services, with the average distance to the nearest MDPP supplier location being 5 to 7

[366] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52505. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[367] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52506. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[368] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[369] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 53254, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[370] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52507. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[371] RTI International. Evaluation of the Medicare Diabetes Prevention Program (MDPP): Second Evaluation Report. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[372] RTI International. *Evaluation of the Medicare Diabetes Prevention Program: Second Evaluation Report.* November 2022. *https://innovation.cms.gov/data-and-reports/2022/mdpp-2ndannevalrpt.*

miles [373]. At the time of the second annual evaluation report, which was released in November 2022 and includes data through December 31, 2021, 39 percent of all Medicare beneficiaries live more than 25 miles from the nearest MDPP location. Extending the PHE flexibilities to allow distance learning will make MDPP more accessible to beneficiaries who live more than 25 miles from the nearest MDPP location or lack transportation [374]. Additionally, the second annual evaluation report (p. 32) [375] noted that suppliers tried to make MDPP services accessible to Medicare beneficiaries by scheduling sessions at locations that were most convenient to Medicare beneficiaries. It was also noted that while beneficiary engagement and connection tend to be stronger with in-person cohorts, moving to distance learning delivery reduced participant barriers (p. 34). While some suppliers and beneficiaries experienced initial challenges migrating to fully virtual delivery, the report noted an overwhelming support from MDPP suppliers for the continued opportunity to administer MDPP through distance learning or a combination of in-person and synchronous virtual delivery. We proposed in the CY 2024 PFS proposed rule [376] the use of synchronous virtual delivery as an acceptable modality for MDPP delivery, because our goal is to use the Extended flexibilities period to increase beneficiary access to and uptake of MDPP while demonstrating that the beneficiaries receiving the Set of MDPP services through distance learning experience similar or better outcomes compared to in-person delivery concerning attendance, achievement of the 5 percent weight loss goal, and cost savings.

We anticipate the proposed programmatic updates will boost supplier enrollment, with the goal of increasing beneficiary participation and retention due to increased access to the Set of MDPP services. Moreover, we believe that extending the PHE flexibilities will increase equitable access to diabetes preventive services among rural and at-risk populations, as well as minority beneficiaries who reside in communities underserved by healthcare providers. For example, for beneficiaries with transportation challenges or child/elder care obligations, the ability to participate in MDPP through a live virtual classroom, or distance learning, may encourage uptake and retention among those participants. Also, for beneficiaries living in rural areas or regions with a limited number of MDPP suppliers, the distance learning option will allow beneficiaries to enroll in programs further away from their homes, making MDPP accessible to more beneficiaries. Finally, we believe that increased participation in the Set of MDPP services through distance learning may provide data necessary to conduct an impactful evaluation of the synchronous virtual delivery of MDPP.

In the CY 2024 PFS proposed rule,[377] we proposed to amend § 410.79(b), (c), and (d) to remove most references to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS final rule,[378] we removed eligibility for the ongoing maintenance sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We proposed to amend § 410.79(b), (c)(2)(i) and (e)(2), and solicited comments on these proposals.[379]

We received public comments on these proposals. Overall, commenters were very supportive of the proposed changes. The following is a summary of the comments we received and our responses.

Comment: Several commenters encouraged CMS to consider adopting the same definitions for MDPP as CDC uses for the National DPP, including distance learning, online delivery, and combination modalities to better align the two programs. Commenters indicated that the addition of these definitions that are consistent with the CDC's definitions will reduce confusion about MDPP.

Response: We agree that MDPP and the National DPP should align terminology where applicable. Although CMS works closely with CDC to coordinate the National DPP and MDPP, there are times when the National DPP and MDPP will naturally diverge given that CMS is a payer of the MDPP Set of services, and CDC sets the quality standards for organizations that deliver the National DPP. CMS and CDC have worked closely to update the National DPP and MDPP for CY 2024, as MDPP updates were proposed in this provision, and CDC is updating its standards in 2024. To the extent possible, CMS may make conforming changes in future rulemaking, including applicable definitions.

Comment: Commenters were overwhelmingly supportive of the proposed changes to streamline the MDPP payment structure. Commenters indicated that improvements to the payment schedule may increase both supplier and beneficiary access to MDPP. MDPP coaches commented that the proposed changes are more streamlined and less burdensome to those responsible for billing.

Regarding the new HCPCS G-codes, commenters were very supportive of our creation of a new G-code for in-person delivery (G9886), distance learning (G9887), and maintenance of 5 percent weight loss from baseline in months 7 to 12 (G9888). Commenters agreed that these new G-codes will enable CMS to track trends related to the distance learning service delivery. One commenter recommended that instead of CMS allowing for six monthly claims for maintaining the 5 percent weight loss from baseline (G9888), CMS should consider a one-time payment of $48 for maintenance of 5 percent weight loss in months 7 to 12 that is paid at the time

[373] RTI International. Evaluation of the Medicare Diabetes Prevention Program (MDPP): Second Evaluation Report. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[374] RTI International. Evaluation of the Medicare Diabetes Prevention Program (MDPP): Second Evaluation Report. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[375] RTI International. Evaluation of the Medicare Diabetes Prevention Program (MDPP): Second Evaluation Report. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[376] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52503.*https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[377] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52502. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[378] Centers for Medicare & Medicaid Services. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 FR 64996. *https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf.*

[379] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52506. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

of program completion. Finally, commenters appreciated CMS simplifying the number of HCPCS G-codes from 15 to 6, reducing the administrative burden while allowing suppliers to collect payments more frequently.

Response: We appreciate comments and support of the proposed rule provisions. Although out of scope for this rule, depending upon the outcomes we observe, we may consider alternative performance payments for maintenance of 5 percent weight loss in future rulemaking.

Comment: Commenters were unanimously supportive of the proposed changes to extend the PHE flexibilities for 4 years. They commented that these flexibilities will allow the MDPP to continue to grow and offer beneficiaries flexibility when determining how they would like to receive services. These flexibilities will allow MDPP to continue to grow and offer beneficiaries increased flexibility when it comes to how they would like to receive services. Such flexibility is important in promoting equity, as well as reaching underserved communities, or individuals who face challenges making in-person appointments, including those lacking access to transportation or those with mobility issues.

Additionally, multiple commenters indicated that they were able to reach more participants through distance learning compared to in-person delivery during the PHE for COVID–19, and that the flexibilities increased access to MDPP for both coaches and participants by removing barriers related to transportation and time. Similarly, another commenter indicated that the Extended flexibilities would help reduce the financial and physical hardship for patients by being able to attend MDPP through distance learning. Another commenter reminded us that distance learning delivery of MDPP does require technological competency and access, so it may not be appropriate for all participants.

Concerning participation, one commenter indicated that the 4-year extension of the flexibilities utilized during the PHE for COVID–19 may incentivize rural beneficiaries to participate with an MDPP supplier that is not local. The commenter further reasoned that CMS could use this 4-year extension to monitor the uptake of the program and make an evidence-based decision on permanently extending virtual services.

Although there is overwhelming support of extending the flexibilities utilized during the PHE for COVID–19, multiple commenters were disappointed that CMS is not allowing virtual-only providers to enroll in Medicare as MDPP suppliers. Virtual-only providers include those that deliver the National DPP services solely by distance learning or online delivery. Commenters indicated that the lack of full alignment between the MDPP expanded model and the CDC's National DPP continues to severely limit supplier participation, thus contributing to increased health inequities by limiting opportunities for the MDPP to reach the most vulnerable Medicare beneficiaries.

Finally, multiple commenters recommended CMS remove the requirement to maintain in-person recognition for distance learning only suppliers, while allowing CDC-defined online providers of CDC's DPRP recognized program to apply to become MDPP suppliers.

One commenter questioned CMS' rationale for excluding virtual-only suppliers, arguing that the proposed rule conflicts with the belief that peer support is less effective when people are not together in person.

Response: We appreciate the widespread support of the proposed changes and are encouraged by the comments received for our proposed changes, in-particular the extension of the PHE flexibilities utilized during COVID–19 to allow distance learning delivery. Although we understand the disappointment of commenters representing distance learning and online delivery organizations, we hope that they will continue to work with CMS to increase the recruitment and retention of beneficiaries to help expand MDPP access and uptake.

Although we updated our definitions in this rule to better align with the National DPP, we will continue to work with CDC to align its National DPP with MDPP to the greatest extent possible. As such, we encourage National DPP organizations, MDPP suppliers, and interested parties to review the updated 2024 DPRP Standards when they are published in 2024. CMS will consider conforming changes, as appropriate, in future rulemaking.

As we stated earlier, MDPP was established as a primarily in-person service since the original DPP test and data used in the certification were based on in-person delivery. At the time of certification, although we did have minimal online delivery data provided to us by CDC and industry, these data did not meet the thresholds required for certification. The PHE for COVID–19 was a unique circumstance that required CMS to quickly establish MDPP pandemic-related flexibilities in the IFC–1, which was released in early April of 2020 to allow for temporary flexibilities that prioritized availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by uncontrollable circumstances during the PHE for COVID–19.

In the CY 2021 PFS final rule, we updated and finalized the policies from the IFC–1. We did not expect the PHE for COVID–19 to last over 3 years, with MDPP suppliers able to deliver services virtually for longer than they delivered services in-person prior to the PHE for COVID–19. Therefore, the PHE for COVID–19 was a unique circumstance that afforded us the opportunity to deliver the MDPP Set of services virtually over the past 3.5 years.

When we established the MDPP flexibilities in the IFC–1, we could not predict when the PHE for COVID–19 would end. In the CY 2021 PFS,[380] we indicated that virtual-only suppliers may not have sufficient time to obtain the CDC's authorization to furnish in-person services. Therefore, permitting virtual-only suppliers to furnish MDPP services during the PHE for COVID–19 could disrupt the provision of MDPP Set of services when services were to resume on an in-person basis. Consequently, virtual only suppliers are not permitted to provide the set of MDPP services because MDPP suppliers need to accommodate beneficiary requests for in-person services.

Our internal data explain that suppliers halted in-person sessions at the beginning of the PHE for COVID–19, with their pauses varying in length. However, most suppliers resumed offering the Set of MDPP services via virtual delivery. Currently, we do not have sufficient data from the PHE for COVID–19 to certify the distance

[380] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84830), December 28, 2020. *https://www.federalregister.gov/d/2020-26815.pdf.*

learning delivery of MDPP. We hope that after the Extended flexibilities period we will have enough data to fully evaluate the impact of distance learning delivery of MDPP on diabetes risk reduction, as well as cost-savings to Medicare.

We also understand that distance learning delivery of MDPP may not be appropriate for every beneficiary. For example, beneficiaries may not have the required technological competency and access to participate in MDPP through distance learning. Given this, we want to remind suppliers that they are required to maintain capacity to deliver MDPP Set of services in-person.

Although commenters expressed concern about MDPP's lack of full alignment with the CDC's National DPP in terms of allowing fully virtual organizations—or organizations that deliver diabetes prevention services solely through distance learning or online delivery—to become MDPP suppliers, we want to remind commenters that MDPP continues to be an expanded model test of in-person delivery of diabetes prevention services. In the CY 2018 final rule,[381] we stated that CDC began recognizing Virtual DPP organizations in 2015. The MDPP certification [382] was publicly released in March 2016 and was based on in-person data from the DPP clinical trial, the DPP test, CDC DPRP data, and a large national DPP provider.

The PHE for COVID–19 was a special circumstance that allowed MDPP suppliers to deliver the MDPP Set of Services virtually, but there remains a lack of data on virtual delivery during the PHE for COVID–19 because many suppliers appear to have paused or stop delivery of MDPP Set of services during the PHE for COVID–19. Although we understand that the exclusion of fully virtual suppliers may limit supplier participation, we do not agree that this exclusion will contribute to increased health inequities among Medicare's most vulnerable beneficiaries. Although virtual delivery of MDPP may make MDPP more accessible for most beneficiaries, it is not appropriate for every Medicare beneficiary. We appreciate this commenter's feedback and will assess the health equity impact of excluding fully virtual suppliers once we have updated data from the PHE for COVID–19 time period.

Additionally, we understand the commenter's concern about the proposed rule conflicting with the belief that peer support is less effective when people are not together in person. We have confidence that distance learning possesses similar elements to in-person delivery such as live instruction from a coach and live interactive peer support, both which we believe will contribute to beneficiary understanding of pre-diabetes management tactics and strategies.

Comment: As part of MDPP's Emergency Policy finalized in the CY 2021 PFS final rule, we allowed for virtual weight collection. In this final rule, we summarized our policies for alternatives to the requirement for in-person weight collection (§ 410.79(e)(3)(iii)), which include virtual weight collection.[383] Overall, commenters were very supportive of CMS continuing to allow virtual weight collection. However, we received several comments regarding barriers suppliers experienced relating to virtual weight collection during the PHE for COVID–19.

For example, several commenters recommended that CMS no longer require date-stamped photos to document the self-reported beneficiary weights. The commenters reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. Thus, this risk has prevented organizations from submitting claims accurately, since they have several participants that live alone and attend sessions via distance education.

Additionally, some participants join virtual sessions from different locations and do not have access to a scale to record their measurement each session. The commenter urged CMS to consider allowing submission of weight photos without the date and time stamp, allowing participants to submit official weights less frequently for example, every 2–3 sessions).

Finally, we received a comment indicating that some participants may not be able to purchase Bluetooth-enabled scales, and the MDPP payment structure does not enable the program to purchase scales without additional funding.

Response: We acknowledge that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. In situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in-person.

In terms of allowing MDPP participants to submit their weight less frequently, the current CDC DPRP Standards [384] state that the participant's body weight must be recorded at all sessions. In addition, in § 424.25(g)(2)(v),[385] we state that documentation for each MDPP session must include each MDPP's beneficiary's weight and date weight taken in a form and manner specified by CMS. Given that we aim to align with the DPRP Standards as much as possible, we are requiring participant body weight to be collected at each MDPP session so that weight loss can be tracked during the MDPP service period.

Suppliers may also consider urging beneficiaries to identify a household member, friend, or family member who could assist the participant with relaying their body weight to the supplier. However, we want to remind MDPP suppliers that beneficiaries may report their weight using scales that securely transmit their weight to the MDPP supplier. Unfortunately, CMS cannot provide funds for a Bluetooth-enabled scale per one commenter request. However, we want to remind suppliers that in the CY 2018 PFS rulemaking, we finalized the use of beneficiary engagement incentives under § 424.210, and suppliers may review the requirements of that regulation.

[381] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 53253, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

[382] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

[383] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52502. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[384] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[385] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 53366, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf.*

Comment: One commenter indicated their appreciation of allowing unlimited make-up sessions and the ability to hold the make-up sessions on the same day as a different session (so that a participant who missed the previous week, can attend the make-up session immediately before the next session). This allows for flexibility for both the participant and the Coach.

Response: In the CY 2018 PFS final rule, we finalized that suppliers may furnish a maximum of one virtual make-up session on the same day as a regularly scheduled in-person session. However, we stated that the intent of this policy was to allow most make-up sessions to be scheduled on different days than regularly scheduled session, since beneficiaries may not be able to attend a make-up session on the same day as a regularly scheduled session.

In the CY 2021 PFS final rule, we finalized in paragraph § 410.79(e)(3)(iv)(B) that the MDPP supplier may furnish to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session and that under paragraph (e)(3)(iv)(C), the MDPP supplier may furnish a maximum of one virtual make-up session per week. In the proposed rule, we proposed to no longer require suppliers to indicate whether the session was delivered as a make-up session or a regularly scheduled session when submitting claims for services. Instead of using the virtual modifier on claims to indicate a virtual make-up session, we proposed to replace the virtual modifier with one of two MDPP G-codes (G9886 or G9887) to indicate whether the session was delivered in-person (G9886) or through distance learning (G9887) [386].

In the current payment schedule (CY 2018 to CY 2023), attendance is paid on a performance basis, after attending the 1st, 4th, and 9th sessions in months 1 to 6, and after the 2nd monthly session in months 7 to 12. Additionally, there is a non-payable session code (G9891) to track attendance. Under the current performance-based schedule,[387] same day make-up sessions were permitted because it did not necessarily impact payments. In contrast, under the CY 2024 PFS [388] proposed payment schedule, which pays for up to 22 sessions on a fee-for-service (FFS) basis over the 12-month MDPP service period, participants have 6 months to attend the first 16 weekly sessions and another 6 months to attend 6 monthly sessions Theoretically, in months 1 to 6, participants can reach 16 sessions at some point in month 4 if they attend most of the weekly sessions and sooner if they attend same-day make-up sessions.

Although § 410.79(e)(3)(iv)(B) and (C) does permit a beneficiary one virtual makeup session on the same day as a regularly scheduled session, and a beneficiary may only have one virtual make-up session per week, we want to encourage suppliers to schedule make-up sessions on days other than the same day of a regularly scheduled session to avoid claims being rejected or denied under the new payment schedule and to allow beneficiaries to receive the benefit as intended by having access to the full 12 months MDPP service period to build the skills needed to reduce their risk for diabetes.

Comment: One commenter requested that CMS affirm that MA plans may use virtual MDPP to meet network adequacy requirements and satisfy the requirements to provide MDPP services by allowing virtual providers to register as Medicare suppliers for this purpose.

Response: We appreciate the commenter's request for clarification regarding allowing virtual providers to enroll in Medicare as MDPP suppliers for the purpose of meeting MA Plan network adequacy requirements. Given that we proposed that MDPP suppliers must have and maintain CDC in-person DPRP recognition, it does not make sense to allow this requirement to be waived for organizations that serve beneficiaries in MA plans.

Comment: Several commenters requested that CMS waive the once per lifetime requirement to allow for multiple attempts at weight loss. Moreover, several commenters expressed concern over the high-risk designation requirements for organizations enrolling in Medicare as MDPP suppliers.

Response: We appreciate the commenters' support and interest in MDPP. These suggested changes are outside the scope of this final rule. The provisions we are finalizing in this rule are to extend the PHE flexibilities for 4 years, update the MDPP payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on an FFS basis and diabetes risk reduction (weight loss), on a performance basis, and remove most references to and requirements of, the Ongoing Maintenance phase.

After consideration of public comments, we are finalizing § 410.79(b), (c)(2)(i), (e)(2), and (e)(3)(iv) as proposed.

2. Changes to § 414.84

Although MDPP has over 300 suppliers representing over 1,000 locations across the US, based on fee-for-service claims analysis, only one-third of them have submitted claims since MDPP launched in April 2018. We have heard anecdotally from suppliers, CDC, and interested parties that our payment structure is complex, which has created barriers to organizations wanting to participate in the MDPP. As a result, the lack of suppliers has contributed to limited beneficiary access to the preventive services offered under this expanded model. Challenges inherent in the current payment structure include irregular flow of operating funds due to the performance-based payment structure, claims denials due to the complicated payment structure, and a lack of incentive to retain participants after the 9th core session due to the potential 4 to 5-month payment lag between the 9th session attended and the 2nd session attended in months 7–9. Consistent with this last challenge, our monitoring data show a sharp drop in claims after the first quarter.

In the proposed rule,[389] we proposed to update the payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on a

[386] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52507. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[387] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52508. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[388] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52507. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[389] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52506. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

FFS basis and diabetes risk reduction (weight loss), on a performance basis.

Given consistent supplier and interested party feedback regarding the complexity of this payment structure and necessary up-front costs incurred by suppliers, we proposed to simplify the payment structure and pay for attendance on a FFS basis. We proposed creating an Attendance Payment, which we proposed to define as a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. We also proposed that suppliers may receive an Attendance Payment after they submit a claim for each MDPP session, starting with the first core session, using a new HCPCS G-code, *Behavioral counseling for diabetes prevention, in-person, group, 60 minutes,* or *Behavioral counseling for diabetes prevention, distance learning, 60 minutes,* for MDPP dates of service on or after January 1, 2024.[390]

This proposed payment structure aligns closely to that of similar benefits such as the Intensive Behavioral Counseling for Obesity (IBTO) and Diabetes Self-Management Training (DSMT), and also allows suppliers to receive regular payments for service for up to a year during a 12-month MDPP service period. We proposed paying for up to 22 sessions of either in-person or distance learning, or a combination of the two, for MDPP dates of services within a 12-month MDPP services period. In months 1 to 6, payments are allowed for one in-person or distance learning session every week up to a maximum of 16 sessions. During months 7 to 12, payments are allowed for one in-person or distance learning session every month up to a maximum 6 sessions.

We proposed to update the performance goal to depict a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment and removing the performance-based payments for attendance from the performance goal.[391] We retained the diabetes risk-reduction performance payments, which include payments for 5 percent and 9 percent weight loss because we want to continue to pay for outcomes, and the MDPP certification includes a diabetes risk-reduction component, the achievement of 5 percent weight loss from baseline. Although we proposed to remove the attendance-based performance goal and pay for attendance on a FFS basis, we want to continue rewarding suppliers for achieving successful outcomes for beneficiaries (weight loss), while motivating suppliers to retain participants and deliver a high-quality program.

As part of the performance payments, MDPP suppliers must still submit a claim when 5 percent weight loss from baseline weight is achieved and will receive a one-time payment for this claim (weight loss G-code). We proposed to create a new HCPCS G-code, ''Maintenance of 5 percent weight loss from baseline, months 7–12'' to be submitted along with the monthly session claim for beneficiaries who have met the 5 percent weight loss performance goal, for whom the one-time claim for 5 percent weight loss has been submitted. This maintenance of 5 percent weight loss code replaces the attendance plus 5 percent weight loss HCPCS G-codes, G9878 and G9879, in months 7–12.

The one-time claim for 5 percent weight loss must be submitted prior to submitting a claim for the enhanced payment in months 7 to 12 for maintaining the 5 percent weight loss. Additionally, suppliers must continue to submit a claim when 9 percent weight loss from baseline weight is achieved per § 414.84(b)(7), so they may receive a one-time payment for this claim.

This proposed payment structure increases the maximum attendance-based payments a supplier may receive in the first 6 months by $56 per MDPP beneficiary, while allowing for similar maximum attendance payments in months 7–12 and maintaining the maximum total payment of $768 per person during the MDPP services period.[392] Also, this proposed payment structure takes into consideration the Extended flexibilities, by adding a distance learning HCPCS G-code. The new structure simplifies the claims submission process because it no longer requires that suppliers submit 11 to 15 G-codes for different attendance-based sessions at irregular intervals.

This proposed payment structure allows suppliers to submit one of two G-codes (depending on whether the MDPP session was delivered in person or via distance learning) for each session. In months 7–12, suppliers may also add the proposed maintenance of the 5 percent weight loss from baseline G-code to their claim once the 5 percent weight loss has been achieved. The proposed payment structure allows suppliers to indicate which sessions were held via distance learning without needing to provide additional information in the claim submission process. The proposed new payment structure reduces complexity by reducing the number of G-codes from 15 to 6.

Table 49 displays the proposed MDPP payment structure and Table 50 indicates the current CY 2023 performance payments.

[390] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52506. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[391] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52506. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[392] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52507. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

TABLE 49: Changes to MDPP Payment Structure to include Attendance-Based Service Payments and Diabetes Risk Reduction Performance Payments

HCPCS G-Code	Payment Description*	CY 2024
G9886*	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes	$25
G9887*	Behavioral counseling for diabetes prevention, distance learning, 60 minutes	$25
G9880	5 percent WL Achieved from baseline weight	$145
G9881	9 percent WL Achieved from baseline weight	$25
G9888**	Maintenance 5 percent WL from baseline in months 7-12	$8
G9890	Bridge Payment	$25
Subtotal Maximum Attendance-Based Payment		**$550**
Total Maximum Payment		**$768**

**Medicare pays up to 22 sessions billed with codes G9886 and G9887, combined, in a 12-month period:*
Months 1-6: 1 in-person or distance learning session every week (max 16 sessions)
Months 7-12: 1 in-person or distance learning session every month (max 6 sessions)
*** Suppliers must submit claim for 5 percent weight loss (G9880) prior to submitting claims for the maintenance 5 percent WL from baseline in months 7-12 (G9888).*

TABLE 50: CY 2023 MDPP Payment Structure

HCPCS G-Code	Payment Description	CY 2023
	Core Sessions (Months 1-6)	
G9873	Attend 1 Core Session	$38
G9874	Attend 4 Core Sessions	$115
G9875	Attend 9 Core Sessions	$191
	Core Maintenance (CM) Sessions (Months 7-12)	
G9876	Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$76
G9877	Attend 2 Core Maintenance Sessions (No 5 percent WL) in CM Interval 2 (Months 10-12)	$76
G9878	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 1 (Months 7-9)	$101
G9879	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 2 (Months 10-12)	$101
G9880	5 percent WL Achieved from baseline weight	$184
G9881	9 percent WL Achieved from baseline weight	$38
G9890	Bridge Payment	$38
G9891	Non-payable session code (This code is for reporting purposes only).	$0
	Ongoing Maintenance Sessions (Months 7-12)**	
G9882	Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$57
G9883	Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$57
G9884	Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$58
G9885	Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$58
Subtotal Maximum Attendance-Based Payment		**$496**
Total Maximum Payment		**$768**

**In the CY 2022 PFS, CMS removed the Ongoing Maintenance Sessions for those beneficiaries who started MDPP services on or after January 1, 2022. MDPP beneficiaries who were participating in the Set of MDPP services on or before December 31, 2021 may continue with the ongoing maintenance phase if they maintain 5 percent weight loss and attendance requirements.

During the CY 2018 PFS rulemaking process,[393] we received comments regarding how to best monitor the use of virtual make-up sessions, and whether we would use an additional HCPCS code or modifier to indicate virtual sessions since there is a limit to the number of virtual make-up sessions a beneficiary can attend. In response, we finalized the use of the virtual make-up

[393] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53255. *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

sessions in § 410.79(d)(2) and stated in the preamble to the CY 2018 PFS final rule that MDPP suppliers must include the virtual modifier on claims to indicate the use of the virtual make-up session.[394] As part of the flexibilities established in response to the COVID–19 PHE, in the CY 2021 PFS final rule, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2), and (d)(3)(i) and (ii),[395] but still required MDPP suppliers to use the virtual modifier to indicate when a beneficiary received MDPP virtually.

In the CY 2024 PFS proposed rule, we proposed to amend our policies on payment for MDPP services § 414.84(a), (b), (c), and newly redesignated paragraphs (d)(1) and (e). We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to move from a performance-based attendance and outcomes (weight loss of 5 and 9 percent) payment structure to a hybrid structure that pays for attendance on an FFS basis, indicating it would reduce the administrative burden associated with billing. Overall, commenters supported allowing payment for up to 22 sessions during the 12-month core services period and indicated that finalizing these proposals should increase efficiency from a timeliness perspective of payments due to an increase of attendance payments for MDPP suppliers, many of whom have been operating MDPP at a loss.

Several commenters added that the National DPP is reimbursable in their States through Medicaid and the Medicaid billing per attendance has been much more efficient than the MDPP billing. Therefore, the FFS changes will be a welcome advancement for suppliers that provide billing management for their community-based partner organizations that furnish the MDPP Set of services.

Additionally, commenters indicated that finalizing these proposals may also help reduce health inequities by reducing disincentives in the current outcomes-based reimbursement approach as many MDPP suppliers serve populations that may be less likely to achieve the 5 percent weight loss threshold, and therefore, would be operating at a financial loss.

For example, several commenters indicated that the streamlined MDPP payment schedule may increase participation in MDPP of community-based settings with limited cash flow and capital. It is critical that MDPP delivered in these types of settings receive payment in a timely manner, so that they may pay staff, rent, and other direct operating expenses.

Concerning Medicare FFS attendance payments, commenters supported CMS moving from performance-based attendance to service-based attendance. Commenters noted that this would create greater consistency for payments. Commenters also appreciated the simplified billing process, as one commenter suggested that it may expand the potential pool of organizations who will be able to provide MDPP Set of services due to more frequent payments. Others commented that the updated payment structure is consistent with other Medicare services, simplifies billing, and assures payment for services that are rendered.

Comments regarding MDPP diabetes risk-reduction one-time performance payments for achievement of 5 percent and 9 percent weight loss were also positive. Commenters indicated that payments for positive health outcomes, including 5 percent and 9 percent weight loss are worthwhile and should be maintained. One commenter agreed with incentivizing weight loss outcomes given that weight loss drives diabetes risk reduction.

Interestingly, comments regarding performance payments consisted mostly of recommendations to CMS concerning including additional performance payments for consideration. Several commenters recommended weight loss performance payments be provided for lesser, yet clinically relevant weight loss such as 3 to 5 percent weight loss, while maintaining a small payment for achieving 9 percent weight loss. Several commenters recommended CMS establish an additional performance payment for 4 percent weight loss, as this would align with the CDC weight loss performance outcomes. One commenter further explained that for National DPPs that serve historically underserved communities, a 4 percent weight loss benchmark is based on evidence that achieving a 5 percent goal is more difficult in these communities and that lower levels of weight loss are associated with improved health.

Several commenters recommended that CMS consider adding a 0.2% reduction in Hemoglobin A1C (HbA1c) as an additional performance measure for diabetes risk reduction. One commenter in particular further clarified that the proposed CY 2024 payment structure, which only accounts for 5 or 9 percent weight loss to receive a performance payment, does not reward suppliers for individuals who have maintained weight or gained muscle mass while reducing HbA1c. Commenters discussed the limitations of body weight and BMI as they do not take into account changes in body composition type such as muscle mass versus fat mass. Commenters referred to an American Medical Association published statement on considering body composition measures in addition to BMI for better indicators of health. (*https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine*).

One commenter recommended that given MDPP's role in preventing the onset of type 2 diabetes, the known underutilization of this service, and the enormous cost to care for patients who transition from prediabetes into full type 2 diabetes, CMS should consider either (1) incentivizing clinicians to facilitate MDPP through increased payment for the program or, (2) creating an incentive for clinician referral to MDPP or oversight of MDPP via a billable CPT code. This commenter clarified that incentivizing clinicians to refer to or oversee the MDPP program via a billable code or increasing payment to administer the MDPP as a clinician would increase program implementation.

Several commenters also recommended that CMS increase the payment rates, indicating that the

[394] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53255. *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

[395] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84838), December 28, 2020. *https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf.*

proposed rates do not cover the costs to deliver MDPP set of services to participants with adverse social determinants. Commenters suggested that the proposed rates do not fully cover staff time, coordination, and follow-up. One commenter indicated that the payment amount is insufficient to incentivize rural providers to enroll and provide MDPP Set of services.

Several commenters recommended that CMS consider paying for up to 26 sessions versus the proposed 22 sessions. One commenter further explained that when they initiated the program, they offered the minimally required 22 sessions (16 sessions followed by monthly meetings once a month). After reviewing their data, they found that participants had significantly better attendance when the sessions were offered weekly compared to monthly. Based on that observation they moved to offering sessions twice a month after the first 16 weeks of the program, which improved program attendance and outcomes.

Regarding our proposed G-Code for the ''Maintenance of 5 percent weight loss from baseline, months 7–12,'' one commenter commended the intent of the G-code, but recommended CMS consider a larger one-time payment for ''Maintenance of 5 percent weight loss in months 7 to 12.'' The commenter recommended this one-time payment take place at the time of program completion, to encourage participant retention.

Response: We appreciate the interest and comments regarding the revised MDPP payment structure, the FFS attendance payments, and the weight loss performance payments. We note that the one-time performance payments for 5 percent and 9 percent weight loss from baseline as well as the monthly performance payments for maintenance of 5 percent weight loss from baseline weight in months 7 to 12 are out of scope of this rule. However, we will review and consider commenters' recommendations for future rulemaking, as appropriate, regarding a second performance measure that considers lower thresholds for weight loss performance payments such as 4 percent weight loss, as well as HbA1c reduction as a performance payment. Historically, CMS has not covered HbA1c as part of the diabetes screening benefit, thus we could not consider it as a performance measure. In a section of the proposed rule [396] that was not specific to MDPP, CMS is finalizing to expand diabetes screening and diabetes definitions, including the addition of HbA1c test as part of the diabetes screening benefit, and we thank commenters for separately supporting this proposal. We may consider an additional performance payment option in future rulemaking. We may also consider other recommendations including suggestions on how to create incentives for clinician referral.

Per the commenters that recommended we increase the MDPP payment rates, we appreciate this feedback. Unfortunately, we run the risk of jeopardizing our certification as an expanded model test if we increase the total payment amount to the rates recommended by these commenters. Moreover, we believe that the current payment schedule aligns with similar Medicare preventive services payment rates such as IBTO and DSMT in terms of per session payment and maximum payment amounts. Per § 414.84(e) we annually adjust the MDPP performance payments, attendance payments, and bridge payments by the percent change in the Consumer Price Index and publish the updated MDPP payment schedule at the beginning of the calendar year.[397]

We appreciate the comments regarding the number of sessions CMS should cover in the new payment schedule. We applaud the commenter who found that offering the program twice a month in the second 6 months instead of monthly increased attendance and improved outcomes. However, should we increase the total number of sessions to 26 versus 22, the maximum payment amount would still have to remain the same given our certification, but the session payment amounts would decrease. In addition, paying for up to 22 sessions allows more flexibility in how sessions are scheduled, encouraging suppliers to retain participants since more sessions will be covered, and allow more suppliers to meet the maximum attendance payments. We are concerned that if we increase the number of payable sessions to 26, fewer suppliers will be able to reach that goal with their participants, and they would not be able to reach the maximum attendance payments for MDPP. We believe that paying for up to 22 sessions provides the right balance between per session payments, supplier success in reaching the maximum attendance payments for beneficiaries, and flexibility with scheduling sessions.

After consideration of public comments, we are finalizing as proposed.

3. Changes to § 424.205 (a), (b)(1), (c), and Newly Designated Paragraphs (c)(1), (d)(14), (f)(2)(i), (g)(1)(i)(C)

The Centers for Disease Control and Prevention (CDC), which administers the Diabetes Prevention Recognition Program (DPRP), is responsible for implementing the quality assurance function of the National DPP at the national level, including for MDPP.[398] The DPRP awards four categories of recognition: Pending, preliminary, full, and full-plus.[399] Organizations may participate in MDPP with preliminary, full, or full-plus CDC recognition. Organizations may advance in CDC DPRP recognition by demonstrating their ability to effectively deliver the behavioral change program (preliminary) and achieve the outcomes shown to prevent or delay type 2 diabetes (full and full-plus). To achieve full CDC recognition, organizations must demonstrate a reduction in risk of developing type 2 diabetes among completers in the evaluation cohort by showing that at least 60 percent of all completers achieved at least one of the following outcomes:

- At least 5 percent weight loss 12 months after the cohort began; or
- At least 4 percent weight loss and at least 150 minutes/week on average of physical activity 12 months after the cohort began; or
- At least a 0.2 percent reduction in HbA1C.

Organizations are granted an additional 2 years of full recognition (full-plus), for a total of 5 years if, at the time full recognition is achieved, organizations meet the following retention criteria:

[396] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52715. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[397] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52713. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[398] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53301. *https://www.govinfo.gov/content/pkg/FR–2018–11–23/pdf/2018–24170.pdf.*

[399] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

- A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions;
- A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and
- A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.[400]

In the CY 2017 PFS final rule,[401] we indicated that we would align the CDC's DPRP and MDPP to the greatest extent possible. When the CY 2018 PFS final rule went into effect on January 1, 2018, CDC's 2018 DPRP Standards had neither been publicly released nor gone into effect. For these reasons, we had to establish an interim MDPP preliminary recognition so that eligible organizations could begin enrolling in Medicare to become MDPP suppliers starting January 1, 2018, and approved suppliers could start serving Medicare beneficiaries on April 1, 2018.

When the CY 2018 PFS final rule was issued, the CDC 2015 DPRP Standards were still in effect, and the CDC only recognized organizations with pending or full DPRP recognition. Consequently, CMS and CDC developed an interim solution that would allow organizations that met the MDPP interim preliminary recognition standard, which went into effect on January 1, 2018, to become eligible to enroll in Medicare as an MDPP supplier.

Because CMS and the CDC understood that there would be a 2- to 4-month gap between when the CY 2018 PFS went into effect for MDPP (January 1, 2018) and when the CDC 2018 DPRP Standards would be cleared and go into effect, CMS worked with CDC to establish an interim solution so that eligible organizations with MDPP interim preliminary or CDC DPRP full recognition could apply to Medicare to become MDPP suppliers before the CDC's 2018 Standards went into effect on March 1, 2018. The CY 2018 PFS final rule[402] at established at § 424.205(c)(2)(ii) that CDC-recognized organizations with pending CDC DPRP recognition could meet additional criteria for an ''interim preliminary recognition'' standard and enroll as MDPP suppliers. With the MDPP new supplier type going into effect on January 1, 2018, and beneficiary enrollment starting on April 1, 2018, CMS wanted suppliers to be able to enroll in Medicare to become MDPP suppliers in time for the April 1 MDPP launch.

With the CDC DPRP Standards for preliminary recognition in effect, in the CY 2024 PFS proposed rule,[403] we proposed to remove § 424.205(c) and retire the MDPP ''interim preliminary recognition'' standard. We also proposed to amend § 424.59(a)(1) (redesignated § 424.205(b)(1)) to require that, at the time of enrollment, organizations have preliminary, full, or full-plus CDC DPRP recognition. As described in the CY 2018 PFS final rule,[404] MDPP suppliers who received MDPP interim preliminary recognition during the 4-month time period between when the CY 2018 PFS final rule was published and when the CDC 2018 Standards went into effect, have achieved CDC preliminary recognition.

To maintain compliance with the current CDC DPRP Standards, organizations that enrolled in Medicare as MDPP suppliers based on their MDPP interim preliminary recognition[405] between January 1, 2018, and February 28, 2018, would have had at least two CDC DPRP evaluations given the 5-year time lapse. Per CDC DPRP Standards, organizations are required to submit data to CDC every 6 months, and undergo evaluation every 12 to 18 months, depending upon the timing of new cohorts.

Since the CDC DPRP Standards were updated in 2018 and 2021 and are due to be updated in Spring 2024, suppliers are required to meet the most current CDC DPRP Standards for preliminary, full, or full-plus recognition to maintain their eligibility to enroll and participate in MDPP as MDPP suppliers. Organizations that are interested in enrolling in Medicare as MDPP suppliers should refer to the CDC DPRP's most current standards[406] to understand how to obtain preliminary, full, or full-plus CDC recognition, and consult § 424.205 for all other enrollment conditions that need to be met, in advance of submitting their application to become a MDPP supplier.

We proposed to amend § 424.205 newly designated paragraphs (c) and (f) to remove reference to and requirements of the Ongoing Maintenance phase described in these sections with the exception of the newly designated requirement at § 424.205(d)(14), which we are retaining for historical recordkeeping and crosswalk purposes.[407] In the CY 2022 PFS final rule,[408] CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We proposed to amend § 424.205(a), (b)(1),[409] newly redesignated paragraphs (c)(1) and (g)(1)(i)(C). We solicited comments on these proposals.

We received public comments on these proposals. The following is a

[400] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[401] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53298. *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

[402] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53298. *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

[403] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52501. *https://-www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[404] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53298. *https://www.govinfo.gov/content/pkg/FR–2018–11–23/pdf/2018–24170.pdf.*

[405] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 53364. *https://www.govinfo.gov/content/pkg/FR–2018–11–23/pdf/2018–24170.pdf.*

[406] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[407] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52750. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[408] Centers for Medicare & Medicaid Services. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 FR 65668. *https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf.*

[409] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52508. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

summary of the comments we received and our responses.

Comment: Commenters were unanimous in their support of CMS' proposal to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition.

Response: We appreciate the public comments in support of the proposed revisions. After consideration of public comments, we are finalizing as proposed.

4. Changes to § 424.210(b) and (d)

We proposed to amend § 424.210(b) and (d) [410] to remove reference to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS final rule,[411] CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We proposed to amend its regulation at § 424.210 by amending paragraphs (b) and (d). We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments regarding CMS removing reference to, and requirements of, the Ongoing Maintenance phase were supportive of this change.

Response: We appreciate the comments regarding this provision.

After consideration of public comments, we are finalizing as proposed.

J. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Since the bill was passed, we have taken steps to implement this program and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information and the program currently operates in this phase.

In the CY 2024 PFS proposed rule (88 FR 52262, at 52509 through 52515), we proposed to pause efforts to implement the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94. We did not propose a timeframe within which implementation efforts may recommence. We stated that we will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking.

1. Background

AUC are evidence-based guidelines that assist clinicians in selecting the imaging studies most likely to improve health outcomes for patients based on their individual clinical presentation. AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). For purposes of this program, AUC are a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient's presenting symptoms or condition. Under this program, any clinician who orders an advanced diagnostic imaging service must consult AUC for the imaging service ordered. Examples of advanced diagnostic imaging services include computed tomography, positron emission tomography, nuclear medicine and magnetic resonance imaging.

To consult AUC, clinicians use clinical decision support mechanisms (CDSMs). CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information; however, may be more effective when they are integrated into electronic health records (EHRs). Ideally, clinicians would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Under the AUC program, clinicians and facilities that furnish the imaging service are responsible for reporting information about the ordering clinician's AUC consultation on the imaging service claim. The furnishing clinician and facility are not paid if the ordering clinician fails to consult and/or if the consultation information is not correctly included on the imaging service claim.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements and Implementation

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals (based on low adherence to AUC) for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). These four components are precursors to the requirement that, beginning for CY 2017, we establish mandatory prior authorization procedures for outlier ordering professionals when ordering advanced diagnostic imaging services (section 1834(q)(6) of the Act).

a. Establishment of AUC

We addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act, establishment of AUC, in the CY 2016 PFS final rule with comment period (80 FR 70886). With this rule, we began to codify the statutory requirements in our regulations at 42 CFR 414.94. We also defined provider-led entity (PLE), as well as additional definitions under section 1834(q)(1) of the Act in our regulations at § 414.94(b). In § 414.94(c)(1) and (2), respectively, we

[410] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. 88 FR 52509. *https://www.govinfo.gov/content/pkg/FR-2023-08-07/pdf/2023-14624.pdf.*

[411] Centers for Medicare & Medicaid Services. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 FR 65668. *https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf.*

set forth the requirements and process by which PLEs become qualified by CMS to develop, modify, or endorse AUC. We qualified the first group of PLEs under the AUC program and posted them to the CMS website in June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

b. Identification of Mechanisms for Consultation With AUC

We addressed the second component under section 1834(q)(3) of the Act, identification of mechanisms for consultation with AUC, in the CY 2017 PFS final rule (81 FR 80170). In this rule we defined clinical decision support mechanism (CDSM) in § 414.94(b). In § 414.94(g)(1) and (2), respectively, we set forth the requirements CDSMs must meet and established a process by which CDSMs may become qualified by CMS in accordance with the statutory requirements under section 1834(q)(3)(B)(ii) of the Act. We qualified the first group of CDSMs under the AUC program and posted them to the CMS website in July 2017.

c. AUC Consultation and Reporting

We addressed the third component under section 1834(q)(4) of the Act, AUC consultation by ordering professionals, and reporting on AUC consultation, primarily in the CY 2018 PFS final rule (82 FR 53190). Additionally, in the CY 2017 PFS final rule, we defined terms in § 414.94(b) (81 FR 80405 and 80406) and identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) of the Act in § 414.94(i) (81 FR 80422 through 80424) which are pertinent to the third component. We also continued to revise the regulation at § 414.94 as needed and in response to comments from interested parties in subsequent rulemaking cycles. These updates, revisions, and clarifications, which continued through annual PFS rulemaking for CYs 2018, 2019, and 2020, are discussed throughout this section as they directly relate to the AUC consultation requirement under section 1834(q)(4)(A) of the Act and reporting requirement under section 1834(q)(4)(B) of the Act.

In the CY 2017 PFS final rule, we defined applicable payment systems consistent with section 1834(q)(4)(D) of the Act to include the PFS established under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment system under section 1833(i) of the Act (81 FR 80406). In the CY 2016 PFS final rule with comment period, we defined applicable setting consistent with section 1834(q)(1)(D) of the Act to include a physician's office, a hospital outpatient department (including an emergency department), and an ambulatory surgical center (80 FR 71105). We later added independent diagnostic testing facility (IDTF) to the definition of applicable setting in the CY 2019 PFS final rule (83 FR 59690 and 59691).

Also in the CY 2017 PFS final rule, consistent with section 1834(q)(4)(C) of the Act, we identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) of the Act in the case of: a service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship (81 FR 80422 through 80424). The significant hardship exception criteria and process under § 414.94(i)(3) was later updated in the CY 2019 PFS final rule (83 FR 59697 through 59700).

In the CY 2018 PFS final rule, we established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who were ready to participate in the AUC program could consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals (82 FR 53193 through 53195). Furnishing professionals who were ready to do so could report AUC consultation information on the claim. To incentivize early use of qualified CDSMs for consulting AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In addition, in the CY 2018 PFS final rule, we established the start date of January 1, 2020, for the Medicare AUC program for advanced diagnostic imaging services in § 414.94(j)(1) (82 FR 53189 through 53195). Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services in § 414.94(j) and furnishing professionals must report AUC consultation information on the Medicare claim in § 414.94(k). In the CY 2019 PFS final rule, we specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified CDSM. In the CY 2018 PFS final rule, we further specified that the AUC program, including the claims denial payment penalty phase, would begin on January 1, 2020, with a year-long educational and operations testing period for CY 2019 during which AUC consultation information was expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information (82 FR 53193 through 53195). As discussed in further detail below, the educational and operations testing period was subsequently extended multiple times and the program currently operates in the educational and operations testing period.

In the CY 2018 PFS final rule and consistent with section 1834(q)(4)(B) of the Act, we established in § 414.94(k) that the following information must be reported on Medicare claims for advanced diagnostic imaging services: (1) the qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional) (82 FR 53190 through 53193). Section 1834(q)(4)(B) of the Act specifies that payment for advanced diagnostic imaging service claims under the AUC program may only be made if the claim submitted by the furnishing professional (of which there can be more than one if the professional component is furnished by a different entity than the technical component) includes this information about the ordering professional's AUC consultation. This statutory requirement establishes a real-time claims-based reporting requirement whereby payment for the imaging service is contingent upon specific information being present on the claim. We worked to operationalize the real-time claims-based reporting requirement by announcing our intention to use G-codes and HCPCS modifiers to report AUC consultation information on the Medicare claims in the CY 2019 PFS final rule.

In the CY 2022 PFS final rule (86 FR 64996), we provided further clarification around the scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services (86 FR 65227 through 65229), the extreme and uncontrollable circumstances significant hardship exception (86 FR 65229 and 65230) and specified claims processing solutions, including creation and use of a new HCPCS modifier intended to accurately identify claims that are and are not subject to the AUC program requirements. We also discussed special circumstances related to: services furnished by a critical access hospital (CAH) (86 FR 65231 and 65232), services paid under the Maryland Total Cost of Care Model (86 FR 65232 and 65233), inpatients converted to outpatients (86 FR 65233 and 65234), Medicare as the secondary payer (86 FR 65234 and 65235), and imaging services ordered prior to the start of the claims denial payment penalty phase but furnished on or after the start of the payment penalty phase (86 FR 65235). We addressed where to identify the ordering professional on practitioner claims for imaging services (86 FR 65231) (we addressed where to identify ordering professionals on institutional claims in educational materials following the CY 2019 PFS final rule claims-based reporting discussion (83 FR 59696)) and confirmed that claims that do not properly append AUC consultation information will be returned for correction and resubmission, rather than denied, when the payment penalty phase begins (86 FR 65234). We did not specify how long claims would be returned before the payment penalty phase would shift to claim denials. Finally, we established that the payment penalty phase would begin on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19. Under this specification and with the declared end of the PHE for COVID–19 on May 11, 2023, the payment penalty phase would have been scheduled to begin on January 1, 2024. However, as announced via the AUC website in 2022 and discussed further below in this section of the proposed rule, the educational and operations testing period will continue until further notice. We did not include provisions pertaining to the AUC program in the CY 2023 PFS final rule (87 FR 69404).

d. Identification of Outlier Ordering Professionals

We began to address the fourth component under section 1834(q)(5) of the Act, identification of outlier ordering professionals, in the CY 2017 PFS final rule by finalizing the first list of priority clinical areas (PCAs) in § 414.94(e)(5) (81 FR 80406 through 80412) which were intended to ultimately guide identification of outlier ordering professionals who would eventually be subject to prior authorization when ordering advanced diagnostic imaging services. Section 1834(q)(5) of the Act directs CMS to: (1) determine on an annual basis no more than 5 percent of total ordering professionals who are outlier ordering professionals; and (2) base the determination of an outlier ordering professional on low adherence to AUC which may be based on comparisons to other ordering professionals and include data for ordering professionals for whom prior authorization applies; and (3) use 2 years of data to identify outlier ordering professionals; and (4) consult with physicians, practitioners and other interested parties in developing methods to identify outlier ordering professionals. To date, we have not proposed or codified the methods for identifying outlier ordering professionals as prescribed by section 1834(q)(5) of the Act, and thus, we have not subjected any ordering professionals to prior authorization when ordering advanced diagnostic imaging services as prescribed by section 1834(q)(6) of the Act.

4. Timeline

As evident from the description of our regulatory activities to date, we have not met the statutory implementation time frame for the AUC program components. The educational and operations testing period began January 1, 2020, and the AUC program continues to operate in this phase currently. In this phase, there are no payment penalties for advanced diagnostic imaging service claims that do not append AUC consultation information. The provisions in section 1834(q) of the Act repeatedly stress the importance of engagement with interested parties in developing the Medicare AUC program. Throughout our implementation activities, we have intentionally taken a diligent, stepwise implementation approach to maximize the opportunity for public comment and engagement with interested parties, and allow for adequate advance notice to physicians and practitioners, beneficiaries and other AUC interested parties of any programmatic changes or updates. These efforts to maximize engagement included speaking and answering live questions at multiple CMS Open Door Forums, participating in external meetings sponsored by and at the request of interested parties like medical specialty societies and health care practitioners, and meeting in person and virtually with interested parties upon request to receive feedback and answer questions to the best of our ability and within the context of already publicly available information. All of these interactions were critical to inform our proposals during each round of notice and comment rulemaking. This approach has allowed us to be comprehensive in our assessment of implementation options and regulatory proposals, responsive to concerns expressed by interested parties, and agile in reacting to unexpected events, like the PHE for COVID–19. Since the CY 2022 PFS final rule was released, we have used the AUC website [412] to publicly announce updates to the AUC program. In July 2022, we updated the AUC website to inform interested parties that the payment penalty phase of the AUC program would not begin on January 1, 2023, even if the PHE for COVID–19 ended in 2022. This update also stated that the educational and operations testing period would continue and that we are not able to forecast when the payment penalty phase will begin. In October 2022, we updated the AUC website again to announce that applications for CDSM and PLE initial qualification and re-qualification would not be accepted for the 2023 application cycle and that all CDSMs and PLEs qualified as of July 2022 would remain qualified through this cycle.

5. Proposal To Pause Program for Reevaluation

Since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As discussed previously in this section of the final rule, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification, leading to prior authorization, by establishing the PCAs. And we began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. At this time, however, we have

[412] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we proposed to pause implementation of the AUC program for reevaluation, and proposed to rescind the current AUC program regulations from § 414.94. We expected this to be a hard pause to facilitate thorough program reevaluation and, as such, we did not propose a time frame within which implementation efforts may recommence.

a. Real-Time Claims-Based Reporting

Section 1834(q)(4)(A) of the Act requires ordering professionals to consult AUC using a qualified CDSM. Section 1834(q)(4)(B) of the Act requires furnishing professionals to report information about the ordering professional's AUC consultation with a qualified CDSM on the Medicare claim for the advanced diagnostic imaging service the ordering professional ordered. This section dictates that payment to the furnishing professional is contingent on reporting the ordering professional's AUC consultation information, which must include the ordering professional's NPI, the qualified CDSM that was consulted, and whether the service ordered adheres or does not adhere to the AUC consulted, or if there were no AUC applicable to the order available for consultation via the qualified CDSM that was consulted as described above.

While each component of the statutory requirements has presented unique challenges to implement, the greatest challenge has been in fully implementing and operationalizing the real-time claims-based reporting requirement consistent with section 1834(q)(4)(B) of the Act to ensure accurate reporting, claims processing and, ultimately, outlier identification and prior authorization. We formally solicited public comment and feedback from interested parties in notice and comment rulemaking in the CY 2017 PFS rulemaking cycle, and have welcomed and encouraged feedback and information from interested parties less formally throughout the duration of our implementation efforts in each successive year. In the CY 2017 PFS final rule, we discussed the importance of developing and operationalizing a meaningful solution for collecting AUC consultation information on Medicare claims. We explained that ''we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system.'' We further noted that ''[m]oving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments'' (81 FR 80420). In addition to consulting with claims processing experts outside of and between rulemaking cycles, we continued to clearly and intentionally solicit feedback and suggestions from interested parties to assist us in developing workable claims processing edits and solutions to operationalize the AUC reporting requirement consistent with section 1834(q)(4)(B) of the Act in rulemaking cycles for the CY 2018, 2019 and 2022 PFS.

Having considered many rounds of input from interested parties, including internal and external experts, and diligent exploration of options, we have come to believe that the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act presents an insurmountable barrier for CMS to fully operationalize the AUC program. To properly apply the statutory provisions of the AUC program, including specifications around settings in which services are furnished and payment systems under which Medicare payments are made, it is critical that claims are accurately identified in the Medicare claims processing system and accurately subjected to system's edits to ensure AUC consultation information is properly reported on the claim. Equally important is ensuring that claims not subject to the AUC program are not inappropriately subjected to claims system's edits. We consider a process where the Medicare claims processing system properly and accurately identifies only claims for services subject to the AUC program requirements, without manual action by practitioners/facilities that submit claims, to be a fully automated process. The existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that are or are not subject to the AUC program requirement to report AUC consultation information as prescribed by section 1834(q)(4)(B) of the Act. This means that the Medicare claims processing system is not able to ensure that claims for services that are not subject to the AUC consultation information reporting requirement will not be improperly denied for failure to append AUC consultation information. We note here that our intention, as announced in the CY 2022 PFS final rule, was to begin the payment penalty phase of the AUC program by returning, rather than denying, claims for advanced diagnostic imaging services that do not contain AUC consultation information for correction and resubmission; however, section 1834(q)(4)(B) of the Act specifies that payment for advanced diagnostic imaging services under the AUC program may only be made if the claim for the imaging service includes specific AUC consultation information. Consequently, the payment penalty phase would eventually need to shift from returning claims for correction and resubmission to denying claims. As such, and without the practicable capacity to fully automate the process for editing claims to ensure only appropriate claims are edited for AUC consultation information, there is a significant risk that full implementation of the penalty phase of the AUC program would result in inappropriate claims denials.

To avoid these inappropriate denials, we considered requiring claims to include certain modifiers that would identify them as not being subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act. However, this would add an extra layer of burden on furnishing professionals, including freestanding and hospital-based imaging facilities, requiring them to append information to the claims even for services that are not subject to the AUC consultation and reporting requirement in order to allow us to identify which imaging services are and are not subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act, and allow us to appropriately process claims.

Additionally, the AUC program is designed to target a subset of advanced diagnostic imaging services furnished in specific settings and paid under specific payment systems, as opposed to, for example, all Medicare part B advanced diagnostic imaging service claims, and includes multifaceted criteria for identifying which services are subject to the program. As such, ordering professionals would need to know, at the time of the order, where each imaging service will be furnished and under which payment system the claim will be paid to determine whether AUC consultation, and transmission of AUC consultation information with the order, is required. Furnishing professionals, including freestanding and hospital-

based imaging facilities, would need to be able to delineate which orders received without AUC consultation information are not subject to the AUC program from those that are subject to the program and its requirements. If they are able to confirm that a service is not subject to the AUC program, then they would need to identify the appropriate modifier to append to the claim so it can be processed and be paid without AUC consultation information. Alternatively, if they find that the order is subject to the AUC program, they would need to take steps to obtain AUC consultation information from the ordering professional, decline to furnish the service, or risk denial of the claim for a furnished service.

An example that highlights the practical complexity and unwieldiness of the AUC program is the, not uncommon, scenario where an advanced diagnostic imaging service is furnished in two settings—only one of which is an applicable setting. For example, this occurs when the technical component (TC) of an imaging service is furnished in a setting, like a critical access hospital (CAH), that is not an applicable setting. As we discussed in the CY 2022 PFS final rule, because the service was not furnished in an applicable setting, the entirety of the service (both the technical and professional component (PC)), is not subject to the AUC consultation requirement. Therefore, neither of the separate claims for the TC and PC for the service are required to include AUC consultation information. However, there is no way in real-time claims processing for us to identify that the PC claim is for an imaging service that was not furnished in an applicable setting. For the claim to process and be paid when it does not include AUC consultation information, the furnishing professional for the PC would need to append a modifier to the claim to identify it as not being subject to the AUC consultation and reporting requirement.

b. Accuracy of Claims Data

Because, as previously noted, the CMS claims processing system is unable to fully automate editing advanced diagnostic imaging claims, risks around reporting accuracy are inherent to the AUC program prescribed by section 1834(q)(4)(B) of the Act. These risks directly impact furnishing professionals, including free-standing and hospital-based facilities, by affecting payment for advanced diagnostic imaging services they furnish, in some cases based on conduct of ordering professionals with whom they have little or no affiliation. Beyond the potential for inappropriate claims denials as previously discussed, by manually appending information to their claims as supplied by ordering professionals, furnishing professionals are attesting to the credibility and accuracy of that information and may find themselves subject to audits or post-pay review. Considering that the AUC program ultimately involved the identification of outlier ordering professionals and imposing a prior authorization procedure for them as prescribed in sections 1834(q)(5) and (6) of the Act, reliance on manual reporting by one party of information supplied by another party presents a serious risk to data accuracy and integrity. Since section 1834(q)(5) of the Act directs CMS to use these data from claims-based AUC consultation information collection to identify outlier ordering professionals, and section 1834(q)(6) of the Act directs CMS to require prior authorization for outlier ordering professionals, the quality and accuracy of the data used to make these determinations is critical to ensure the AUC program leads to appropriate application of prior authorization for advanced diagnostic imaging services.

c. Effect on Medicare Beneficiaries

We recognize that a program to promote the use of AUC for advanced diagnostic imaging could improve imaging utilization patterns for Medicare beneficiaries. Ideally, beneficiaries would undergo fewer and more appropriate imaging procedures to inform more efficient treatment plans and address medical conditions more quickly and without unnecessary tests. In the CY 2019 PFS final rule, we estimated how adding AUC consultation to an ordering professional's workload would directly impact a Medicare beneficiary based on the additional office visit time needed for consultation and ordering. We estimated this impact by calculating the cost to beneficiaries associated with the additional consultation time to be $68,001,000 annually (83 FR 60040), representing the opportunity cost of time spent in the office. In the CY 2022 PFS final rule, we updated this estimate based on Medicare claims data and changes in wage estimates to $54,789,518 annually. We estimated that potential savings would offset this opportunity cost of time spent by beneficiaries in the office by $27,394,759 annually based on process efficiencies that may be implemented over time by ordering professionals (86 FR 65626). In the CY 2019 PFS final rule, we estimated other impacts associated with the AUC program including potential savings to the Medicare program. We estimated potential savings of $700,000,000 annually by extrapolating savings from a clinical decision support pilot project performed by the Institute for Clinical Systems Improvement in Bloomington, Minnesota.[413] (83 FR 60043) Since this estimate was based on information from previous clinical decision support experiences and not Medicare claims data or wage estimates, we did not update this estimate in the CY 2022 PFS final rule. The prior savings estimate is no longer an accurate reflection of savings that could be achieved and CMS will not realize the estimated $700,000,000 annual savings because, as described in the final rule, the AUC program cannot be implemented as written in statute; therefore, expected savings are negligible.

While the incorporation of any new process into workflows can be expected to impart burden that eventually lessens, we have additional concerns about risks for beneficiaries stemming from the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act. Beyond the burden of adding to the workload of the ordering and furnishing professionals for advanced diagnostic imaging services, the AUC consultation program can produce risk to beneficiaries in receiving timely imaging services, and potentially being financially liable for advanced diagnostic imaging service claims denied by the Medicare program, whether properly or due to omissions or errors in conveying AUC consultation information on claims. Beneficiaries may experience delays in scheduling and receiving imaging if AUC information is not properly provided with the order from the ordering professional to furnishing professionals/facilities. This may happen, even if the imaging service is not subject to the AUC program requirements, in any circumstance where the furnishing professional/facility is unclear whether the AUC consultation and reporting requirements apply (for example if Medicare is the secondary payer, or under other circumstances as discussed in the CY 2022 PFS final rule). Section 1834(q) of the Act does not separately establish protections to Medicare beneficiaries from financial liability for advanced diagnostic imaging service claims not paid by Medicare as required under the AUC program. As discussed above, because the Medicare claims processing system cannot fully automate

[413] Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. Healthcare IT News. November 10, 2010.

a process to ensure only claims for advanced diagnostic imaging services subject to the AUC program reporting requirement under section 1834(q)(4)(B) of the Act are edited as such, there is a risk of inappropriate claims denials. Additionally, in the event that an ordering professional fails to consult AUC or neglects to communicate AUC consultation information (or relevant exception information) to the furnishing professional/facility and the furnishing professional/facility proceeds with furnishing the imaging service despite the absence of this information, the beneficiary may incur unwarranted financial liability for the imaging service.

d. Summary

Taken together and, in particular, due to the inability of the Medicare claims processing system to automate claims processing edits that ensure only claims subject to the AUC program requirements as prescribed in section 1834(q) of the Act will be processed as such, returned or denied accordingly, we believe the inherent risks in terms of data integrity and accuracy, beneficiary access, and potential beneficiary financial liability for advanced diagnostic imaging services render the AUC program impracticable, and have led us to our proposal to pause efforts to implement the AUC program for reevaluation and rescind current regulations. Working within the parameters prescribed under section 1834(q) of the Act, we have not identified any practical way to move the AUC program forward beyond the educational and operations testing period. Further, without a way forward to fully implement the AUC program, we believe there is no utility in continuing the educational and operations testing period. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking. We note, and discuss further below in this section of the final rule, that clinical decision support tools can be beneficial in assisting with clinical decision making and we encourage continued use of clinical decision support in a manner that best serves and assists clinicians.

6. Summary of Other Quality Initiatives

As discussed above, section 218(b) of the PAMA of 2014 entitled ''Promoting Evidence-Based Care'' established the Medicare AUC program. The statute was designed to promote the use of AUC for advanced diagnostic imaging services with enforcement through immediate non-payment of claims for which there was no AUC consultation and, eventually, prior authorization for ''outliers'' that more frequently neglect to consult AUC. Promoting the use of AUC in clinical practice is an activity that encourages the use of evidence-based information/guidelines/recommendations to guide patient care thus resulting in improved value and quality. Subsequent to PAMA, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program, which is an incentive program to tie Medicare PFS payment to performance by rewarding high-value, high-quality care. After enactment of these laws, we worked to implement both programs by successfully establishing and fully operationalizing the Quality Payment Program (both the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)) and, as discussed above, taking steps to implement each component of the AUC program up to and through the ongoing educational and operations testing period. We have developed outreach and educational materials and made all AUC program-related information available on the CMS AUC website.[414] We believe that many goals of the AUC program have been met by the QPP and other more comprehensive accountable care initiatives such as the Medicare Shared Savings Program, advances in electronic clinical quality measures (eCQMs) and interoperability requirements of Certified Electronic Health Record Technology (CEHRT), and new Innovation Center models such as ACO REACH and Kidney Care Choices where physicians and other health care providers join together to take responsibility for both the quality of care and total cost of care their patients experience. These quality and value-based care programs are designed to achieve quality of care goals by addressing issues of utilization, cost and quality holistically instead of via claim-by-claim examination and improvement initiatives for specific types of services.

While these initiatives, including the Shared Savings Program, do not specifically target advanced diagnostic imaging, we expect that this more global approach to improving quality and accountable care would broadly affect all services, including advanced diagnostic imaging utilization. Both ACO participation and episode of care payment models promote accountability for beneficiary cost of care as well as improving or maintaining quality of care according to applicable quality measures. Similarly, the MIPS ties together quality and costs by measuring and scoring performance in four performance categories: quality, cost, improvement activities, and promoting interoperability. MIPS uses measures and activities in each of these categories, such as the Total Per Capita Cost (TPCC) specialty measure, which focuses on effective primary care management to support Medicare savings. While also not specific to advanced diagnostic imaging, improvements in primary care management including ordering of diagnostic tests may involve consideration of appropriate imaging orders.

More specific to advanced diagnostic imaging, MIPS includes 10 specific quality measures pertaining to imaging or under the ''Diagnostic Radiology'' Specialty Measure Set. Additionally, the Meaningful Measures 2.0 Framework includes a priority area for safety with the goal of ''Reduced Preventable Harm'' (*https://edit.cms.gov/files/document/cascade-meaningful-measures-framework.xlsx*). An objective under this goal is ''Diagnostic Accuracy/Error'' which includes a cascade measure concept/family of ''Appropriate use of radiology and lab testing.'' An example of an existing measure within this concept is ''Appropriate Follow-up Imaging for Incidental Abdominal Lesions'' (*https://www.cms.gov/files/document/cascade-measures.xlsx*).

While a standalone program specifically requiring AUC consultation when ordering advanced diagnostic imaging services would directly target goals of improving advanced diagnostic imaging ordering patterns, our experience in recent years has demonstrated that the goals of appropriate, evidence based, coordinated care can be achieved more effectively, efficiently and comprehensively through other CMS quality initiatives.

7. Summary of the Proposal To Rescind (§ 414.94)

We provided clarity to interested parties as we proposed to amend our regulations to rescind the current regulations by removing the text of § 414.94 and reserve it for future use. This section contains the entirety of the regulations we adopted in the course of implementing elements of section 1834(q) of the Act. We believe the removal of these regulations is consistent with our proposal to pause

[414] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

efforts to implement the AUC program for reevaluation, and would avoid the potential confusion that could result if we were merely to retain or amend the regulation text at § 414.94.

We acknowledge and emphasize the value of clinical decision support to bolster efforts to improve the quality, safety, efficiency and effectiveness of health care. We welcome and encourage the continued voluntary use of AUC and/or clinical decision support tools in a style and manner that most effectively and efficiently fits the needs and workflow of the clinician user. Across many specialties and services, not just advanced diagnostic imaging, clinical decision support predates the enactment of the PAMA and, given its utility when accessed and used appropriately, we expect it to continue being used to streamline and enhance decision making in clinical practice and improve quality of care. Resources on clinical decision support are available on HHS Agency websites including the following:

- Office of the National Coordinator—*https://www.healthit.gov/topic/safety/clinical-decision-support*.
- Agency for Healthcare Research and Quality—*https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html*.
- Centers for Disease Control and Prevention—*https://www.cdc.gov/opioids/healthcare-admins/ehr/clinical-decision-support.html*.

8. Summary

In conclusion, we proposed to pause efforts to implement the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94 and reserve this section in the CFR. We did not propose a timeframe within which implementation efforts may recommence. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to pause efforts to implement the AUC program for reevaluation. The majority of these commenters also supported our proposal to rescind and reserve the current AUC program regulations at § 414.94. Most commenters cited their agreement with our explanations of the insurmountable barriers presented in the discussion on the real-time claims-based reporting requirement and claims processing issues, as well as other operational challenges. Many stakeholders that represent health care providers who would be considered ordering professionals expressed support for the proposals because they believe the AUC program imposes undue burdens and administrative costs on providers. Many discussed aspects of the time, training effort, and costs of complying with the regulations. A few health systems and providers discussed their specific technical challenges with integrating CDSMs into their clinical workflow, disrupting patient care. Others noted that after years of the educational and operations testing period, they continue to have significant problems with reviewing orders received from outside their system and challenges in contacting ordering professionals to get correct information. One also noted technical challenges getting their electronic systems to correctly include AUC information on claims. One commenter stated that the regulatory requirement to implement a clinical decision support tool ''focused solely on imaging appropriateness creates a large burden on health systems and clinicians, without evidence that the program reduces high-cost imaging.'' Many commenters agreed with CMS's concerns about unintended costs to beneficiaries for improperly denied claims, as well as potential delays in accessing needed imaging services. Many commenters that represent professionals who furnish imaging services also thanked CMS for recognizing their concerns that the penalty portion included in the statute would penalize furnishing professionals who are unable to control the behaviors of ordering professionals. Several commenters agreed with CMS's concerns that the claims processing systems challenges present substantial risks for data integrity and accuracy. Many commenters expressed hope that CMS would permanently forgo the AUC program and/or that Congress would repeal or substantially change the PAMA statute. Many commenters recommended that CMS should provide clarity as to the status of the AUC program and not take steps to continue future implementation except through additional public engagement and public notice and comment. Several commenters thanked CMS for engaging with stakeholders and being responsive to comments and concerns of all interested parties over the last 8 years.

Response: We thank commenters for their support.

Comment: Some commenters provided mixed comments and a few commenters noted that they were unclear about their support or opposition to the proposal. Of the commenters that had mixed views, several expressed support for pausing the program for reevaluation and working toward a redesigned program but were either silent about rescinding the regulations or believed that rescinding the regulations at § 414.94 is premature. A few commenters noted they believed that the PAMA statute must be changed in order to successfully implement an AUC program that eases utilization and does not inappropriately deny claims.

Response: As discussed in the CY 2024 PFS proposed rule (88 FR 52514 through 52515), we acknowledge and emphasize the value of clinical decision support to bolster efforts to improve the quality, safety, efficiency, and effectiveness of health care. We welcome and encourage the continued voluntary use of AUC and/or clinical decision support tools in a style and manner that most effectively and efficiently fits the needs and workflow of the clinician user. Across many specialties and services, not just advanced diagnostic imaging, clinical decision support predates the enactment of the PAMA and, given its utility when accessed and used appropriately, we expect it to continue being used to streamline and enhance decision-making in clinical practice and improve quality of care.

While we are finalizing our proposal to pause the AUC program for reevaluation and to rescind the regulations at § 414.94 at this time, reserving it for future use, we will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking, including implementing any amendments Congress might make to the AUC program statutory provisions. We appreciate some commenters' concerns that rescinding all or part of § 414.94 is premature; however, given the need for clarity on the status of the program, we believe rescinding the regulations and reserving § 414.94 is the most appropriate and straightforward option.

Comment: Some commenters stated opposition to the proposal to both pause the AUC program and to rescind the regulations. Generally, most of these commenters cited the benefits of using AUC such as promoting cost containment and better test results. A few commenters expressed concern about the time, effort, money, and staff training resources they have spent to implement AUC consultation within their health system or practices. Several commenters that represent EHR

vendors, developers of clinical decision support tools, and a developer of AUC expressed strong concerns over delaying progress in development and use of AUC and CDSMs to advance use of high-quality imaging services as well as the potential chilling effect a pause could have on innovation within Medicare and across health care as a whole including Medicare Advantage and commercial plans. One commenter stated that CMS is concentrating too much on the payment mechanism in PAMA rather than focusing on the quality improvement aspect which in their view is the foundational aspect of the program. Three commenters stated that CMS has incorrectly interpreted various sections of the statute, including the requirement for AUC real-time claims-based reporting. Two commenters suggested that CMS is not interpreting enough flexibility into the PAMA or subsequent authorizing statutes; and if we follow commenters' interpretations instead, then we would have the authority already to incorporate the AUC program into other quality and value-based care programs. Several commenters also expressed concerns regarding the time and resources spent developing, qualifying, and marketing clinical decision support tools and AUC; and the revenue they fear losing if CMS does not mandate use of AUC within the Medicare program. One commenter requested that CMS at minimum keep the PLE and CDSM subsections of § 414.94. One commenter urged CMS to set a timeline for reevaluation and promulgation of new regulations so that phases of the program can continue.

Response: As previously mentioned, use of clinical decision support in the healthcare industry predates the enactment of the PAMA across many specialties, not just advanced diagnostic imaging. Given its utility when accessed and used appropriately, we expect it to continue being used to streamline and enhance decision making in clinical practice and improve quality of care. We disagree with commenters' suggestions that we could and should simply ignore or reinterpret the PAMA statute to disregard the real-time claims-based processing requirement in section 1834(q)(4)(B) of the Act. We also disagree with interpretations of the statute that read a flexibility into the PAMA or subsequent authorizing statutes that would allow CMS to incorporate AUC into other quality and value-based care programs without additional amendments to the statute. As noted in the previous response, we are finalizing our proposal to pause the AUC program for reevaluation and to rescind the regulations at § 414.94 at this time, reserving it for future use. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking, including implementing any amendments Congress might make to the AUC program statutory provisions. We appreciate comments recommending that we keep certain parts of § 414.94; however, we believe it would be confusing for all interested parties if CMS were to continue annually reviewing and qualifying PLE and CDSM applications while the rest of the program is paused. As noted in the proposed rule and previous comment response, the use of AUC and clinical decision support pre-dates the statutory AUC program for advanced diagnostic imaging. We note that many commenters indicated that they may continue to incorporate AUC and/or clinical decision support tools into their clinical decision making. Therefore, we expect, and encourage, that clinicians may continue to use clinical decision support, likely including mechanisms that had been qualified CDSMs under the AUC program, in a style and manner that best fits their needs and workflow. As such, while CMS will not be qualifying PLEs or CDSMs, we expect the industry and market for them will continue. We did not propose and cannot specify a timeframe within which implementation efforts may recommence, as that depends on the time needed for reevaluation and findings, as well as any potential Congressional action to revise the statute.

Comment: Some commenters recommended that CMS hire a third-party contractor (technology vendor) to make any necessary changes to the claims processing system in order to avoid pausing the program for reevaluation. One commenter stated their ''surprise'' at learning for the first time of the claims processing difficulties as a reason for pausing the program. Other commenters disagreed with our descriptions of the claims processing barriers and questioned the accuracy of our explanations of the risks for improperly denied claims and inaccurate claims data. One commenter stated their belief that we over-estimated the numbers of inaccurate claims and improperly denied claims. This commenter believed instead that the worst result of implementing the program as is would be ''occasional incidents of a consultation occurring that was not required.''

Response: We thank commenters for their suggestion that we contract for additional technical assistance, and will take it into further consideration. In the CY 2024 PFS proposed rule (88 FR 52510 through 52512), we explained that since 2015, we have taken a thoughtful, stepwise approach to implementing the statute that maximized engagement and involvement of interested parties. In the proposed rule (88 FR 52512 through 52513), we detailed the years of effort and public engagement to solve the claims processing aspects required by the statute. As described in the proposed rule on pages 52512 through 52514, we considered many factors and believe we have exhausted all reasonable options for fully operationalizing the AUC program and resolving the issues with the real-time claims-based reporting requirement. We disagree with assertions that implementing the payment penalty portion of the statute with the current capabilities would not result in the potential for millions of improperly denied claims and would not implicate beneficiary liability for those denied claims. We also disagree with assertions that the only negative impacts would be occasional incidences of ordering professionals consulting AUC when it is not required. In the CY 2022 PFS final rule we updated the regulatory impact analysis based, in part, on updated claims data for advanced diagnostic imaging. Using only services billed on the professional claim type, we estimated over 30 million advanced diagnostic imaging services to be subject to the AUC program (86 FR 65626). Since only professional claims were used for these estimates, the number of claims only increases once institutional claims for the same services are considered. Because we cannot fully automate the claims processing system to accurately identify the claims for services that are and are not subject to the real-time claims-based reporting requirement as discussed above, millions of claims are in fact at risk of improper processing, including unwarranted denials. As noted in a previous response, while we are finalizing our proposal to pause the AUC program for reevaluation and will rescind the regulations at § 414.94 (reserving this section) at this time. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking, including implementing any amendments Congress might make

to the AUC program statutory provisions.

Comment: One commenter recommended that CMS should require the CDSMs to provide CMS data on compliance and problem areas that may exist. Another commenter similarly recommended that CMS change the AUC program to transfer responsibility for reporting and auditing on CDSM/Guideline usage to the CDSMs. This commenter stated the CDSM reports could then be used ''on an ex post facto basis'' to enforce the program as originally envisioned, leading outlier physicians to have to follow pre-certification steps until their usage of AUC was within established limits.

Response: This suggestion would require a change in the statute to remove the current real-time claims-based reporting requirement in section 1834(q)(4)(B) of the Act. As noted in the proposed rule, we would use the public notice and comment rulemaking process to reinstate any regulations and make future changes to the AUC program, including to implement any amendments Congress might make to the AUC program statutory provisions.

Comment: A few commenters indicated that in recent years they have made efforts to work directly with Congress to revise or rescind the PAMA statute and will continue to do so given the discussion in the proposed rule. Several commenters requested that CMS partner directly with Congress; some suggested that this partnership work toward removing the requirements for the AUC program from the statute, others suggested CMS and Congress should modify the statute to remove the real-time claims-based reporting requirements and provide CMS with more flexibility in how to implement AUC within Medicare. Several suggested modifying the statute to align or incorporate the AUC program with other quality improvement and value-focused programs authorized under other sections of the statute. One commenter requested that CMS work to advance legislation with Congress that enables implementation of an advanced payment model for advanced diagnostic imaging based on the use of AUC embedded in CDSMs and to consider other opportunities in Federal policy making to use CDSMs.

Response: As noted, the commenters are suggesting legislative changes to the AUC program, which would require Congressional action. We appreciate these suggestions and will respond appropriately to any amendments to the statute that impact the AUC program.

Comment: One commenter wished to ''. . . remind CMS that, in July 2021, the House Appropriations Committee approved the Fiscal Year (FY) 2022 Labor, Health and Human Services, Education spending bill and included an accompanying report that called on CMS to report to Congress on the implementation of the AUC Program, including program challenges and successes. The report language further directed CMS to consider existing quality improvement programs and relevant CMS Innovation Center models and their influence on appropriate use of advanced diagnostic imaging.''

Response: We provided a response to this Appropriations Committee request in February 2023. Additionally, in the proposed rule (88 FR 52514 through 52515) in section 6. ''Summary of Other Quality Initiatives'', we discussed that, subsequent to PAMA, in accordance with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114 10, April 16, 2015) we established and fully operationalized the Quality Payment Program (both the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)). We discussed the Quality Payment Program and stated that we believe that many goals of the AUC program have been met by the Quality Payment Program and other more comprehensive accountable care initiatives such as the Medicare Shared Savings Program, advances in electronic clinical quality measures (eCQMs) and Interoperability requirements of Certified Electronic Health Record Technology (CEHRT), and new Innovation Center models such as ACO REACH and Kidney Care Choices where physicians and other health care providers join together to take responsibility for both the quality of care and total cost of care their patients experience. These quality and value-based care programs are designed to achieve quality of care goals by addressing issues of utilization, cost, and quality holistically instead of via claim-by-claim examination and improvement initiatives for specific types of services. While a standalone program specifically requiring AUC consultation when ordering advanced diagnostic imaging services would directly target goals of improving advanced diagnostic imaging ordering patterns, our experience in recent years has demonstrated that the goals of appropriate, evidence based, coordinated care can be achieved more effectively, efficiently, and comprehensively through other CMS quality initiatives.

Comment: Many commenters noted that other quality and efficiency programs may have a greater impact on improving quality of care and promoting high-value care. Several commenters stated that the current AUC program does not consider patient outcomes, or other important factors related to quality, which they believe are more appropriately addressed in APMs. Additionally, one commenter stated that physicians participating in APMs are ''already accountable for the quality and cost of their care, including strong incentives to reduce unnecessary utilization of costly imaging services, rendering the AUC program unnecessary.'' Another commenter stated that their organization has always been concerned that implementation of the AUC program would detract from the developments of the Quality Payment Program made in the years since the AUC program was signed into law. One commenter recommended adjusting the MIPS to better serve as an incentive for use of AUC; they noted that practices and customers have difficulty gauging the benefit of AUC contribution to their MIPS credit scoring and have concerns that including AUC in their submissions could actually reduce their MIPS credits if used as an alternative.

Response: We thank commenters for these comments and suggestions and will keep them in consideration as we reevaluate the AUC program. As noted in the previous responses, we are finalizing our proposal to pause the AUC program for reevaluation and to rescind the regulations at § 414.94 at this time, reserving it for future use. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking, including implementing any amendments Congress might make to the AUC program statutory provisions. As noted in the proposed rule, and in responses above, our experience in recent years has demonstrated that the goals of appropriate, evidence based, coordinated care can be achieved more effectively, efficiently, and comprehensively through other CMS quality initiatives. However, as discussed in the proposed rule (88 FR 52514 through 52515) in section 6. ''Summary of Other Quality Initiatives'', those other programs have different authorizing statutes.

Comment: A few commenters commended CMS for reinforcing the beneficial role of clinical decision support tools and commended CMS for welcoming and supporting voluntary use of AUC and clinical decision support tools even as we pause efforts to implement the AUC program for

reevaluation and rescind the current AUC program regulations. Several commenters wrote of their commitment to the AUC program's overarching goal of enhancing patient safety and reducing healthcare costs by curbing unnecessary imaging studies, even without the AUC program.

Response: We thank commenters for their support.

Comment: One commenter requested that CMS take steps to limit prior authorization burden for any impacted clinicians as CMS reevaluates the AUC program and designs any future quality or AUC related program. Another commenter stated that AUC is necessary for targeting prior authorization to practitioners who ordered diagnostic imaging services inconsistent with appropriate, evidence-based care to reduce the amount of ''low-value'' care in the traditional Medicare program.

Response: We thank the commenter for their suggestions and will note these concerns as we continue to reevaluate the program.

Comment: One commenter recommended that CMS audit the current eight priority clinical areas to assess the impact of clinical decision support on quality of care.

Response: We thank the commenter for their recommendation and will consider this suggestion as part of our reevaluation.

Comment: Several commenters expressed their willingness to provide help to CMS in its reevaluation, for example, ''insights on how automated tools in the EHR can support CMS's goals of implementing the program in a manner that does not increase provider burden.'' Several commenters representing various sectors of the healthcare industry urged CMS to engage with representatives of their respective industries while reevaluating the program, including but not limited to various physician specialties, the radiology and revenue cycle communities, the EHR industry, and independent guideline authors.

Response: We thank commenters for their offers to assist with reevaluation and to continue to engage with CMS and provide feedback. We continue to welcome and encourage feedback and information from interested parties. While we did not propose and are not finalizing a timeframe within which implementation efforts may recommence, we will continue efforts to identify a workable implementation approach and will include stakeholder engagement as part of that process and will propose to adopt any such approach through subsequent rulemaking, including implementing any amendments Congress might make to the AUC program statutory provisions.

Comment: One commenter stated their primary concern with the AUC program continues to be the regulatory definition of Provider Led Entity, which they believe continues to be inconsistent with the statute and prevents independent evidence-based guideline authors from participating in the AUC program. The commenter took issue with our previous responses to this comment in past rulemaking cycles.

Response: As discussed in prior responses, we are finalizing our proposal to pause the program and rescind the current regulations at § 414.94, including the regulatory definition of a Provider Led Entity.

After consideration of public comments, we are finalizing our proposal to pause the AUC program for reevaluation and to rescind the regulations at § 414.94, keeping this section reserved for future use.

K. Medicare and Medicaid Provider and Supplier Enrollment

1. Medicare Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider or supplier is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider or supplier is reporting a change in its ownership.
- Revalidation—The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)
- Reactivation—The provider or supplier is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discuss in this section III.K of this final rule, we proposed several changes to our existing Medicare provider enrollment regulations.

(We note that section III.K of this final rule also addresses a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Medicare Provider Enrollment Provisions

i. Revocation and Denial Reasons and Revisions to Other Revocation Policies

(A) Revocations

Under § 424.535(a), we may revoke a Medicare provider's or supplier's enrollment for any of the reasons specified within that paragraph. (The revocation grounds are currently identified as § 424.535(a)(1) through (22), with paragraphs (a)(15) and (16) designated as reserved.) These reasons include, for instance, the provider's or supplier's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii) felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing, prescribing of Part B or Part D drugs, or ordering/referring/certifying of Medicare services or items; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing (and preventing payment to) Medicare providers and suppliers that have engaged in problematic or otherwise non-compliant behavior. When a provider or supplier is revoked, they are generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this ''reenrollment bar'' is predicated upon the severity of the basis of the revocation. The maximum reenrollment bar is typically restricted to egregious acts of misconduct.

We have previously finalized a number of regulations adding new revocation reasons to § 424.535(a) to address particular program integrity vulnerabilities and types of provider or supplier behavior. We have also used rulemaking to refine other policies regarding revocations, such as the reenrollment bar and the effective dates of certain revocations. Given our continuing obligation to assess potential vulnerabilities and establish payment safeguard measures, we proposed several additions and revisions to our revocation policies in § 424.535(a).

(1) Non-Compliance Revocation Ground (§ 424.535(a)(1))

Existing § 424.535(a)(1), in part, permits revocation if the provider or supplier is determined to not be in compliance with the enrollment requirements described in subpart P or in the enrollment application applicable to its provider or supplier type. We proposed to change the language therein that reads ''described in this subpart P or in the enrollment application'' to ''described in this title 42, or in the enrollment application . . .'' This is because there are enrollment requirements located outside of 42 CFR part 424, subpart P; for instance, certain enrollment requirements pertaining to opioid treatment programs are in § 424.67(b). All enrollment requirements, regardless of their placement in title 42, must be adhered to, which is why we believed the scope of § 424.535(a)(1) should be expanded.

We received the following comments on this proposal:

Comment: A commenter expressed support for our proposed expansion of § 424.535(a)(1).

Response: We appreciate the commenter's support.

Comment: A commenter asked CMS to outline the enrollment provisions outside of subpart P to which this new revocation authority could apply; otherwise, the commenter stated, CMS should not finalize this proposal because commenters would not have had adequate opportunity to comment on this change.

Response: As noted above, the proposed rule cited as an example certain enrollment requirements pertaining to opioid treatment programs that are found in § 424.67(b). Other examples include conditions for Medicare diabetes prevention program enrollment in § 424.205 and certain enrollment requirements for home infusion therapy suppliers in § 424.68. However, as the provider community is largely familiar with the enrollment provisions outside of subpart P, we do not believe it is necessary to list all of them aside from citing examples of the expanded applicability of § 424.535(a)(1). Each enrollment section of title 42 outside of subpart P, moreover, is denoted as applying to enrollment either in the title or the text of the section; for instance, § 424.68(c) is titled ''Specific requirements for enrollment.'' We hence believe that adequate notice was furnished to stakeholders regarding the scope of our proposal.

After consideration of these comments, we are finalizing this provision as proposed.

(2) Misdemeanor Convictions

As already alluded to, a provider or supplier can be revoked under § 424.535(a)(3)(i) if the provider, supplier, or any owner, managing employee, officer, or director of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. Section 424.535(a)(3)(ii) lists examples of such felonies, though they are not limited in scope and severity to these offenses.

Section 424.535(a)(3) does not include misdemeanor convictions, and there currently is no regulatory authority to revoke a provider or supplier based solely on a misdemeanor. We noted in the proposed rule that we have become aware of and increasingly concerned about providers and suppliers convicted of misdemeanors for conduct that could endanger the Trust Funds' integrity and Medicare beneficiaries' health and safety. To this end, we proposed in new § 424.535(a)(16)(i) that CMS may revoke a provider's or supplier's enrollment if they, or any owner, managing employee or organization, officer, or director thereof, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. Proposed § 424.535(a)(16)(ii) stated that offenses under § 424.535(a)(16) include, but are not limited in scope or severity to, the following:

- Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

We solicited comments on this proposal. We specifically sought feedback on: (1) whether there are any potential unintended consequences of our proposal that we are not

considering; or (2) any guardrails we should consider so as not to create unintended impacts on persons with misdemeanor convictions.

Comment: We received numerous comments opposing our proposed misdemeanor revocation authority. Among the principal concerns expressed, commenters noted:

- The purview of our proposal was too broad in that it could encompass many types of misdemeanors involving comparatively modest conduct.
- Physicians with misdemeanor convictions for violating State laws restricting gender-affirming care or reproductive rights (particularly in States with near-total bans on abortion) could have their enrollments unfairly revoked.
- The provision could negatively impact equity given that some individuals with misdemeanors for minor offenses could be denied the opportunity to work in the health care field because provider organizations may be reluctant to hire them out of concern that they may be revoked.

Response: After reviewing the comments received, we are not finalizing proposed § 424.535(a)(16). We will nonetheless continue to monitor cases of misdemeanor convictions involving significant misconduct and may pursue future rulemaking to address them. We emphasize that many misdemeanors, especially those involving assault, battery, neglect, or abuse of a patient (including sexual offenses), can pertain to activity that remains of concern to us.

(3) False Claims Act Civil Judgments

The False Claims Act (FCA) (31 U.S.C. 3729–3733) is the Federal government's principal civil remedy for addressing false or fraudulent claims for Federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant, such as knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

Although the FCA's scope is not restricted to the health care arena and applies to all types of Federal government programs, the FCA has proven effective in helping to stem Medicare fraud. However, an FCA civil judgment against a provider or supplier does not, in and of itself, impact the latter's Medicare enrollment. Even if, for example, a provider is found to have knowingly submitted fraudulent claims and is liable for $100,000 in damages, we have no ability to revoke the provider's enrollment exclusively on this basis. This concerns us, for the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior. We believe we must address this vulnerability to protect the Medicare program and its beneficiaries.

We accordingly proposed in § 424.535(a)(15) that we could revoke enrollment if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. (Strictly for purposes of (a)(15), the term ''civil judgment'' would not include FCA settlement agreements. The provision would require a judgment against the provider or supplier.) Recognizing that the specific facts and circumstances of each case will differ, we proposed to consider the following factors in our decision:

- The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).
- The types of provider or supplier actions involved.
- The monetary amount of the judgment.
- When the judgment occurred.
- Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).
- Any other information that CMS deems relevant to its determination.

We noted that we would include FCA civil judgments against owners, managing employees and organizations, and officers and directors (as those terms are defined in § 424.502) of the provider or supplier within the scope of this revocation basis. This is consistent with our approach to several other revocation reasons in § 424.535(a) and reflects our recognition that certain owning and managing parties exercise great influence over the provider or supplier organization and its daily operations. Should such a party have an FCA civil judgment against them, this could present a program integrity risk. We therefore stated our belief that § 424.535(a)(15) should encompass such situations. However, we would consider the degree of the owning or managing party's control over the provider or supplier (for example, percentage of ownership, scope of day-to-day operational authority) as a factor in our determination.

We received the following comments on this proposal:

Comment: A commenter expressed support for our proposed revocation authority regarding FCA judgments.

Response: We appreciate the commenter's support.

Comment: Several commenters opposed our proposed FCA authority. They were concerned that it could: (1) harm good-faith providers and suppliers that inadvertently submitted false claims; and (2) compel providers and suppliers to settle their case—even though the provider or supplier believes it committed no wrongdoing and wishes to contest the government's claims—to maintain their Medicare enrollment. One commenter stated that this second scenario could impose serious financial costs on such providers and suppliers, hence diverting resources from patient care. This commenter added that if CMS nonetheless finalizes its proposal, the 10-year window should apply prospectively. This would prevent CMS from revoking enrollment for judgments that occurred many years ago when the provider or supplier could not have accounted for Medicare enrollment in determining whether to settle or contest the case.

Response: We appreciate these comments. We first note that our authority under § 424.535(a)(15) will be purely discretionary and not mandatory. We would only take action after a careful assessment of the factors outlined in § 424.535(a)(15) and the circumstances of the case. However, we respectfully do not believe our new authority will compel providers and suppliers to settle FCA cases rather than challenge them. In our view, the provider's or supplier's decision on this matter will be based on many considerations, some of which may be more critical to the provider or supplier than Medicare enrollment. We are unaware, for example, of situations where providers and suppliers have pled guilty to a misdemeanor charge instead of contesting a felony charge out of concern that their Medicare enrollment would be revoked if convicted of a felony. We believe the same will hold true regarding § 424.535(a)(15).

Concerning the final comment, we only intend to apply § 424.535(a)(15) prospectively—that is, to FCA judgments occurring on or after the effective date of this final rule.

Comment: Several commenters stated that situations involving false claims already fall under: (1) CMS' existing revocation authority; or (2) OIG or DOJ authorities. Consequently, there is no need for proposed § 424.535(a)(15).

Response: At this time, we believe we lack explicit authority to revoke enrollment in every possible instance where a false claim is implicated. The closest authority is § 424.535(a)(8)(ii), but this requires a pattern or practice of submitting non-compliant claims and does not allow us to take action based solely on the FCA judgment itself. Had

we believed we had the legal authority to revoke in all false claim situations, we would not have proposed § 424.535(a)(15). Moreover, while we partner with OIG and DOJ to protect the Medicare program and its beneficiaries, we also have an independent responsibility to do so. Consequently, we must have administrative means at our disposal to promptly act in Medicare's best interests.

Comment: A commenter asked CMS to explain what an FCA ''settlement'' is.

Response: We refer the commenter to the DoJ False Claims Act web link at *https://www.justice.gov/civil/false-claims-act* for information concerning FCA settlements.

After consideration of these comments, we are finalizing this proposal without modification.

(4) Violation of Provider and Supplier Standards

As alluded to previously, § 410.33(g) lists detailed enrollment standards that IDTFs must meet to enroll and maintain enrollment in Medicare. Likewise, § 424.57(c) identifies 30 enrollment standards that DMEPOS suppliers must meet as conditions of enrollment. These IDTF and DMEPOS standards address matters such as the maintenance of liability coverage, solicitation of patients, and customer service requirements. In addition, §§ 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) contain enrollment standards and conditions for, respectively, opioid treatment programs (OTPs), home infusion therapy (HIT) suppliers, and Medicare diabetes prevention programs (MDPPs). The standards and conditions in §§ 410.33(g), 424.57(c), 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) are in addition to, and not in lieu of, the more general enrollment requirements in subpart P with which IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, MDPPs, and all other provider and supplier types must comply.

We proposed to add new paragraph (a)(23) to § 424.535 that would permit CMS to revoke an IDTF's, DMEPOS supplier's, OTP's, HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), 424.68(c) or (e), or 424.205(b) or (d). No revocation reason in existing § 424.535(a) specifically references these regulatory paragraphs or violations thereof. Although we have sometimes applied a comparatively broad revocation basis in § 424.535(a)(1) to certain non-compliant IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, and MDPPs (for example, an invalid practice location under § 424.535(a)(5)), we believed that a narrower approach that allows us to target violations of these standards and conditions is preferable. That is, our proposal would more directly tie these regulatory paragraphs to § 424.535(a) by establishing a new revocation reason restricted to non-compliance with any of them.

We received the following comments on this proposal:

Comment: A commenter stated that proposed § 424.535(a)(23) is unnecessary because CMS can currently deactivate providers and suppliers for non-compliance.

Response: We respectfully disagree. As we will discuss further in this section III.K., there are varying degrees of non-compliance and some of them are substantial enough to warrant a revocation as opposed to a deactivation. In other words, the non-compliance is of a sufficiently serious nature that we believe revocation—and a consequent reenrollment bar to keep the provider or supplier out of the Medicare program for a period of time—are needed to protect Medicare and its beneficiaries. We accordingly must retain the ability to take such action as circumstances dictate.

Comment: Several commenters stated that CMS should only apply § 424.535(a)(23) when the provider or supplier has a pattern of non-compliance and refuses to remedy the matter when requested to do so; one commenter explained that isolated instances of minor non-compliance can inadvertently occur.

Response: We respectfully do not believe a pattern or multiple acts of non-compliance should be required to invoke § 424.535(a)(23). While we acknowledge that an isolated instance of non-compliance can take place, this can nonetheless involve a serious violation of an enrollment condition or standard. We do not believe we should be compelled to wait for the provider or supplier in such cases to commit additional violations (and, in the process, potentially further threaten the Medicare program) before taking revocation action.

After reviewing the comments received, we are finalizing our proposal without modification.

(5) Scope of § 424.535(a)(17)

Under § 424.535(a)(17), we may revoke enrollment if the provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury. In determining whether a revocation is appropriate, we consider the six factors outlined in § 424.535(a)(17)(i) through (vi); these include, for instance, the reason for the provider's or supplier's failure to pay the debt. The purpose of § 424.535(a)(17) is to spur providers and suppliers to repay their financial obligations to Medicare. In our view, their failure to do so raises doubts as to whether the provider or supplier can be a reliable partner of the Medicare program.

We received inquiries from interested parties concerning the scope of this provision, such as whether paragraph (a)(17) applies to debts that are no longer being collected or are being appealed. We proposed to revise paragraph (a)(17) to address these issues.

First, and to help accommodate our revisions, existing § 424.535(a)(17)(i) through (vi) would be re-designated as paragraphs (a)(17)(i)(A) through (F).

Second, in new paragraph (a)(17)(ii), we proposed to exclude from paragraph (a)(17)(i)'s purview those cases where: (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired. We believed the debts in these two situations have not been finally and fully adjudicated for purposes of paragraph (a)(17)(i)'s applicability. For this reason, we believed basic fairness to the provider or supplier justifies revised paragraph (a)(17)(ii).

Third, in § 424.535(a)(17)(i) we proposed to change the term ''existing debt'' to ''failure to repay a debt''. This would allow us to potentially use our revocation authority even if collection action has ceased and the debt was ultimately terminated as a result, since the provider or supplier had still failed to repay it.

We received the following comments on our proposal:

Comment: Several commenters expressed concerns about our proposed terminology change in § 424.535(a)(17) to ''failure to repay a debt.'' The commenters stated that there are many circumstances where a debt may be ''written off'' that do not involve a provider's or supplier's intent to avoid its legal obligations under Medicare. One commenter requested that CMS clarify: (1) the circumstances under which a provider or supplier would be revoked under our proposal; and (2) the length of time that must elapse before a provider or supplier is deemed as having failed to repay the debt,

including how many points of contact CMS will attempt before moving a provider or supplier into such a status.

Response: We appreciate these comments and address them in turn. First, we recognize that failures to repay certain debts may not involve any nefarious intent by the provider or supplier. Yet the core issue is not the provider's or supplier's state of mind but the repayment failure itself. As we explained at length in the proposed rule, any non-payment, whether deliberate or not, harms the Trust Funds and the taxpayers, and we must have means to address such situations, hence our change to § 424.535(a)(17). However, this change will not alter the criteria we consider in determining whether a revocation is appropriate or the care and conscientiousness with which we review the facts and circumstances of the case. Providers and suppliers should also not assume they will now be more likely to be revoked under § 424.535(a)(17). Nonetheless, we cannot outline fact patterns for which CMS will always invoke § 424.535(a)(17) due to the need to retain our flexibility to address each case on its own unique characteristics.

Regarding the latter commenter's second request for clarification, CMS Publication 100–06, Medicare Financial Management, Chapter 4 (hereafter Chapter 4) outlines CMS procedures for recovering debts, referring unpaid debts to the Department of Treasury, and determining when debts are written-off or closed out. This includes information regarding the timeframes in which debts are placed in certain debt statuses and the steps that occur (such as demands for repayment) prior thereto. We: (1) will continue to follow these procedures upon implementation of revised § 424.535(a)(17); and (2) encourage the commenter and other interested stakeholders to review Chapter 4 for more information regarding the operational aspects of debt collection, including the number of attempted contacts before a provider or supplier is moved into a certain status.

After reviewing the comments received, we are finalizing our proposal without modification.

(B) Reasons for Denial

As previously discussed, we proposed new revocation authorities in § 424.535(a)(15), (16), and (23), as well as expanded the scope of § 424.535(a)(1) to include non-compliance with any enrollment provision in title 42. Since we believed that the rationales for these revocation reasons (and our associated program integrity concerns) were equally applicable to newly enrolling providers and suppliers, we proposed corresponding denial reasons on these bases. Specifically, proposed denial reasons § 424.530(a)(16), (a)(17), and (18) involved, respectively, misdemeanor convictions, FCA judgments, and supplier standard/condition violations, with revised § 424.530(a)(1) addressing violations of enrollment provisions in title 42.

In general, the previously identified comments in section III.K.1.c.i.(A) did not distinguish between revocations and denials. The commenters' concerns were the same irrespective of whether, for example, a misdemeanor conviction resulted in a denial or revocation. For this reason, we will not repeat these comments in this section III.K.1.c.i.(B). Yet we fully considered these comments and will take the same approach for our denial reasons that we did for our revocation grounds; that is, the rationales behind our responses to those revocation-related comments are equally applicable to our proposed denial bases. We are accordingly finalizing proposed § 424.530(a)(17) and (18) (respectively, FCA judgments and supplier standard/condition violations), as well as our proposed change to § 424.530(a)(1) without modification. We are not finalizing proposed § 424.530(a)(16) concerning denials for misdemeanor convictions.

(C) Effective Date of Revocation

Section 424.535(g) addresses revocation effective dates. It states that a revocation becomes effective 30 days after CMS or the contractor mails notice of its determination to the provider or supplier. Yet there are exceptions. If the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or non-operational practice location, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation, or the date that CMS or its contractor determined that the provider or supplier was non-operational. The purpose of these exceptions is to prevent payment to a provider or supplier while it is out of compliance with Medicare enrollment requirements.

With this overarching principle in mind, we proposed several organizational changes to and expansions of § 424.535(g).

First, we would split existing § 424.535(g) into several paragraphs. Paragraph (g)(1) would include the previously mentioned 30-day effective date policy, though with the following language at its beginning, ''Except as described in paragraphs (g)(2) and (g)(3) of this section''. New paragraph (g)(2) would list the four retroactive revocation situations in existing § 424.535(g). Each situation (and its associated revocation effective date) would be incorporated into a separate paragraph to make paragraph (g)(2) clearer and more readable.

Second, paragraph (g)(2) would include the following additional situations where a retroactive effective date would be warranted:

- Revocations under proposed § 424.535(a)(16) (regarding misdemeanor convictions): the effective date would be the date of the misdemeanor conviction.
- Revocations based on a State license surrender in lieu of further disciplinary action: the effective date would be the date of the license surrender.
- Revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid): the effective date would be the date of the termination.
- Revocations based on termination of a provider agreement under 42 CFR part 489: the effective date would be, as applicable to the type of provider involved, the later of the following: (1) the date of the provider agreement termination; or (2) as applicable, the date that CMS establishes under 42 CFR 489.55. (Section 489.55 permits payments beyond the provider agreement termination date in certain instances and for a certain period.)
- Revocations based on proposed § 424.535(a)(23) would be as follows:

++ If the standard or condition violation involved the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the revocation effective date would be the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

++ If the standard or condition violation involved a non-operational practice location (for example, an IDTF's failure to maintain a physical facility on an appropriate site per § 410.33(g)(3)), the revocation effective date would be the date the non-operational status began.

++ If the standard violation involved a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the revocation effective date would be the date of the felony conviction.

For all other standard violations, the effective date in paragraph (g)(1) would apply if the effective date in new § 424.535(g)(3) does not. Under

§ 424.535(g)(3), we proposed that if the action that triggered the revocation occurred before the provider's or supplier's enrollment effective date, the revocation effective date would be the enrollment effective date that CMS assigned to the provider or supplier. The aim of § 424.535(g)(3) was to merely reiterate that we could not apply a revocation effective date that is earlier than the date the provider or supplier is enrolled.

We received the following comments on this proposal.

Comment: A commenter expressed support for our proposed retroactive revocation effective dates.

Response: We appreciate the commenter's support.

Comment: A commenter stated that retroactive revocations can result in the imposition of an overpayment for services that were medically reasonable and necessary and delivered in good faith. The commenter expressed concern that, given the discretionary nature of revocations, a supplier who becomes aware of a potential retroactive revocation must decide whether to: (1) stop billing Medicare (which in many cases, the commenter believed, would result in the supplier going out of business); or (2) take their chances that they will not receive a retroactive revocation notice many months in the future, which could leave the supplier with a six or seven-figure overpayment. The commenter thus requested that CMS place a cap on the overpayment period for retroactive revocations, such as a maximum 30-days after CMS became aware of the action resulting in the revocation; this policy, the commenter added, should also apply to retroactive deactivation grounds under § 424.540(b).

In support of their request, the commenter noted that under existing § 424.535(g) (and as referenced previously in section III.K of this final rule), a revocation based on a felony conviction, license suspension or revocation, or a non-operational practice location is applied retroactively. Because these three revocation grounds (like other revocation bases) are discretionary, CMS might not revoke a provider or supplier for these reasons, meaning the provider or supplier can continue to be paid. Consequently, the commenter stated, CMS cannot justify retroactive revocation and deactivation effective dates on the contention that it is unable to pay for services while a provider or supplier is non-compliant, since CMS is doing so when it elects not to impose a revocation or deactivation when it has the authority to do so.

Response: We respectfully do not believe an overpayment cap is warranted. Providers and suppliers must always remain compliant with Medicare enrollment requirements, and any failure to do so can result in CMS action. Merely because CMS might decline in a particular instance to impose, for example, a revocation for non-compliance does not mean CMS should be barred from ever assessing overpayments in cases where it does apply a revocation. That is, it does not follow that CMS non-action in a potential revocation situation mandates similar non-action (and subsequent non-assessment of overpayments) in every other situation where the same revocation reason under § 424.535(a) is involved. As discussed further in section III.K.1.c.ii of this final rule, there are varying degrees of non-compliance. When we impose a revocation instead of, for instance, a deactivation or a stay of enrollment, it is generally because the conduct involved was of such significance that we believe the provider or supplier should be removed from the Medicare program. Given, accordingly, the seriousness of the provider's or supplier's action or inaction in revocation cases, we do not believe we should be prohibited from assessing overpayments to the extent we deem appropriate. It is ultimately the provider's or supplier's responsibility to: (1) maintain compliance; (2) take rapid measures to resume adherence if they fall out of compliance or suspect that they have; and (3) not engage in the applicable misconduct, such as felonious behavior. Doing so will avoid the situation the commenter describes in their first paragraph concerning physicians who believe they might be revoked.

After reviewing the comments received, we are finalizing them as proposed excluding the language in paragraph (g)(2) referencing misdemeanor convictions. We are not finalizing this paragraph because we are not finalizing § 424.535(a)(16).

(D) Timeframes for Reversing a Revocation Under § 424.535(e)

Section 424.535(e) states that if a revocation was due to adverse activity (sanction, exclusion, felony) by one of the parties listed in § 424.535(e) (for example, owner, managing employee, authorized or delegated official, supervising physician), the revocation can be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation notification. As we explained in the proposed rule, we have been concerned about this 30-day period. We do not believe a provider or supplier should be afforded so much time to terminate this business relationship. Each day the revoked provider or supplier remains affiliated with the party in question, the more Medicare dollars that could be paid until the 30-day timeframe expires. It is the provider's or supplier's constant responsibility to ensure that its owning and managing personnel present no program integrity risks to the Medicare program. To give the provider or supplier 30 days to terminate a relationship that should have been promptly ended upon the commission of the adverse action (for example, when the owner became excluded) would be inconsistent with our obligation to protect the Trust Funds. It could also convey a false impression that maintaining affiliations with problematic parties is acceptable so long as the relationship ceases within a month of the revocation notice.

To this end, we proposed to revise § 424.535(e) to reduce the 30-day period therein to 15 days. We did not propose, for instance, a 5-day period because we recognized that it might be administratively and financially difficult to immediately terminate the business relationship in question, especially an owner's interest in the provider or supplier. Still, the reduction from 30 days to 15 days evidences our concern about making Medicare payments to providers and suppliers that have relationships with parties presenting program integrity risks.

We received the following comments on our proposal:

Comment: Several commenters opposed our proposed reduction from 30 days to 15 days. They stated that this is insufficient time to terminate the affiliation and submit proof thereof, especially since there could be administrative and legal processes to complete before the relationship can be severed. They noted that revocation letters can take 5 or more days to reach the provider (and even longer to reach the appropriate person within the provider organization), leaving the latter no more than 10 days to comply with § 424.535(g)'s requirements. They stated the current 30-day period should remain, adding that merely because the provider or supplier can appeal the revocation does not make the proposed reduction to 15 days more palatable. Some commenters recommended that if CMS finalizes this proposal: (1) a provider or supplier should have 15 days (business or calendar, though preferably the former) from the documented date of receipt of the

revocation letter to end the affiliation and furnish proof thereof; and (2) CMS should send all revocation notices via certified mail.

Response: We recognize that affected providers and suppliers will need to act expeditiously to comply with revised § 424.535(g). However, and as explained in the proposed rule and this final rule, it is imperative that providers and suppliers always take quick measures to resume compliance with enrollment requirements. The overriding concern, in our view, must be the protection of the Trust Funds from improper payments, even if this means the provider or supplier has less time to satisfy § 424.535(g)'s requirements. The longer the provider or supplier remains non-compliant, the more taxpayer monies that can be inappropriately paid; this is especially true with respect to excluded providers, suppliers, owners, etc., for we are prohibited by statute from paying for services furnished by such parties. While Days 16–30 (that is, the difference between current and proposed § 424.535(g)) may only represent two weeks of payments, many thousands of dollars could still be paid to non-compliant providers. In sum, while we understand the commenters' contentions, our foremost obligation is to safeguard the Trust Funds, and we respectfully believe this must take precedence over the inconvenience of a shorter period under proposed § 424.535(g).

In terms of the stakeholders' suggestions, we do not believe the 15-day timeframe should commence upon the provider's receipt of the revocation notice. Such a policy could amount to a reduction in existing § 424.535(g)'s timeframe from 30 days to 20 days, which would still not address to our satisfaction the need to reduce improper payments as much as possible; five extra days of payments (Days 16–20) could, again, involve thousands of dollars. We maintain our position that 15 days is the appropriate period. As for sending revocation notices via certified mail, we appreciate this suggestion and may consider it as a future enhancement to the enrollment process.

Comment: A commenter did not believe that retaining the 30-day period (and foregoing the proposed reduction to 15 days) substantially increases the risk to the Medicare program. Another commenter stated that keeping the existing timeframe will support patient care by reducing the potential for unnecessary disruption.

Response: As previously explained, each additional day where the provider is non-compliant with enrollment requirements threatens the Medicare program due to the potentially significant volume of payments that could be made to the provider or supplier. Regarding the second comment, we do not believe our revision to § 424.535(g) will have a deleterious effect on patient care. It has been our experience that patients whose treating physicians, practitioners, and providers have been revoked were able to obtain care from other parties, and we do not foresee this changing because of a mere 15-day reduction in § 424.535(g)'s timeframe. We also note that rebuttals of deactivations under § 424.540 and payments suspensions under § 405.371 must be submitted within 15 days. Providers and suppliers have generally been able to meet this timeframe, and we believe this will be true regarding § 424.535(g) new timeframe, too.

Comment: A commenter asked whether the timeframe in § 424.535(g) begins on the day that the offending owner, manager, etc., was notified of the adverse action or the day when the organization with which he or she is affiliated was notified.

Response: The timeframe under § 424.535(g) commences on the date of the revocation notice to the organization with which the owner, manager, etc., is associated. This has long been our operational policy and is consistent with the current language in § 424.535(g) that requires provider compliance within ''30 days of the revocation notification.''

Comment: Several commenters disagreed with our belief in the proposed rule that a 30-day period could convey the false impression that maintaining affiliates who have engaged in improper conduct is acceptable.

Response: We respectfully do not concur with the commenters' position. We believe that reducing the period to 15 days will expedite provider action and make clear that allowing, for example, 28 or 29 days to pass before compliance is reached (especially when it could have accomplished in 10–15 days) is inappropriate. It is critical for revoked providers under § 424.535(g) to understand that they cannot take their time in resuming compliance but must act quickly to remedy the situation.

After reviewing the comments received, we are finalizing our proposal without modification.

ii. Stay of Enrollment

Pursuant to § 424.540, we may deactivate a provider's or supplier's Medicare billing privileges for any of the reasons specified in paragraph (a) of that section. A deactivation differs from a revocation in that the former: (1) merely involves the stoppage, rather than the termination, of the provider's or supplier's billing privileges; and (2) does not entail any reenrollment bar under § 424.535(c). The latter is a particularly important distinction, for a deactivated provider or supplier can reactivate its billing privileges by following the procedures in § 424.540(b). A deactivated provider or supplier need not wait (as a revoked provider or supplier must) for the expiration of the 1 to 10-year bar period referenced in § 424.535(c) before attempting to restore its ability to bill Medicare.

Nevertheless, we explained in the proposed rule that: (1) a deactivation can still impose burden on a provider or supplier; and (2) a middle ground between deactivation and non-action on our part is needed. In our view, we need as much flexibility as possible to take appropriate, fair, and reasonable measures that are commensurate with the degree of the provider's or supplier's non-compliance.

For these reasons, we proposed in new § 424.541 a new enrollment status labeled a ''stay of enrollment.'' This would be a preliminary, interim status—prior to any subsequent deactivation or revocation—that would represent, in a sense, a ''pause'' in enrollment, during which the provider or supplier would remain enrolled in Medicare; in this vein, CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment. We would also notify the affected provider or supplier in writing of the stay.

We proposed two prerequisites for a stay's implementation. First, the provider or supplier must be non-compliant with at least one enrollment requirement in Title 42. Second, CMS ascertains that the provider or supplier can remedy the non-compliance by submitting, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application (hereafter collectively and occasionally referenced ''Form CMS–855 change request,'' ''change of information application,'' or similar term). This change request could involve, for instance, reporting a new street number (to illustrate, a provider's address changed from 10 Smith Street to 15 Smith Street) that the provider previously failed to disclose to CMS. We believed these two comparatively bright-line standards would clearly articulate when a stay can be implemented and the specific vehicle for remedial action.

We proposed that when a stay is imposed, the provider or supplier could not receive payment for services or items furnished during this period because the provider or supplier is non-compliant with enrollment requirements. Although we acknowledged that this denial of payment mirrors what occurs with a deactivation under § 424.540, we explained that there are critical differences between the two actions. First, § 424.541 made clear that a stay lasts no more than 60 days. A deactivation, on the other hand, has no finite timeframe, meaning that services and items may not be payable for a long period of time if the provider or supplier does not submit the required reactivation application. Second, MACs can generally process Form CMS–855 change requests more rapidly than reactivation applications. A provider or supplier subject to a stay could therefore begin receiving payments again sooner than would a deactivated provider or supplier. Third, while a reactivation application typically involves the provider's or supplier's completion of the entire Form CMS–855, a change of information application may only involve the submission of a limited amount of data (such as the information that is changing and basic identifying data). Completion of a change of information application is, in short, considerably less burdensome for providers and suppliers than completion of a reactivation application.

Indeed, the issue of burden was the core consideration behind our proposal. As previously indicated, we do not wish to have to proceed to a deactivation (much less a revocation) in all cases of non-compliance. This is especially true if CMS believes the non-adherence can be promptly corrected via the provider's or supplier's submission of updated enrollment data. We again acknowledged that payments for services and items furnished during the stay would not be covered, but we noted that this would also occur if CMS imposed a deactivation or revocation, with the important distinction that the period of non-payment would often be significantly shorter with a stay than with a deactivation and certainly a revocation. In all, we believed that our stay provision would ultimately reduce the burden on providers and suppliers that would otherwise be deactivated or revoked for non-compliance.

Notwithstanding this, we believed the affected provider or supplier should have an opportunity to raise a concern about a stay by submitting a rebuttal. The rebuttal process would generally mirror that for deactivations and payment suspensions (outlined in §§ 424.546 and 405.374, respectively), the two actions most akin to a stay. We recognized that given the comparatively short period of a stay, the stay may have expired by the time CMS makes its rebuttal determination. In addition, if the provider or supplier can quickly return to compliance, they may likely pursue this course rather than submit a rebuttal (although the provider or supplier may still do so). Yet merely because some providers and suppliers may forego submitting a rebuttal does not mean the process should be unavailable to them.

Consistent with all the foregoing, we proposed several provisions in § 424.541. In paragraph (a)(1), we proposed that CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

- Is non-compliant with at least one enrollment requirement in title 42; and
- Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

We emphasized that our authority to impose a stay would be discretionary. More specifically, our authority to apply a revocation, deactivation, or a stay lies within our discretion. Our decision as to which of these actions is most appropriate would depend upon the facts and circumstances of the case in question. We emphasize that we may impose a deactivation or revocation (if grounds exist for either) without first applying a stay; that is, a stay is not a mandatory prerequisite for a subsequent deactivation or revocation. Too, there may be situations where we impose a stay and, if the non-compliance is not addressed, we would then exercise our discretion to impose a deactivation or revocation. The effective date of the deactivation or revocation will be applied in accordance with the applicable regulations in 42 CFR part 424, subpart P, and could, depending on the specific regulatory provision involved, be retroactive to the date of the non-compliance.

In paragraphs (a)(2)(i) and (ii), respectively, we would state that during the stay period:

- The provider or supplier remains enrolled in Medicare; and
- Claims submitted by the provider or supplier with dates of service within the stay period will be denied.

In paragraph (a)(3), we proposed that a stay would last no longer than 60 days from the postmark date of the notification letter.

In paragraph (a)(4), we proposed that CMS must notify the affected provider or supplier in writing of the stay's imposition.

In paragraph (b), we outlined our proposed rebuttal process, which, as stated, would largely align with that for deactivations and payment suspensions.

In paragraph (b)(1), we proposed that if a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under § 424.541, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay.

In paragraph (b)(2), we proposed that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1).

In paragraphs (b)(3)(i) through (iv), we proposed that the rebuttal must:

- Be in writing.
- Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.
- Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.
- Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or non-physician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in § 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

In paragraph (b)(4), we proposed that the provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all the requirements of paragraph (b)(3) of § 424.541 constitutes a waiver of all rebuttal rights under this section.

In paragraph (b)(5), we proposed that upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

In paragraph (b)(6), we proposed that a determination made under paragraph

(b) is not an initial determination under § 498.3(b), and therefore not appealable.

In paragraph (b)(7), we proposed that nothing in paragraph (b) requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5).

We proposed in paragraph (b)(8) to clarify the interaction between a stay and a subsequent deactivation or revocation.

In paragraph (b)(8)(i), we proposed that nothing in paragraph (b) would require CMS to delay the imposition of a deactivation or revocation pending completion of the review described in paragraph (b)(5) of this section.

In paragraph (b)(8)(ii)(A), we proposed that if CMS deactivates the provider or supplier during the stay, any rebuttal to the stay the provider or supplier submits that meets the requirements of § 424.541 will be combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal. (This is meant to facilitate efficiency and simplicity in the review process of both rebuttals.) In paragraph (b)(8)(ii)(B), however, we proposed that in all cases other than that described in paragraph (b)(8)(ii)(A), a stay rebuttal that was submitted in compliance with § 424.541 would be considered separately and independently of any review of any other rebuttal or provider enrollment appeal.

Finally, existing § 424.555(b) states that payment may not be made for Medicare services and items furnished to a Medicare beneficiary by a deactivated, denied, or revoked provider or supplier. The paragraph further states that the beneficiary has no financial liability for such services and items provided by these providers and suppliers. To clarify the issues of payment and beneficiary liability for purposes of § 424.541, we proposed to add providers and suppliers currently under a stay of enrollment to the categories of providers and suppliers falling within § 424.555(b).

We received the following comments on our proposal:

Comment: Several commenters supported the basic concept of a stay of enrollment in lieu of deactivating or revoking a provider or supplier for minor instances of non-compliance.

Response: We appreciate the commenters' support.

Comment: Notwithstanding the previous comments, numerous commenters opposed the prohibition against payment for services and items furnished during the stay. At a minimum, they requested that these services and items be payable retroactively; that is, once the provider or supplier has resumed compliance and the stay has been lifted, payment can be made for services and items provided during the stay. They noted that it would be unfair to deny payment—which could, more importantly, seriously harm providers' cash flow and hinder patient access to care—for inconsequential cases of non-compliance that CMS did not even deem significant enough to warrant a deactivation or revocation. Some commenters added that they saw little difference between the provider burden imposed by a stay and that by a deactivation.

Response: We agree with these commenters on two principal grounds. First, and above all, the central purpose of the stay proposal was to ameliorate provider burden. We believe, upon further reflection and after reviewing these comments, that this objective would be largely unmet if we applied to stays the same policy of ''no retroactive payment'' that we use for deactivations. Second, we stated in the proposed rule that a stay would prove less burdensome for providers than a deactivation because, for instance: (a) completion of a Form CMS–855 change of information application generally entails less provider burden (and takes less time for a MAC to process) than a reactivation application; and (b) a stay would last a maximum of 60 days whereas a deactivation lasts until the provider complies with the reactivation requirements. While (a) and (b) are true, we do not believe these burden differences are so substantial as to offset the provider burden associated with prohibiting retroactive payments. In other words, we concur with commenters who did not see an appreciable difference in burden between stays and deactivations notwithstanding (a) and (b). Another way, in our view, to materially distinguish between stays and deactivations in terms of provider impact is to permit retroactive payment in the former instance.

We acknowledge our statement in the proposed rule whereby we deemed retroactive payment prohibitions for stays to be necessary because ''(t)o permit payment for these services and items [while the provider was non-compliant with enrollment requirements] would be contrary to our obligation to safeguard the Trust Funds.'' [415] Yet, upon further consideration, we do not believe that allowing retroactive payments in stay situations would be inherently inconsistent with this statement. During the stay period, the non-compliant provider or supplier would indeed not be receiving payment for services furnished therein, as the above-quoted language indicates. Once the stay ends, these payments could be retroactively made if the requirements outlined in this final rule are met. We raise this matter because we do not want stakeholders to believe that, by permitting retroactive payments in stay cases, we are now allowing all non-complaint providers and suppliers—whether stayed, deactivated, revoked, etc.—to receive continuous payments for services and items furnished while out of adherence. This is untrue, as evidenced by our stoppage of payments for services furnished during the stay. We emphasize that we remain fully committed to ensuring that providers remain in full and constant compliance with enrollment requirements and will take measures, such as imposing a stay, if they are not.

Considering the foregoing, proposed § 424.541 will be revised as follows:

- As proposed, paragraph (a)(2)(ii) states that during the stay period, claims submitted by the provider or supplier with dates of service within the stay period will be denied. We will change this paragraph in two principal ways.

First, the paragraph will be redesignated as paragraph (a)(2)(ii)(A), though with the insertion of the following caveat at its beginning: ''Except as stated in paragraph (a)(2)(ii)(B) of this section''. We will also change ''denied'' to ''rejected,'' which we believe will make it easier for the provider or supplier to later resubmit the claims.

Second, new paragraph (a)(2)(ii)(B) will state that these claims are eligible for payment (and may be resubmitted by the provider or supplier within applicable timeframes specified in title 42) if: (1) CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and (2) the stay ends on or before the 60th day of the stay period. This will clarify that retroactive payment is permissible (assuming all other requirements for payment of the claim are met) but only if the provider or supplier returned to compliance within the stay period. The purpose of this latter proviso is to spur the stayed provider or supplier to resume compliance quickly. Without this condition, the provider or supplier might indefinitely continue its non-compliance beyond the 60-day stay period because it knows it may

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eventually receive retroactive payments. This, in our view, is unacceptable, and we believe that providers must understand they cannot disregard their obligation to always adhere to enrollment requirements. If they wish to receive retroactive payments, they must fulfill this obligation in a timely manner.

• As indicated previously, and with respect to payment prohibitions, we proposed to add the language ''if the provider or supplier is currently under a stay of enrollment'' to § 424.550(b). We will add the following parenthetical to end of this language: ''(except as stated in paragraph (a)(2)(ii)(B) of this chapter).'' This means that payments can be made when the circumstance in paragraph (a)(2)(ii)(B) applies.

Comment: A commenter stated that if compliance is not reached within the 60-day stay timeframe, CMS should extend the period an additional 60 days rather than deactivate the provider or supplier.

Response: We respectfully disagree for two reasons. First, we believe 60 days is adequate time for a provider or supplier to remedy its non-compliance, particularly considering the relatively minor nature thereof. Second, if we were to permit a subsequent 60-day period, providers and suppliers might be less incentivized to come into compliance within the initial 60-day timeframe. In our view, it is imperative that providers and suppliers resume compliance promptly, and we believe the commenter's recommendation, while appreciated, is contrary to this.

Comment: A commenter stated that the 15-day rebuttal period should be extended to 30 days because it may take 5 or more days for the stay notice to reach the provider or supplier, leaving little time to prepare and submit the rebuttal.

Response: We respectfully disagree. As previously noted, rebuttals of deactivations under § 424.540 and payments suspensions under § 405.371 are subject to a 15-day period, and it has been our experience that providers and suppliers have generally been able to meet this timeframe. We believe the same will occur for stay rebuttals.

Comment: A commenter stated that a stay should not be imposed for mere clerical or administrative errors that result in non-compliance. The commenter stated this would be overly punitive.

Response: While we are respectfully uncertain what the commenter considers to be simple clerical or administrative errors for enrollment purposes, we believe that any form of non-compliance is cause for concern. To permit even minor non-compliance to go unremedied could threaten the Trust Funds, and we respectfully do not believe the commenter's apparent suggestion for CMS to merely dismiss such non-adherence is a feasible solution. Yet we recognize that there are degrees of non-compliance, and it is with this in mind that we proposed the stay provision. We sought a measure that could address minor cases of non-compliance without involving a more significant action, such as a deactivation. We believe an enrollment stay, particularly given our above-mentioned change to § 424.541(a)(2)(ii), is a suitable remedy.

Comment: Several commenters sought clarification about the operational aspects of the stay process, including the commencement date of any stay, when the stay ends, and how providers will be notified of the stay. One commenter asked whether the stay would end on the date the contractor processes the changed information, which we interpret to mean the date on which the contractor completes its application processing and approves the application submission.

Response: We appreciate these questions and address them in § 424.541 as follows:

• Commencement—Paragraph (a)(3) states that a stay lasts no longer than 60 days from the postmark date of the notification letter. The effective date is therefore the notification letter's postmark date. To clarify this point, we will add the following language at the end of paragraph (a)(3): ''which is the effective date of the stay.''

• End-Date of the Stay—We will clarify in paragraph (a)(5) that the stay's end-date will be the date on which CMS or the contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first. We believe this is consistent with our aforementioned change concerning paragraph (a)(2)(ii)(B).

• Notification of the Stay—Per paragraph (a)(4), CMS notifies the affected provider or supplier in writing of the stay's imposition.

Other operational matters of the stay process will be addressed via, as appropriate, subregulatory guidance or future rulemaking.

Comment: A commenter stated that CMS should outline the types of conduct that would result in (1) a deactivation, (2) a stay of enrollment, or (3) no CMS action at all. The commenter expressed concern that a stay could be a more punitive option in situations where CMS previously would not have taken any action against the provider or supplier.

Response: We are unable in this final rule or in subregulatory guidance to provide further detail about the forms of non-compliance that fall within these three categories for two principal reasons. First, there are many types of non-compliance involving many different regulatory requirements and data elements. To list them all is not feasible. Second, we cannot publicly commit ourselves to a specific course of action in these cases because there could be different facts and circumstances associated with each situation. We must always retain the flexibility to address them on an individual basis. As for the stakeholder's remaining comment, the stay provision is not primarily intended to now penalize providers for matters that previously would not have involved CMS action. It is instead to reduce the severity of CMS action for minor cases of non-compliance that would ordinarily have triggered a deactivation. In other words, the goal is to reduce the level of burden rather than create new, harsher penalties for certain actions.

Comment: A commenter asked CMS to explain the resources it will dedicate to the MACs to ensure that: (1) they will expedite the processing of ''stay of enrollment'' changes of information; and (2) such applications will indeed be processed within 60 days. The commenter also appeared to ask whether CMS will explicitly direct MACs to process these applications within the stay period. The commenter stated that if the MAC does not timely process the change, the provider or supplier should not be penalized with deactivation. The commenter also expressed concern that the 60-day stay period may not be sufficient time for: (1) the MACs and providers to resolve complex issues; and (2) the rebuttal process to be completed.

Response: We will work very closely with the MACs regarding the implementation of this final rule's stay provisions and will issue detailed subregulatory guidance to them. We are confident the MACs will: (1) be able to process these Form CMS–855 applications within the stay period; and (2) have the resources to do so. We will also establish timeliness standards that MACs must meet when processing applications submitted pursuant to a stay.

We cannot commit in this final rule to never impose a subsequent deactivation if the application is not timely processed; this is because of the

variety of factual scenarios that can arise. Yet we understand the commenter's concern regarding cases where the 60-day period expires without a contractor decision, and we will account for such circumstances in determining whether to proceed with a deactivation or revocation.

We also acknowledge the commenter's remaining concern that the 60-day period may be too brief to resolve all potential issues. However, we reiterate that the provider or supplier is out of compliance with enrollment requirements during this time, and it is imperative that providers and suppliers act rapidly to resume adherence. We believe 60 days appropriately balances the need for the latter while giving providers and suppliers adequate time to do so.

After reviewing the comments received, we are finalizing our stay provisions in § 424.541 as proposed except for the previously noted.

- Modification to paragraph (a)(2)(ii);
- Addition of new paragraph (a)(5); and
- Addition of the parenthetical ''(except as stated in § 424.541(a)(2)(ii)(B) of this chapter)'' to the end of the first sentence of § 424.550(b).

iii. Reporting Changes in Practice Location

Consistent with §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii), respectively, the following provider and supplier types must report a change in practice location within 30 days of the change: (1) DMEPOS suppliers; (2) IDTFs; and (3) physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations. All other provider and supplier types are required per § 424.516(e)(2) to report practice location changes within 90 days of the change. We proposed two sets of regulatory revisions regarding practice location changes. First, we proposed to revise § 424.516(e)(1) to require such location changes involving providers and suppliers other than the categories previously described to be reported within 30 days of the change. Second, we proposed to clarify in §§ 410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1) that a change of practice location includes adding a new location or deleting an existing one.

There were two main reasons for our proposals. One is that Medicare payments are often based on the provider's or supplier's specific geographic location. If we are not timely informed of the change in location, we could be making incorrect payments to the provider or supplier for an extended period (for instance, 90 days); this would be inconsistent with CMS's obligation to protect the Trust Funds. The other reason is that we would be unable to promptly determine whether the new site is compliant with Medicare provider enrollment requirements (for example, via a site visit) because we would not yet know of the change. The provider or supplier may be furnishing services from an invalid location, hence resulting in improper payments.

We also noted that for purposes of reporting practice location changes, we have always included additions and deletions of locations within the scope of such changes. We sought to reemphasize this interpretation via our proposed revisions.

We received the following comments on our proposal:

Comment: A commenter stated that the list of providers and suppliers in § 424.516 that are subject to the 30- or 90-day reporting timelines is not exhaustive, which could create confusion among providers outside these categories (particularly pharmacies enrolled as DMEPOS suppliers). The commenter recommended that CMS elucidate which timeframes are applicable to providers and suppliers that are enrolled as multiple provider or supplier types (for example, pharmacy and DMEPOS).

Response: All provider and supplier types are addressed in § 424.516. Those types not explicitly referenced (such as home health agencies (HHAs), community mental health centers, etc.) fall within § 424.516(e). The applicable timeframe category is determined by the provider or supplier type involved. For instance, suppose an entity is enrolled as an HHA and an IDTF. The timeframes in §§ 424.516(b) and 410.33(g)(2) apply to the IDTF enrollment and those in § 424.516(e) to the HHA enrollment. Using the commenter's example, since the pharmacy is enrolled as a DMEPOS supplier, the applicable reporting timeframes are those for DMEPOS suppliers (addressed in §§ 424.516(c) and 424.57(c)(2)).

Comment: A commenter stated that our practice location reporting proposal should be coordinated with the DEA's telehealth requirements to avoid subjecting suppliers to conflicting standards.

Response: While we appreciate this comment, we are respectfully uncertain as to the specific DEA standard to which the commenter is referring. We further note that we must adopt policies that are best-suited to protect the Medicare program.

Comment: Several commenters opposed our practice location reporting proposal, stating that the existing burden and difficulty in meeting timeframes for reporting changes in enrollment data would be exacerbated if all practice location changes must be disclosed within 30 days.

Response: We note that over 2 million currently enrolled physicians and non-physicians are required under § 424.516(d)(1)(iii) (as are over 60,000 enrolled DMEPOS suppliers per § 424.57(c)(2)) to report practice location changes within 30 days. This requirement has been effective for over a decade, and we are unaware of any significant, wide-ranging challenges these supplier types have encountered in meeting the timeframe. We accordingly and respectfully do not believe that providers and suppliers that must now report practice location changes within 30 days will have great difficulty doing so.

Comment: A commenter asked: (1) how providers should report required changes of information when the contractor is currently processing a pending application from the provider; and (2) whether a provider can report a change of information 30 days prior to the change becoming effective.

Response: Providers and suppliers must report changes of information within required timeframes irrespective of whether the contractor is processing a pending application. They are welcome to submit such changes prior to the change's effective date.

After reviewing the comments received, we are finalizing our proposal without modification.

iv. Definitions

We also proposed several new and clarified definitions to help explain the meaning of certain provider enrollment concepts.

(A) ''Pattern or Practice''

The following current Medicare enrollment revocation reasons are based upon the provider or supplier engaging in a pattern or practice of conduct:

- Section 424.535(a)(8)(ii): The provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
- Section 424.535(a)(14): The physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements.
- Section 424.535(a)(21): The physician or eligible professional has a pattern or practice of ordering,

certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

We have received questions from interested parties over the years as to what constitutes a pattern or practice under these provisions. Accordingly, we proposed to define ''pattern or practice'' in § 424.502. It would mean:

- For purposes of § 424.535(a)(8)(ii), at least three submitted non-compliant claims.
- For purposes of § 424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.
- For purposes of § 424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

To accommodate our definition, we also proposed to make several minor technical changes to § 424.535(a)(8)(ii), (14), and (21).

We received several comments on our proposed ''pattern or practice'' definition.

Comment: Some commenters opposed the definition. They noted that the threshold of three non-compliant claims, orders, etc. (1) is too low, (2) cannot adequately establish a pattern or practice of intentional or harmful behavior, and (3) could be arbitrarily applied by CMS. One commenter stated that the term ''pattern or practice'' is typically understood to require more than three instances and means activity done in a systematic way. The commenter stated that our proposed definition in inconsistent with this standard meaning.

Response: After reviewing the comments received, we are not finalizing our proposed definition of ''pattern or practice'' or the corresponding technical revisions to § 424.535(a)(8)(ii), (14), and (21). We may reconsider this issue for future rulemaking.

(B) Indirect Ownership

We also proposed to define ''indirect ownership interest'' in § 424.502. Some interested parties have expressed uncertainty about what indirect ownership is. An understanding of indirect ownership is important for providers and suppliers because they are required to report on their enrollment application all their 5 percent or greater indirect owners. Section 420.201 defines an ''indirect ownership interest'' as ''any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.'' We believed this definition (albeit with certain modifications for purposes of clarity and to conform to the terminology of subpart P) would provide the desired elucidation. Consequently, our proposed definition of ''indirect ownership interest'' would state:

- Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.
- Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

We proposed to designate this portion of our definition as paragraphs (1)(i) and (ii). To further elucidate the concept of indirect ownership, we proposed in paragraph (2) to mirror an example contained in § 420.202(a). Paragraph (2) would state: ''The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership entity in the provider or supplier and need not be reported.''

We received the following comment on our proposal to define ''indirect ownership'' in § 424.502.

Comment: A commenter supported our proposed definition.

Response: We appreciate the commenter's support.

After reviewing the comment received, we are finalizing our proposed definition of ''indirect ownership'' without modification.

(C) PTs and OTs in Private Practice and Speech-Language Pathologists

Physical therapists in private practice (PTPPs), occupational therapists in private practice (OTPPs), and speech-language pathologists (SLPs) are permitted under the Act to receive payment for furnished Medicare services. However, they do not fall within the regulatory definition of ''supplier'' under § 400.202. The reason is that while the services they provide are payable under Medicare (thus allowing these individuals to enroll in the program), PTPPs, OTPPs, and SLPs are not formally recognized in either the Act or the CFR as types of ''suppliers.'' Nevertheless, we have applied the provisions of subpart P to PTPPs, OTPPs, and SLPs via current guidance. We have also afforded PTPPs, OTPPs, and SLPs the same appeal rights (for example, appeals of enrollment denials and revocations) as all other enrolling or enrolled individuals and entities. To codify these practices in the CFR, we proposed several regulatory provisions.

First, we proposed to define ''supplier'' in § 424.502 as follows: ''Supplier means, for purposes of this subpart, all of the following: (1) the individuals and entities that qualify as suppliers under § 400.202; (2) physical therapists in private practice; (3) occupational therapists in private practice; and (4) speech-language pathologists.'' Second, we included within new § 405.800(d) the same definition of ''supplier'' we proposed in § 424.502. This is because subpart H of part 405 addresses various types of provider enrollment appeals under Medicare Part B. Third, 42 CFR part 498, too, contains various provisions concerning provider enrollment appeals. Section 498.2 defines ''supplier'' for purposes of part 498 by outlining several categories of suppliers. One such category, codified in paragraph (6) of this definition, reads, ''Physical therapist in independent practice.'' We proposed to revise paragraph (6) to state: ''For purposes of this part, physical therapist in private practice, occupational therapist in private practice, or speech-language pathologist.''

We received the following comment on this proposal:

Comment: A commenter supported our proposed inclusion of PTPPs, OTPPs, and SLPs within § 498.2, as well as our proposed definition of supplier in § 424.502.

Response: We appreciate the commenter's support.

After reviewing this comment, we are finalizing these proposals without modification.

(D) Authorized Officials

Under § 424.510(d)(3), an authorized official or delegated official must sign the Medicare enrollment application (for example, Form CMS–855A) on behalf of the provider or supplier if the latter is a corporation, partnership, group, limited liability company, or other organization. The terms

authorized official and delegated official are defined in § 424.502. The former is ''an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.'' A delegated official is defined as an individual ''who is delegated by the 'Authorized Official' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of, the provider or supplier.''

With respect to the authorized official definition, interested parties have asked CMS whether the term ''organization'' as used therein means: (1) the entity listed in Section 2 of the Form CMS–855 as identified by its legal business name (LBN) and tax identification number (TIN); or (2) the provider or supplier type that is enrolling. To illustrate, suppose Entity A (with its unique LBN and TIN) submits three separate Form CMS–855A initial enrollment applications to enroll an HHA, a hospice, and a skilled nursing facility (SNF), all of which have Entity A's LBN and TIN. In this type of situation, the question is whether ''organization'' refers to Entity A or instead to three separate ones—that is, the HHA, hospice, and the SNF.

We proposed to add a sentence to the conclusion of the ''authorized official'' definition clarifying that the term ''organization'' therein—and exclusively for purposes of applying the ''authorized official'' definition—means the enrolling entity as identified by its LBN and TIN and not the provider or supplier type(s) that the entity is enrolling as. Using our previous illustration, this is because the HHA, hospice, and the SNF are not legal entities (such as corporations) separate and distinct from Entity A but are, in effect, part of Entity A itself; Entity A, in other words, is enrolling as an HHA, hospice, and SNF. In practical terms, this means an authorized official serves in that role on behalf of the enrolling entity (Entity A). Per our example, the individual could sign CMS provider enrollment applications concerning the HHA, hospice, and the SNF.

We received no comments on our proposed change and are therefore finalizing it without modification.

2. Medicaid and CHIP Enrollment

a. Background

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that, as of June 2023, covers more than 85 million low-income individuals. States have considerable flexibility with respect to the design of their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (Title XXI of the Act) is a joint Federal and State health care program that (as of June 2023) provides health care coverage to nearly 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll if the providers wish to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.[416] States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements, outlined in 42 CFR part 455. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

The provider enrollment provisions in part 455 to which States must adhere include requirements relating to denial or termination of enrollment. Under § 455.416, the State must deny or terminate a provider's Medicaid or CHIP enrollment for reasons specified therein. These include, for example:

- Any person with a 5 percent or greater direct or indirect ownership interest in the provider fails to: (1) submit timely and accurate information; and (2) cooperate with any screening methods required under part 455, subpart E.
- Any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with Medicare, Medicaid, or CHIP in the last 10 years.

Of particular relevance to this rulemaking is that, under section 1902(a)(39) of the Act and § 455.416(c), the State must deny or terminate the provider's enrollment if the provider is terminated under the Medicare program, or the Medicaid program or CHIP of any other State.

b. The 21st Century Cures Act's Medicaid and CHIP Provider Enrollment Requirements

Section 5005 of the 21st Century Cures Act (Pub. L. 114–255; hereafter referred to as the Cures Act) addresses, in part, Medicaid and CHIP provider enrollment and provider terminations. For purposes of our proposals discussed in section of this final rule, section 5005's most pertinent provisions are:

- Section 5005(a)(1) of the Cures Act added a new paragraph (8) to section 1902(kk) of the Act requiring the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. Section 5005(a)(1) of the Cures Act also outlines data that must be included in the termination notification that the State sends to CMS. However, paragraph (8)(A) limits this reporting requirement to terminations for reasons specified in § 455.101 as in effect on November 1, 2015, which are limited to terminations ''for cause'' (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality). Paragraph (8)(B) provides that, for purposes of the reporting requirement, the effective date of a Medicaid termination is the later of: (1) the effective date specified in the notice of termination; or (2) the date on which applicable appeal rights have been exhausted or the timeline for appeal has expired.
- Section 5005(a)(3) of the Cures Act added a new paragraph (ll) to section 1902 of the Act stating that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary shall review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.
- Section 5005(a)(4)(A) of the Cures Act added a new paragraph (D) to section 1903(i)(2) of the Act providing that, except for emergency items or services (but not including items or services furnished in a hospital emergency department), no Federal financial participation (FFP) funds may be paid for items and services furnished by a provider terminated under

[416] Section 1902(kk)(7) also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

Medicaid or CHIP (as described in section 1902(kk)(8)) beginning 60 days after the date the termination is included in the termination database.

We have issued extensive subregulatory guidance to assist States in implementing Medicaid and CHIP screening and enrollment provisions outlined in 42 CFR part 455. This guidance is compiled in a document titled ''Medicaid Provider Enrollment Compendium'' (MPEC) (*https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf*), originally issued in May 2016 and subsequently updated several times. After the enactment of the Cures Act, CMS again updated the MPEC to clarify the operational details concerning several of the statutory provisions amended by section 5005.

Under CMS' existing process (under the statute and MPEC guidance), when a State reports a ''for cause'' termination, CMS determines whether: (1) the State submitted the required termination data in accordance with section 1902(kk)(8) of the Act; and (2) the termination is, indeed, ''for cause.'' If CMS concludes that the reported termination is ''for cause'' and is thus appropriate to be included in the database referenced in section 1902(ll) of the Act, the information is uploaded into a CMS-managed database. This database contains information on Medicaid and CHIP terminations and Medicare revocations, the latter of which is updated at least monthly. The database enables a State to review Medicaid and CHIP terminations in other States, as well as Medicare revocations, and, under § 455.41(c), to deny enrollment or take its own termination action against a provider if the latter is also enrolled in the State. Moreover, the database gives CMS access to information on Medicaid and CHIP provider terminations nationwide, which permits us to take a Medicare revocation action against the provider under § 424.535(a)(12)(i), if appropriate, based on the Medicaid or CHIP termination.

c. Proposed Provisions

i. Termination Lengths—Background

There are two termination database-related matters that have generated uncertainty during our implementation of the § 455.416(c) termination requirement. They involve: (1) the length of time for which a termination remains active in the termination database; and (2) the interaction of different termination periods imposed by the States and/or the Medicare program.

Under § 424.535(c), if a Medicare provider or supplier is revoked from Medicare, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar, which, under existing § 424.535(c), is generally for a period of 1 to 10 years. This 1- to 10-year period typically constitutes: (1) the period for which the provider or supplier is revoked from Medicare; and (2) the amount of time that the Medicare revocation will remain in the termination database.

Many States have similar reenrollment bars for terminated Medicaid and CHIP providers. (Hereafter, and for purposes of consistency, the terms ''termination period'' and ''reenrollment bar'' as used in this section III.K.2 of this final rule, refer to a Medicaid or CHIP reenrollment bar, unless otherwise noted.) Yet these termination periods often differ among the States. For instance, State A may terminate a provider for 3 years for a particular transgression while State B might do so for 10 years for the same conduct. As noted in the proposed rule, we recognize the traditional deference given to States regarding the establishment of reenrollment bars. However, the interplay between varying termination period lengths (especially as they relate to the termination database and the termination requirement in § 455.416(c)) has caused confusion among the States, provider communities, and other interested parties. Accordingly, we proposed to specify in regulation the length of time for which ''for cause'' provider terminations will remain in the database and, by extension, the period for which other States must deny or terminate the provider under § 455.416(c).

ii. Revision to § 455.416(c)

We proposed to add the following clause to the end of § 455.416(c): ''and is currently included in the termination database under § 455.417.'' This would clarify that the denial and termination requirement under § 455.416(c) is predicated on the provider's inclusion in the termination database.

iii. Length of Inclusion in Database (§ 455.417)

For the reasons outlined above and in the proposed rule, we proposed several provisions in new § 455.417 as follows:

- In paragraph (a)(1), we proposed that a provider would remain in the termination database referenced in section 1902(ll) of the Act for a period that is the lesser of:

++ The length of the termination period imposed by the initially terminating State Medicaid program or CHIP, or the reenrollment bar imposed by the Medicare/program; or

++ 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

- Under proposed paragraph (a)(2,) all other State Medicaid programs or CHIPs in which the provider is enrolled or seeking to enroll would be required to terminate or deny the provider's enrollment from their respective programs (under § 455.416(c)) for at least the same length of time as the termination database period).

- In paragraphs (b)(1)(i) and (ii), respectively, we proposed that nothing in paragraph (a) would prohibit:

++ The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

++ Another State from terminating the provider, based on the original State's termination, for a period: (A) of greater than 10 years; or (B) that is otherwise longer than that imposed by the initially terminating State.

In paragraph (b)(2), however, we proposed to clarify that the period established under paragraph (b)(1)(ii) must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a).

In paragraph (c)(1), we proposed that if the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State program or Medicare, CMS would remove the provider from the termination database after the reinstatement has been reported to CMS.

In paragraph (c)(2), we proposed that if the provider is removed from the database due to reinstatement by the originally terminating State agency, nothing prohibits CMS from immediately re-including the provider in the database if a separate basis for doing so exists under 42 CFR part 455 or 424.

In paragraph (d), we proposed that, for purposes of § 455.417 only, terminations under § 455.416(c) (which, as previously discussed, are based on another State's termination of the provider) are not themselves considered ''for cause'' terminations, and therefore, need not be separately reported to CMS for inclusion in the termination database.

We received the following comments on our termination database proposal:

Comment: Several commenters supported our termination database

provisions, believing that they would furnish needed elucidation.

Response: We appreciate the commenters' support.

After reviewing the comments received, we are finalizing our termination database proposals without modification.

3. Miscellaneous Comments

We also received the following miscellaneous comments concerning our proposals, as well as on provider enrollment in general.

Comment: Several commenters asked us to: (1) provide detailed public guidance for providers and suppliers regarding our new revocation reasons and how they will affect providers and suppliers; and (2) monitor the impact of our revocation policies on providers' and suppliers' workforces.

Response: As we typically do upon issuing new provider enrollment regulatory provisions, we will: (1) release subregulatory guidance to stakeholders explaining our new requirements and the provider activity involved; and (2) keep abreast of any impacts these provisions may have on the provider community.

Comment: A commenter stated that in proposing our enrollment provisions, we failed to justify why our existing regulatory authority is insufficient to protect program integrity. The commenter urged CMS to engage with the provider community via town hall discussions, requests for comments, and other modes of dialogue before initiating what the commenter believed was a sweeping expansion of administrative authority. Another commenter recommended that CMS not finalize its enrollment proposals and instead obtain feedback from stakeholders (including via conferences with provider groups and State medical boards, as well as requests for information (RFI) published in the **Federal Register**) to better understand the proposals' potential consequences, including with respect to patient care.

Response: We respectfully disagree that we did not sufficiently justify our proposals or the need for them. We detailed in the proposed rule the reasons for our provisions and the gaps in our current authority that we were attempting to close. For instance, we explained why an across-the-board 30-day practice location reporting period was critical, how the current 90-day period for some provider types can leave CMS without accurate practice location information for months, and the program integrity risks this posed. Insofar as public consultation, CMS regularly communicates with stakeholders, such as provider organizations, on provider enrollment issues, including at conferences, chatrooms, etc., and solicits recommendations on means of improving the provider enrollment process and addressing important payment safeguard issues. Part of this also involves the notice-and-comment process in rulemaking, wherein we receive valuable observations and suggestions from interested parties, such as occurred with our enrollment proposals in this rule. We believe the comments we received helped us make informed decisions regarding our provisions, which, except as otherwise noted, we are finalizing as proposed.

Comment: Several commenters stated that CMS should: (1) revoke providers and suppliers only for severe infractions involving clear potential harm to Medicare beneficiaries or financial malfeasance and not for minor errors unrelated to patient care; (2) outline the criteria it will use when determining whether to revoke and explain when providers and suppliers can anticipate a revocation, including the degree of improper conduct necessary for such an action; (3) always give providers and suppliers an opportunity to correct any errors and to present their side before revocation; (4) ensure that all providers and suppliers are treated equally when considering whether revocation is necessary; (5) clarify the expertise of the personnel making such determinations; and (6) recognize and ameliorate the impact that revocations (include those we are finalizing) can have on longstanding physician-patient relationships and beneficiary access to care. Regarding the fourth recommendation, a commenter requested that CMS explicitly confirm that it will adopt this approach.

Response: In reviewing some of these comments, it was unclear whether the stakeholders were referring only to our proposed revocation reasons or to all revocation grounds under § 424.535(a). To ensure that these comments are fully addressed, our responses will jointly pertain to our existing revocation bases and those we are finalizing in this rule.

We are very cognizant of the impact a revocation can have on providers and suppliers. We do not take this decision without a careful and thorough analysis of the facts and circumstances of the case. For many revocations, we also diligently consider specific factors outlined in regulation. Revocation is always the least desired step for CMS in addressing a particular provider enrollment situation. But it is sometimes the necessary one if circumstances warrant. As already explained in this final rule, our primary obligation is to safeguard the Medicare program and its beneficiaries, and revocation action may occasionally be required to facilitate this goal. It is not possible for us in this rule, as the commenters appeared to request, to: (1) articulate every type of conduct that will automatically result in a revocation; or (2) establish a minimum threshold or bright-line test regarding the severity of behavior or impact on Medicare (or beneficiary care) that is required for revocation action. While we always ensure that providers and treated fairly and consistently in our reviews, which (in response to the commenter's fifth issue) are conducted by experienced enrollment personnel, every case is and must be considered on its own unique facts. Nevertheless, CMS typically does not revoke providers for modest errors but instead may deactivate the provider or, per this final rule, impose a stay of enrollment.

Concerning the request for an opportunity to correct or for a hearing before any revocation is imposed, we reiterate that we generally take revocation action only when the non-compliance or conduct is of a sufficiently significant nature that we must move quickly to protect the (1) Trust Funds and (2) Medicare beneficiaries. The longer we wait to act (such as via a pre-revocation hearing), the greater the threat to both. Moreover, if we were to furnish corrective opportunities and hearings before each revocation, providers and suppliers would have little incentive to consistently adhere to enrollment requirements because they would know they could avoid revocation by waiting until the pre-revocation period to remedy the problem. It would, in our view, negate the provider's or supplier's obligation to always remain compliant with our requirements.

Comment: A commenter stated that the ''any other information that CMS deems relevant to its determination'' criterion CMS uses in some of its denial and revocation determinations (including in its FCA proposal) should include mitigating factors (for example, efforts the provider took to address the concern, cooperation in the investigation, etc.)

Response: CMS always considers mitigating factors under this criterion in its denial and revocation determinations and will continue to do so.

Comment: Several commenters stated that our proposals, such as the revision to § 424.535(g), give CMS the opportunity to eliminate the use of standard mail when communicating with providers and instead adopt more

reliable and cost-efficient means of communication, such as electronic delivery, PECOS, or certified mail. The commenters believed this would help providers and suppliers meet strict timeframes for responding to CMS requests for information.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter expressed concern about the 10-year maximum length of the reenrollment bar, stating that: (1) this period is longer than most OIG exclusions and has the same effect as an exclusion; and (2) there is no published guidance as to how CMS determines the length of a reenrollment bar (that is, how it ascertains the severity of the conduct resulting in the revocation).

Response: We believe this comment is outside the scope of this final rule.

Comment: A commenter stated that CMS' original justification for not extending appeal rights to deactivations—that a deactivation carried no payment consequences and thus no appeal rights were warranted—is invalid because § 424.540(e) states that a provider or supplier may not receive payment while deactivated.

Response: We believe this comment is outside the scope of this final rule.

Comment: A commenter contended that there should be an expedited right of judicial review (we assume the commenter was referring to enrollment revocations and denials) as exists in the Medicare claims and the Provider Reimbursement Review Board processes. The commenter stated that a provider or supplier seeking to raise a constitutional or regulatory procedural or arbitrary and capricious challenge currently must go through several years of the enrollment appeals process before being able to present such challenge in court. The commenter added that notice-and-comment procedures are not required to implement a procedural rule such as an expedited appeals process.

Response: We believe this comment is outside the scope of this final rule.

Comment: A commenter stated that CMS should eliminate gaps in payment stemming from provider enrollment actions, particularly with respect to deactivations. The commenter stated that the definition of ''deactivate'' in § 424.502 states that a provider's or supplier's billing privileges can be ''restored'' (which, the commenter contended, means to be put back in the original state) and that CMS, at one time, did not have payment gaps for deactivations. Eliminating such gaps would be consistent with both the definition of deactivate, as well as previous CMS policy.

Response: We believe this comment is outside the scope of this final rule.

L. Expand Diabetes Screening and Diabetes Definitions

In the CY 2024 PFS proposed rule (88 FR 52262), we proposed to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening (§ 410.18(a)), Medical Nutrition Therapy (MNT) (§ 410.130) and Diabetes Outpatient Self-Management Training Services (DSMT) (§ 410.140).

Medicare coverage for diabetes screening tests under Part B are described in statute (sections 1861(s)(2)(Y), 1861(ww)(2)(K), 1861(yy), and 1862(a)(1)(M) of the Act) and in regulation at 42 CFR 410.18. The statute and regulations allow for diabetes screening tests:

- The Fasting Plasma Glucose (FPG) test (section 1861(yy)(1)(A) of the Act and § 410.18(c)(1));
- The Post Glucose Challenge Test, also called the Glucose Tolerance Test (GTT) (§ 410.18(c)(2)); and
- Such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations (section 1861(yy)(1)(B) of the Act) and that may be determined through a national coverage determination (§ 410.18(c)(3)).[417]

We proposed to exercise our authority in section 1861(yy)(1) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), after consultation with appropriate organizations.

Section 1861(yy)(3) of the Act limits the frequency of diabetes screening tests to not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Our regulations currently allow two screening tests per calendar year if the patient was previously diagnosed with pre-diabetes and one screening test per year for patients who were previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). We proposed to exercise our authority in section 1861(yy)(1)(3) of the Act to simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We also proposed to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a) to remove the codified clinical test requirements from the definition of ''diabetes.'' We also proposed to remove the definition of ''pre-diabetes'' at § 410.18(a). The diabetes and prediabetes definitions at § 410.18(a) supported existing regulatory frequency limitations in § 410.18(d), which describe separate frequency limitations between individuals previously diagnosed, and those terms would no longer be needed under our proposed updates. We recognized that it is unnecessary to codify clinically specific test criteria into the regulatory definition of diabetes, which reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. The proposed revised definition of diabetes for screening purposes will be shortened to describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

Medicare coverage for MNT under Part B is described in statute (primarily sections 1861(s)(2)(V), 1861(vv), and 1861(ww)(2)(I) of the Act, in regulations at 42 CFR part 410, subpart G, and in National Coverage Determination (NCD) (Section 180.1 of the Medicare National Coverage Determinations Manual (NCD Manual)). Section 410.130 currently describes a number of definitions for purposes of the MNT benefit, including ''diabetes.'' The regulatory definition of diabetes for MNT purposes at § 410.130 is currently identical to the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We proposed to simplify the regulatory definitions of ''diabetes'' for the purpose of MNT at § 410.130 to remove the codified clinical test requirements. The proposed revised definition of diabetes for MNT purposes will be shortened to simply describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. NCD 180.1 refers to the regulatory definition of diabetes at § 410.130, so no modifications would be required to the NCD.

Medicare coverage for DSMT under Part B is described in statute (sections 1861(s)(2)(S), 1861(qq), 1861(ww)(2)(F) of the Act) and in regulation at part 410 subpart H. Section 410.140 currently describes a number of definitions for the purposes of the DSMT benefit,

[417] The Secretary, as of the date of this final rule, has not approved additional diabetes screening tests by through a national coverage determination.

including ''diabetes''. The regulatory definition of diabetes for DSMT purposes at § 410.140 is identical to the existing regulatory definition of diabetes for MNT purposes at § 410.130 and the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We proposed to exercise our authority to simplify the regulatory definitions of ''diabetes'' for the purpose of DSMT at § 410.140 to remove the codified clinical test requirements. The proposed revised definition of diabetes for DSMT purposes will be shortened to simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

1. Background

Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2 and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[418] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[419] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the US.[420] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

In October 2015, the United States Preventive Services Task Force (USPSTF) issued a revised final recommendation statement, with a grade of B, for screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese and again identified the FPG, GTT and HbA1c tests as appropriate for diabetes screening.[421] In August 2021, the USPSTF issued a revised final recommendation statement, with a grade of B, that expanded recommended screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity, and that clinicians should offer or refer patients with prediabetes to effective preventive interventions, which are discussed in their report. The USPSTF again recommended the FPG, GTT and HbA1c tests as appropriate for diabetes screening and noted, ''Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level (FPG) or an oral glucose tolerance test (GTT).'' [422] The grade of B is indicated when the USPSTF has high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial.

Both the USPSTF and specialty societies have identified the HbA1c test as clinically appropriate for diabetes screening. In addition, the HbA1c test has certain unique advantages and disadvantages compared to the FPG and GTT tests that should be considered by the practitioner and patient when choosing a diabetes screening test. The American Diabetes Association (ADA) Standards of Care in Diabetes—2023 reads, ''Generally, FPG, 2-h PG during 75-g OGTT (aka GTT), and A1C (aka HbA1c) are equally appropriate for diagnostic screening . . . The same tests may be used to screen for and diagnose diabetes and to detect individuals with prediabetes . . . A1C (aka HbA1c) has several advantages compared with FPG and OGTT (aka GTT), including greater convenience (fasting not required), greater preanalytical stability, and fewer day-to-day perturbations during stress, changes in nutrition, or illness. However, these advantages may be offset by the lower sensitivity of A1C (aka HbA1c) at the designated cut point, greater cost, limited availability of A1C (aka HbA1c) testing in certain regions of the developing world, and the imperfect correlation between A1C (aka HbA1c) and average glucose in certain individuals . . . Despite these limitations with A1C (aka HbA1c), in 2009, the International Expert Committee added A1C (aka HbA1c) to the diagnostic criteria with the goal of increased screening.'' [423] We also recognized that the American Association of Clinical Endocrinology (AACE) also recommends screening for diabetes and prediabetes with similar tests, including HbA1c.[424]

The regulatory texts for diabetes screening, MNT, and DSMT currently include a clinically specific test-based definition for ''diabetes'' that has since been overtaken by evolving clinical standards. Since 2020, the ADA has revised and expanded its criteria for the diagnosis of diabetes to also include the HbA1c test and a random plasma glucose test for a patient appearing to have hyperglycemia or hyperglycemic crisis.[425]

2. Statutory Authority

Section 613 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1861(yy) to the Act and mandated coverage of diabetes screening tests in the Medicare Part B program. Section 1861(yy)(1) of the Act describes diabetes screening tests as testing furnished to an individual at risk for diabetes for the purpose of early detection of diabetes, including the FPG test and such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(yy)(2) of the Act describes ''individual at risk for diabetes'' as an individual who has any of a number of listed risk factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older. Section 1861(yy)(3) of the Act mandates that the Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of

[418] CDC website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html*.

[419] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf*.

[420] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021*.

[421] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes-october-2015*.

[422] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes*.

[423] Diabetes Care 2023;46(Suppl. 1):S19–S40: *https://doi.org/10.2337/dc23–S002*.

[424] Lawrence Blonde, Guillermo E. Umpierrez, S. Sethu Reddy, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update. Endocrine Practice, 2023; 28: 923–1049, *https://doi.org/10.1016/j.eprac.2022.08.002*.

[425] Diabetes Care 2020;43(Supplement_1):S14–S31, *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes*.

that individual. Section 1861(yy) of the Act does not include a definition of diabetes.

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) added section 1861(vv) to the Act and mandated coverage of MNT under Part B. Section 1861(s)(2)(V) of the Act limits coverage of MNT to patients with diabetes or a renal disease. Section 1861(vv)(1) of the Act describes MNT, in pertinent part, as nutritional diagnostic, therapy, and counseling services for the purpose of disease management. Sections 1861(s)(2)(V) and (vv) of the Act do not include a codified definition of diabetes.

Section 4105(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) added section 1861(qq) to the Act and mandated coverage of DSMT. Section 1861(qq) of the Act describes DSMT, in part, as educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting by an individual or entity, but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge to participate in the management of the individual's condition. Section 1861(qq) of the Act does not establish a definition of diabetes.

3. Regulatory Authority and National Coverage Determinations

Our implementing regulations for diabetes screening tests are codified at § 410.18. The current regulatory definition of diabetes and prediabetes for the purposes of diabetes screening were created, in part, to distinguish separate frequency limitations for each. Section 410.18(d) allows two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before. Section 410.18(e) limit diabetes screening to ''individual at risk for diabetes'' with a list of qualifying eligibility factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor (§ 410.18(e)(3)) and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older) (§ 410.18(e)(5)).

Our implementing regulations for MNT are codified at part 410 subpart G. Section 410.130 describes a number of definitions for purposes of the MNT benefit, including ''diabetes.'' MNT is also described as a covered service at section 180.1 of the NCD Manual. NCD 180.1 does not include a codified definition of diabetes but does refer to ''diabetes, as defined at § 410.130.'' Our implementing regulations for DSMT are codified at part 410 subpart H. Section 410.140 describes a number of definitions for the purposes of the DSMT benefit, including ''diabetes.''

NCD 190.20, Blood Glucose Testing, describes the indications and limitations of blood glucose testing generally but refers to § 410.18 and the Claims Processing Manual for specific policies on diabetes screening. NCD 190.21, Glycated Hemoglobin/Glycated Protein, authorizes coverage of the HbA1c test for the management of diabetes but does not address screening for diabetes.

In the CY 2004 PFS final rule (68 FR 63195), we finalized proposals to adopt regulatory definitions of diabetes for the purposes of MNT and DSMT. We codified in regulatory text at §§ 410.130 and 410.140 that diabetes is defined as ''diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.'' The definition of diabetes was based, in part on a clinical recommendation submitted by the American Association of Clinical Endocrinologists. In the CY 2005 PFS final rule (69 FR 66235), we finalized proposals to adopt implementing regulations for diabetes screening, which was recently added as a Medicare covered benefit in the Section 613 of the MMA. We adopted a new regulatory definition of prediabetes as condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL, as well as including the conditions of impaired fasting glucose and impaired glucose tolerance. We also adopted the regulatory definition of diabetes finalized in the CY 2004 PFS for MNT and DSMT. Neither the statutes nor the regulatory text for diabetes screening, MNT and DSMT distinguish between different types of diabetes.

4. Revisions to the Final Rule

We proposed to exercise our authority in section 1861(yy)(1)(B) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), consistent with a recently revised recommendation by the USPSTF. The USPSTF recommended the HbA1C test for diabetes screening in their October 2015 and August 2021 revised final recommendation statements. We also engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the Association of Diabetes Care & Education Specialists (ADCES), the National Clinical Care Commission (NCCC) and the Diabetes Advocacy Alliance (DAA). In addition, we consulted the published clinical recommendations from the USPSTF (described earlier), the ADA [426] and the AACE [427] in developing our proposal. We also solicited comments from other organizations through the notice and comment rulemaking process.

We received public comments on these proposals. Overall, commenters expressed broad support and approval of our proposal to exercise our authority in section 1861(yy)(1)(B) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c). The following is a summary of the comments we received and our responses.

Comment: Commenters agreed that adding the HbA1c test to the types of diabetes screening tests covered under § 410.18(c) will make available a screening option that will reduce patient burdens. Many commenters agreed that a screening option with reduced patient burden will be especially impactful for patients with diabetes, a disease that disproportionally impacts minority and disadvantaged populations. Many commenters agreed that expanding coverage of diabetes screening to include the HbA1c test will allow measurement of different aspects of diabetes pathology compared to the already covered FPG and GTT tests. Commenters also expressed appreciation that our proposal to cover the HbA1c test for diabetes screening will support increased patient referral to the Medicare Diabetes Prevention Program. Commenters also supported aligning Medicare coverage policies

[426] *https://diabetesjournals.org/care/article/45/Supplement_1/S17/138925/2-Classification-and-Diagnosis-of-Diabetes.*

[427] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

with USPSTF and ADA clinical recommendations.

Response: We thank the commenters for their support of our proposal to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c) and we are adopting those changes in this final rule We are also finalizing corresponding updates to regulatory text as proposed.

Comment: Many commenters recommended that CMS eliminate Part B cost-sharing (deductible and coinsurance) for the HbA1c test when furnished as a diabetes screening test.

Response: We are happy to clarify that Congress has made Part B coinsurance (section 1833(a)(1)(Y) of the Act, § 410.152(l)(9)) and deductibles (section1833(b)(1) of the Act) not applicable for covered prevention services recommended with a grade of A or B by the USPSTF. As described earlier in our rule, in August 2021, the USPSTF issued a revised final recommendation statement, with a grade of B, that expanded recommended screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity, and that clinicians should offer or refer patients with prediabetes to effective preventive interventions, which are discussed in their report. The USPSTF recommended the FPG, GTT and HbA1c tests as appropriate for diabetes screening. Thus, the HbA1c test will require no Part B coinsurance and deductible when furnished as a covered diabetes screening test. We clarify that the HbA1c test will continue to require Part B coinsurance and deductible when furnished for diabetes management.

We also proposed to exercise our authority in section 1861(yy)(1)(3) of the Act to expand and simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. We also proposed to remove the current regulatory definition of pre-diabetes for the purposes of diabetes screening at § 410.18(a), which functionally served, in part, to distinguish the separate frequency limitations of diabetes screening at two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). We noted in the PFS proposed rule that our proposal to remove the regulatory definition of pre-diabetes was intended to simplify and expand diabetes screening while reducing unnecessary regulatory complexity. We also noted that we recognize that pre-diabetes and diabetes exist on a continuum, and both are screened and identified through common diabetes screening tests. Our proposal to remove the regulatory definition of pre-diabetes did not reflect a change in our position on pre-diabetes screening and treatment as a Medicare benefit. In making this proposal we recognized that the FPG, GTT and HbA1c tests include different levels of burden for the patient and also measure different aspects of diabetes pathology. The August 2021 USPSTF revised final recommendation statement states ''HbA1c is a measure of long-term blood glucose concentration and is not affected by acute changes in glucose levels caused by stress or illness. Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level or an oral glucose tolerance test. Both fasting plasma glucose and HbA1c levels are simpler to measure than performing an oral glucose tolerance test. The oral glucose tolerance test is done in the morning in a fasting state; blood glucose concentration is measured 2 hours after ingestion of a 75-g oral glucose load. The diagnosis of prediabetes or type 2 diabetes should be confirmed with repeat testing before starting interventions.'' [428] We noted we had engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the ADCES, the NCCC, and the DAA. We noted we also consulted with the written recommendations of a number of specialty societies and the USPSTF in developing our proposal. We acknowledged that the USPSTF, ADA and AACE recommend diabetes screening frequency screening of once every 3 years.[429] [430] [431] We proposed expanding the frequency limitations for diabetes screening to twice in a 12-month period under the theory that additional flexibility in screening frequency will remove barriers and empower clinicians to apply screening by multiple types of tests or with increased frequency where the circumstances of the patient demonstrate a medical necessity. We noted in the PFS proposed rule that we looked forward to further consultation with organizations through the public notice and comment rulemaking process and solicited comments on our proposal.

The following is a summary of the comments we received and our responses.

Comment: We received numerous public comments expressing approval of our proposal to exercise our authority in section 1861(yy)(1)(3) of the Act to expand and simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Many commenters agreed that expanding frequency limitations for diabetes screening to not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual will remove barriers, expand access and empower clinicians to apply multiple types of tests or with increased frequency when the circumstances of the patient demonstrate a medical necessity.

Response: We thank commenters for their support and in this final rule we are expanding and simplifying our frequency limitations for diabetes screening as proposed. We are also finalizing corresponding updates to regulatory text as proposed.

Comment: One commenter disagreed with our proposal to expand and simplify our frequency limitations for diabetes screening and suggested that diabetes screening frequency be determined by the furnishing clinician (with no statutory or regulatory frequency limitations imposed by CMS).

Response: We disagree with the commenter's recommendation that diabetes screening frequency be entirely determined by the furnishing clinician without any frequency limitations. First, we have no authority to disregard or remove the frequency limitation for diabetes screening included in section 1861(yy)(1)(3) of the Act. Second, frequency limitations are important to protect beneficiaries from clinically inappropriate services and protect beneficiaries and the Medicare program from fraud, waste, and abuse. We are not adopting the commenter's suggestion.

Comment: We received numerous comments expressing support for our proposal to remove the regulatory definition of pre-diabetes from

[428] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

[429] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

[430] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

[431] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel--10.*

§ 410.18(a). Many commenters agreed that pre-diabetes and diabetes exist on a continuum, are detected by the same screening tests, and that removing the definition of pre-diabetes from diabetes screening regulations will remove barriers and expand access to care for patients and providers. Many commenters agreed that our proposal will simplify claims processing and reduce the risk of denied claims due to frequency limitations.

Response: We thank commenters for their support and will remove the regulatory definition of pre-diabetes for the purposes of diabetes screening at § 410.18(a). We are also finalizing corresponding updates to regulatory text as proposed.

We also proposed to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a), MNT at § 410.130 and DSMT at § 410.140. In all three instances, we proposed to remove the codified clinical test requirements from the definition of ''diabetes'' and keep a shorted version of the existing definition that would define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We noted in the proposed rule that we now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of diabetes for screening, MNT and DSMT benefit reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We noted that we believe that our proposal will empower practitioners to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. By analogy, we considered that end stage renal disease (ESRD) is not described with specific clinical test criteria in section 226A and 1881 of the Act, nor in regulations at § 406.13. We noted in the proposed rule that we generally believe that scientific advancements in understanding and measuring disease pathology outpace the lengthy and formal notice and comment rulemaking process. In the instance of diabetes screening, MNT and DSMT, the regulatory codification of clinical test criteria into disease definitions may not be necessary nor ideal. We noted that even without clinical test criteria codified in the regulatory definitions of diabetes and pre-diabetes, a Medicare claim that includes a diagnosis of diabetes or pre-diabetes would still need to include appropriate coding, substantiation in the medical record and compliance with claims processing instructions from CMS and Medicare Administrative Contractors (MACs).

In the alternative, we considered not removing the clinical test criteria for the regulatory definitions of diabetes or removing the regulatory definition of pre-diabetes. We considered adding the HbA1c test criteria result of 6.5 percent or greater into the regulatory definition of diabetes for screening, MNT and DSMT and the HbA1c test criteria result of 5.7 percent to 6.4 percent to the regulatory definition of pre-diabetes for screening. The alternative would be consistent with our proposal to expand coverage of diabetes screening by adding the HbA1c test, and would also be consistent with clinical recommendations by the USPSTF [432] and the ADA.[433] However, we did not propose this alternative because, while currently clinically appropriate, we believed it would further, unnecessarily complicate the regulatory definition of diabetes and pre-diabetes. As noted earlier, we noted in the proposed rule that we now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of ''diabetes'' and ''pre-diabetes'' for screening, and ''diabetes'' for the MNT and DSMT benefits reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We solicited comments on our proposal and alternative considered.

The following is a summary of the comments we received and our responses. No commenters opposed our proposed rule and no commenters favored the alternative.

Comment: Numerous public commenters expressed approval and support for our proposal to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a), MNT at § 410.130 and DSMT at § 410.140 by removing the codified clinical test requirements from the definition of ''diabetes'' and keeping a shorted version of the existing definition that will define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. Many commenters expressed that our proposal will increase patient access to care to diabetes screening and related services by improving the referral process and reduce the risk of claims being denied. Many commenters also expressed support and appreciation that our simplified regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT would remove potential future misalignment between specific clinical test criteria in regulations and evolving standards of care.

Response: We thank the commenters for their support and will simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a), MNT at § 410.130 and DSMT at § 410.140 by defining diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We are also finalizing corresponding updates to regulatory text as proposed.

Comment: We received several comments that were outside the scope of the proposals made in the CY 2024 PFS proposed rule. Comments included removing the clinical test criteria from the definition of ''Chronic renal insufficiency'' in the MNT regulations at 410.130, to expand the regulatory definition of Chronic Kidney Disease, to allow the HbA1c test for diabetes screening to be furnished at pharmacies and allowing for coverage of diabetes screening regardless of the licensure of the ordering physician.

Response: Although we are not summarizing and responding to these comments in the final rule, the have been informative and we will take them into consideration for possible future rulemaking.

After considering public comments, we are finalizing the proposals made in the CY 2024 PFS proposed rule to (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening (§ 410.18(a)), Medical Nutrition Therapy (MNT) (§ 410.130) and Diabetes Outpatient Self-Management Training Services (DSMT) (§ 410.140).

We noted in the CY 2024 PFS proposed rule that we believe that our proposal to expand and simplify coverage for diabetes screening aligns with the administration's strategic pillar to advance health equity by addressing the health disparities that underlie our health system. The August 2021 updated USPSTF final recommendation statement reads, ''The prevalence of diabetes is higher among American Indian/Alaska Native (14.7 percent), Asian (9.2 percent), Hispanic/Latino (12.5 percent), and non-Hispanic Black (11.7 percent) persons than among non-Hispanic White (7.5 percent) persons. Disparities in diabetes prevalence are the result of a variety of factors. A large

[432] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel-6.*

[433] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment.'' [434] The HbA1c test does not require fasting or drinking an unappetizing glucose solution. We noted in the CY 2024 PFS proposed rule that expanding coverage for diabetes screening to include the HbA1c test will reduce screening burdens for a disease that disproportionally impacts minority and disadvantaged populations. In addition, earlier identification of diabetes and prediabetes among minorities and disadvantaged persons may lead to improved diabetes control and reduce its complications, which currently occur disproportionately in those groups.

We recognize that expanded access and appropriate utilization of diabetes screening is critical to mitigating and avoiding downstream health complications that significantly impact beneficiary wellbeing, as well as being costly and burdensome to the healthcare system. We also note that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) website states, ''diabetes can cause serious health problems, such as heart disease, stroke, and eye and foot problems. Prediabetes also can cause health problems. The good news is that type 2 diabetes can be delayed or even prevented. The longer you have diabetes, the more likely you are to develop health problems, so delaying diabetes by even a few years will benefit your health.'' [435] The U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation recently published a Report to Congress on the Affordability of Insulin that included a number of generalized findings on costs and downstream impacts of serious diabetes related complications on health care use.[436] We believe our final rules will expand access to quality care and improve health outcomes for patients through prevention, early detection, and more effective treatment.

[434] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

[435] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, website: *https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes.*

[436] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Report on the Affordability of Insulin. December 16, 2022. *https://aspe.hhs.gov/reports/insulin-affordability-rtc.*

M. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

In the CY 2021, CY 2022, and CY 2023 PFS final rules, we finalized policies for the CMS EPCS Program requirements specified in section 2003 of the SUPPORT Act (Pub. L. 115–271, October 24, 2018). We refer readers to 85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70014 for the details of the statutory requirements and those finalized policies. Specifically, in the CY 2022 PFS final rule, we extended the date of compliance actions to no earlier than January 1, 2023 and, for prescribers writing Part D controlled substances prescriptions for beneficiaries in long-term care (LTC) facilities, January 1, 2025 (86 FR 65364 and 65365). We also finalized a proposal requiring prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366); finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369); and finalized our proposal to limit compliance actions with respect to compliance through December 31, 2023 to a non-compliance notice (86 FR 65370).

In the CY 2023 PFS final rule (87 FR 70012 through 70013), we extended the existing non-compliance action of sending notices to non-compliant prescribers, which we had finalized for the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023), to the CY 2024 Program implementation year (January 1, 2024 through December 31, 2024). We also finalized a change to the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 70011 through 70012) and finalized our proposal to use the Prescription Drug Event (PDE) data from the current evaluated year instead of the preceding year when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009 through 70011).

2. CMS EPCS Program Terminology

In the CY 2021, CY 2022, and CY 2023 PFS final rules (85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70013), we used various terminology to describe aspects of the requirements for EPCS. In order to provide consistency and clarity throughout the CMS EPCS Program and future rules, we will use the following terms going forward.

- *CMS EPCS Program.* We will refer to the program requirements for EPCS at § 423.160(a)(5) as the ''CMS EPCS Program.'' We believe this provides an appropriate distinction from the prescriber's act of electronically submitting individual prescriptions for controlled substances, which is also referred to as EPCS.
- *Non-compliance action or action for non-compliance.* We will use ''non-compliance action'' or ''action for non-compliance'' to refer to a consequence for not meeting the CMS EPCS Program compliance threshold, as described at § 423.160(a)(5), after exceptions have been applied.
- *Measurement year.* When we refer to ''measurement year,'' we mean the time period (beginning on January 1 and ending on December 31 of each calendar year) during which data is collected to calculate outcomes for the CMS EPCS Program. In prior rules, we have used the term ''current year'' or ''evaluated year,'' but moving forward we will use the term ''measurement year.''
- *Compliance threshold.* For the CMS EPCS Program, ''compliance threshold'' is the requirement at § 423.160(a)(5) that prescribers must conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, after exceptions, each measurement year.
- *Compliance analysis period.* The ''compliance analysis period'' is the time period after the measurement year where data is analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program.
- *Notification period.* The ''notification period'' is the time period during which we notify a prescriber of the prescriber's initial compliance status and any associated review or waiver process that may be available prior to CMS determining the prescriber's final compliance status.
- *Measurement cycle.* The ''measurement cycle'' is generally a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period.

3. Standard for CMS EPCS Program

a. Updates to the NCPDP Standards

In the CY 2021 PFS final rule (85 FR 84804), we finalized a requirement for

Part D prescribers to use the NCPDP SCRIPT standard version 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances covered under Medicare Part D. In the CY 2021 PFS proposed rule, we had stated our belief that because prescribers were already required to use this standard when e-prescribing for covered Part D drugs for Part D eligible individuals, prescribers should use this same standard when e-prescribing controlled substances (85 FR 50261).

In the CY 2024 PFS proposed rule (88 FR 52532), we noted that on December 27, 2022, as part of the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (herein referred to as the ''CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule'') (87 FR 79550), we proposed to update provisions related to e-prescribing standards at § 423.160(b), including, after a transition period, requiring the NCPDP SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for covered Part D drugs for Part D eligible individuals. The CY 2024 Medicare Advantage and Part D Policy and Technical Changes final rule appeared in the April 12, 2023 **Federal Register** (88 FR 22120). We noted that we did not address comments received on the provisions of the proposed rule related to e-prescribing standards as these provisions were not finalized in the final rule. We also noted that we will address provisions of the proposed rule that we did not finalize at a later time, such as in possible future rulemaking, as appropriate.

As stated in the CY 2021 PFS proposed rule (85 FR 50261), our intent with the CMS EPCS Program is for prescribers to use the same version of the NCPDP SCRIPT standard for their electronic prescribing of Schedule II–V controlled substances that are Part D drugs as for other electronic prescribing for Part D eligible individuals. Although we finalized the NCPDP SCRIPT standard version 2017071 as the standard in the CY 2021 PFS final rule, we want to clarify that, based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. This is based on the requirement at § 423.160(a)(5) that prescribers conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of § 423.160. Therefore, any proposals from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule to standards at § 423.160(b) that are finalized will apply to electronic prescribing for the CMS EPCS program as well.

Although we did not make a formal proposal in this section, we did receive public comments requesting clarification on when the new NCPDP SCRIPT standard version would be adopted and the implications for measuring long-term care (LTC) compliance. Because we did not make a proposal in regard to the date on or after which compliance actions will commence against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility, the responses that follow are for clarification purposes only.

Comment: A few commenters supported our clarification that the CMS EPCS Program will require use of the same NCPDP SCRIPT standard version that is required for Part D e-prescribing. One commenter noted their belief that the following preamble text from the CY 2024 PFS proposed rule was confusing: ''In the final rule, we did not address comments received on the provisions of the proposed rule related to e-prescribing standards as these provisions were not finalized in the final rule. Rather, we will address provisions of the proposed rule that we did not finalize at a later time, such as in possible future rulemaking, as appropriate.'' The commenter recommended removing that statement and substituting the following: ''Therefore, any proposals from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule to standards at § 423.160(b) that are finalized will apply to electronic prescribing for the CMS EPCS program as well.''

Response: We appreciate this feedback. We are further clarifying that the CMS EPCS Program will require use of the same version (or versions) of standards that are finalized through rulemaking for Medicare Part D e-prescribing by virtue of the cross reference in § 423.160(a)(5) to ''the applicable standards in paragraph (b) of this section,'' which refers to the standards in § 423.160(b). In particular, the CMS EPCS Program will require use of the same version (or versions) of standards that are required for prescribers, dispensers, and Part D sponsors transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals using electronic media consistent with the general rules governing requirements for electronic prescribing at § 423.160(a)(1) and (2).

Comment: A few commenters sought clarification for when the Medicare Part D standards for electronic prescribing would be finalized and noted the implications for LTC. Commenters noted that the proposed NCPDP SCRIPT standard version 2022011 offered new and important functionality that addresses longstanding challenges with implementing e-prescribing in the post-acute care sector. These commenters sought clarification as to CMS' timeline for adopting and implementing this new standard, given that prescriptions written for a beneficiary in an LTC facility were excluded from compliance until January 1, 2025 and compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in an LTC facility will commence on or after January 1, 2025.

Response: As of publication of this final rule, we acknowledge that we have not finalized our proposal to update the standard that was proposed in the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule (88 FR 22120).

In the 2022 PFS final rule (86 FR 65364), we noted that the intent of extending the date on or after which we will pursue compliance actions for prescriptions written for beneficiaries in LTC facilities to January 1, 2025 was to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping to ensure that these facilities eventually implement EPCS, given the benefits of EPCS. Furthermore, we noted that we were not persuaded to further delay commencing compliance actions to await publication of the NCPDP SCRIPT 2022011 standard. We acknowledged that three-way communication is not as seamless in the 2017071 version of the standard as it may be in upcoming versions. We also stated that it is still possible with some modifications to EPCS, and therefore, we did not believe it would be appropriate to adopt a further delay on this basis alone. We know that some prescribers prescribing for beneficiaries in LTC facilities have

adopted EPCS, but that others have waited for the standard to be updated. Our current policy is to start including prescriptions written for a beneficiary in a LTC facility in compliance calculations starting January 1, 2025. However, if the updated NCPDP SCRIPT standard is finalized for a date after January 1, 2025, we may explore whether a waiver is appropriate for prescribers who are not compliant solely as a result of prescriptions they have written for beneficiaries in LTC facilities or we may revisit the compliance start date, if needed, through future rulemaking.

b. Standards for Same Legal Entity

In the CY 2022 PFS final rule (86 FR 65366), we finalized an exception at § 423.160(a)(5)(i) for prescriptions issued where the prescriber and dispensing pharmacy are the same entity (hereafter called the same entity exception). We stated our belief that a requirement to use the NCPDP SCRIPT standard version 2017071 within a closed system could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when a unified database is split into a transaction system that relays information to and from the same entity.

As we have implemented the same entity exception, our experience has been that the Prescription Drug Event (PDE) data, which we use for CMS EPCS Program compliance calculations, does not have a field that consistently and accurately identifies prescribers and dispensing pharmacies that are part of the same entity, making it impossible to exclude these prescriptions from the compliance calculations using PDE data. Additionally, we realized that we can include prescriptions where the prescriber and dispensing pharmacy are the same entity without triggering the concerns that led us to us to finalize the same entity exception, if we remove the requirement to use the NCPDP SCRIPT standard listed in § 423.160(b), as described below.

Medicare Part D has an existing electronic prescribing regulation that permits the use of either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity while still maintaining the requirement for e-prescribing. The Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581), which appeared in the November 7, 2005 **Federal Register**, codified at § 423.160(a)(3)(ii), that either HL7 messages or the NCPDP SCRIPT standard could be used when all parties to a transaction are, for example, employed by and part of the same legal entity. We subsequently finalized a proposal to move the provision to § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405).

In the CY 2024 PFS proposed rule (88 FR 52532), we proposed to integrate this regulation into the CMS EPCS Program, as it provides alignment across electronic prescribing policies for prescriptions prescribed and dispensed within the same legal entity without forcing these entities to adopt the NCPDP SCRIPT standard for such transmittals. We are finalizing this proposal. As a result, prescribers in the same legal entities as the dispensing pharmacy will have multiple methods to conduct internal electronic transmittals for Schedule II, III, IV, and V controlled substances that are Part D drugs, as permitted in § 423.160(a)(3)(iii). Therefore, we believe that these prescribers' prescriptions can be included in the CMS EPCS Program compliance calculation so long as prescribers' electronic prescriptions are transmitted consistent with the exemption in § 423.160(a)(3)(iii).

By finalizing this proposal, we will no longer need to separately identify and apply different methodologies based on whether the prescriber and dispensing pharmacy are the same entity. We will identify electronic prescriptions for Schedule II–V controlled substances that are Part D drugs using the Prescription Origin Code data element in the PDE record, where a value of three indicates electronic transmission. Additionally, this proposal will expand the available standards for prescribers that are within the same legal entities as the dispensing pharmacy under the CMS EPCS Program, as defined by the Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581), by cross-referencing the standards at § 423.160(a)(3)(iii), which broadens the requirements of the e-prescribing standard that can be used to meet CMS EPCS Program requirements. We believe that by aligning with the regulation at § 423.160(a)(3)(iii), we are advancing e-prescribing standardization and addressing potential concerns about burdening prescribers within the same legal entity, including workflow and data errors.

Therefore, to address our data limitations and to provide flexibility where prescriptions are transmitted within the same legal entity, we are finalizing our proposals to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements and to redesignate paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively. We also are finalizing our proposal to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). As a result, prescriptions that are prescribed and dispensed within the same legal entity will be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers will not be exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II–V controlled substances that are Part D drugs—but such prescriptions will only have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii).

We solicited comments on the proposals to remove the same entity exception and expand the available standards for same legal entities within the CMS EPCS Program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to remove the same entity exception and use HL7 messages or the NCPDP SCRIPT standard, which is identified in the exemption at § 423.160(a)(3)(iii), because it reduces administrative burden and promotes interoperability and data sharing which can improve patient outcomes.

Response: We thank the commenters for their support of the proposal to remove the same entity exception and align e-prescribing practices with Medicare Part D.

Comment: One commenter did not support the proposal to remove the same entity exception and use HL7 messages or the NCPDP SCRIPT standard as they believed broader flexibility would not solve this issue because some prescribers, especially those in rural communities, may use proprietary codes rather than HL7 messages or the NCPDP SCRIPT standard, which is identified in the exemption at § 423.160(a)(3)(iii), and LTC participants have unique requirements. The commenter suggested that CMS consider alternative options for excluding same entity prescriptions and allow some level of exception.

Response: Generally speaking, we intend to align CMS EPCS Program requirements with the Medicare Part D electronic prescribing standards, as we do not want to create different

requirements regarding the use of electronic prescribing standards between the Medicare Part D program as a whole and the CMS EPCS Program. The concerns the commenter identified with respect to EPCS within the same entity would also be applicable to electronic prescriptions for non-controlled Part D drugs. However, as noted in the CY 2024 PFS proposed rule and as we reiterate above, due to the limitations in the data we have already described, we intend to identify electronic prescribing through the Prescription Origin Code with a value of three found in the PDE record, which is based on the NCPDP definitions for electronic transmission.[437]

After consideration of public comments, we intended to finalize these policies as proposed.

4. Definition of Prescriptions for Compliance Calculation

In the CY 2022 PFS final rule, we finalized the compliance threshold requirement for the CMS EPCS Program such that prescribers are required to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies (86 FR 65366). Additionally, we indicated that the compliance threshold for each prescriber would be calculated by examining PDE data at the end of the measurement year and dividing the number of Part D controlled substances that were e-prescribed by the total number of Part D controlled substance prescriptions (excluding from both the numerator and denominator any prescriptions issued while a prescriber falls within an exception or is subject to a waiver) (86 FR 65365). Previously, we did not define how prescriptions with multiple fills would affect the compliance threshold calculation. We proposed to specify how the compliance threshold is affected by multiple fills within the same year.

For purposes of CMS EPCS Program, we will count unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and included in the Part D claims data. All prescriptions, regardless of how they are transmitted, may include a number of refills so that the pharmacy may provide additional fills of the prescribed medication without the need for a new prescription from, or visit to, a prescriber. Refills are not separately transmitted prescriptions; they are documented as part of the original prescription transmittal, which includes any refills issued against the original prescription (by the pharmacy). However, renewals of prescriptions (such as those for maintenance medications) require prescribers to generate a new prescription along with a new set of refills. Because of this distinction, we will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year.

We believe, if we were to include every fill in the compliance threshold calculation, an increased burden could be placed on small prescribers, as they would potentially no longer qualify for the small prescriber exception at § 423.160(a)(5)(ii) (which we proposed to be redesignated to § 423.160(a)(5)(i), as described in the regulation text in this rule). If we were to count every single fill, preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers would no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers would be considered non-compliant. For this reason, we will count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations.

We received public comments on the definition of prescriptions for the CMS EPCS program compliance calculation. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported counting prescription renewals, but not refills, toward the CMS EPCS program's compliance threshold calculation and to only include a refill in the calculation if it is the first occurrence of that unique prescription within a measurement year. One commenter noted that many prescribers who currently qualify for the small prescriber exception would be at risk of no longer qualifying if each refill of a prescription counted towards the compliance threshold calculation.

Response: We agree with commenters that if we were to include every fill in the compliance threshold calculation, an increased burden could be placed on small prescribers, as they would potentially no longer qualify for the small prescriber exception.

After consideration of public comments, we are finalizing the policy as proposed to count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations.

5. Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances

a. Background

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized two exceptions related to exceptional circumstances that may prevent prescribers from being able to conduct EPCS. The first exception, codified at § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. Prescribers in a geographic area of an emergency or disaster declared by a Federal, State, or local government entity are excluded from the CMS EPCS Program requirements. In the CY 2023 PFS final rule (87 FR 70012), we modified the exception to use the prescriber's PECOS address or, in situations where a prescriber does not have a PECOS address, the prescriber's address in the National Plan and Provider Enumeration System (NPPES) data, to determine whether the exception at § 423.160(a)(5)(iii) is applicable.

The second exception, codified at § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which we grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. We defined ''extraordinary circumstance'' for purposes of this exception to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary (86 FR 65367).

In the CY 2024 PFS proposed rule (88 FR 52533), we proposed to further modify the recognized emergency exception and extraordinary circumstances waiver (which we codified at § 423.160(a)(5)(ii) and (iii), respectively, as described in section III.M.3.b of this rule). We proposed to modify the rules for when these exceptions apply by enabling prescribers to apply for waivers in times of an emergency and disaster and by limiting the emergencies or disasters that would trigger the recognized emergency exception. Additionally, we proposed to modify the duration of both

[437] *https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.*

exceptions and proposed timing requirements for submitting a waiver application.

b. Updating the Circumstances Applicable for the Recognized Emergency and Extraordinary Circumstances Waiver Exceptions

At the time we made proposals in the CY 2024 PFS proposed rule (88 FR 52533 through 52534), the exception for recognized emergencies applied to all prescribers with an address in PECOS, or alternatively in NPPES, in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. As we explained in that proposed rule, we have realized there may be unintended consequences to our policy based on our experience implementing it. First, while we can identify emergencies recognized by the Federal Emergency Management Agency (FEMA) or pandemics recognized by the Department of Health and Human Services (HHS), we may not be able to identify every local or state emergency. Because we excluded emergencies and disasters from our extraordinary circumstances waiver policy, some prescribers may not be able to receive an exception for an emergency or disaster we did not identify. Second, we realized that not every emergency may impact the ability of prescribers to conduct EPCS, and thus it may not be appropriate to automatically apply the exclusion to all prescribers in the affected geographic area of some emergencies. Third, we realized that some of our policies do not align with other emergency policies of CMS programs for quality reporting and performance. Therefore, in order to address these concerns, we looked to the Quality Payment Program Merit-based Incentive Payment System (MIPS) automatic policy for extreme and uncontrollable circumstances and to the extraordinary circumstances exceptions (ECE) for many of our quality reporting and value-based purchasing programs for hospitals and other types of facilities to see other examples of when we apply automatic exceptions versus when we ask clinicians or facilities to apply for a waiver.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38410) and CY 2018 OPPS/ASC final rule (82 FR 52584), we worked to align common processes for our ECE policies across many of our quality programs including the Hospital IQR Program, Hospital OQR Program, IPFQR Program, ASCQR Program, and PCHQR Program, as well as the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program. Using the Hospital IQR Program as an example, generally, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital (42 CFR 412.140(c)(2)). A hospital may submit such a request in the form and manner described on QualityNet.org. CMS may also grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance, such as an act of nature (for example, hurricane), has affected an entire region or locale (*see* § 412.140(c)(2)(ii) and 76 FR 51651). We stated that if we make the determination to grant an ECE to hospitals in a region or locale, we would communicate this decision through routine communication channels (76 FR 51652).

Separately, in the context of clinicians participating in MIPS, we established another ECE policy. In the Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year (CY 2018 Quality Payment Program final rule), we adopted in an interim final rule with comment period an automatic extreme and uncontrollable circumstances policy for one performance period due to several hurricanes (82 FR 53895 through 53900). In discussing the triggering events for this policy (82 FR 53897), we stated that we have discretion not to require MIPS eligible clinicians to submit an application for reweighting the performance categories in cases where an extreme and uncontrollable circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. We noted that we anticipate the types of events that could trigger this policy would be events designated by the Federal Emergency Management Agency (FEMA) as major disasters or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis. We also noted our intention to align the automatic extreme and uncontrollable circumstance policy with the ECE policies for other Medicare programs such that events that trigger ECE policies would also trigger the automatic extreme and uncontrollable circumstance policy (82 FR 53897). In the CY 2019 PFS final rule (83 FR 59875), we finalized a similar policy for all future years, which we codified at § 414.1380(c)(2)(i)(A)(*8*) and (C)(*3*).

As we stated in the CY 2024 PFS proposed rule (88 FR 52534), we believe that it will be beneficial to interested parties for the CMS EPCS Program to have a similar policy as it relates to applying for an exception versus having an automatic exception for all prescribers in an affected region. This will streamline communications across CMS programs, as well as ensure that CMS can, where appropriate, except all prescribers for an appropriate circumstance beyond their control, including disasters or emergencies. In order to facilitate this transition, for the waiver exception at § 423.160(a)(5)(iv) (which we proposed to codify at § 423.160(a)(5)(iii), as described in the regulation text in this rule), we are finalizing our proposal to modify the definition of ''extraordinary circumstance'' to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug. This updated definition will drop the restriction ''other than an emergency or disaster,'' that we previously included when discussing this exception. This modification will allow prescribers the ability to request a waiver regardless of whether we trigger the recognized emergency exception.

Additionally, we proposed to modify the recognized emergency exception at § 423.160(a)(5)(iii) (which is codified at § 423.160(a)(5)(ii), as described in the regulation text in this rule) so that we will identify which events trigger the recognized emergency exception. We believe the ability to identify triggering events will allow us to ensure that the emergency affects widespread EPCS functionality. In applying this determination of which emergencies or disasters would trigger this exception, we will review each emergency situation on a case-by-case basis but will generally look to events designated as a FEMA major disaster or a public health emergency declared by the Secretary. We also intend to align the determination of the emergency exception with the MIPS automatic extreme and uncontrollable circumstances policy, such that events that would trigger this policy, in most instances, will also qualify under the CMS EPCS Program exception for recognized emergencies. We expect any deviation from MIPS automatic extreme and uncontrollable circumstances policies would be rare and only in circumstances which may cause disruption for MIPS performance but should not affect a prescriber's ability to

electronically prescribe Schedule II–V controlled substances that are Part D drugs, or vice versa.

We will inform prescribers of which emergencies or disasters qualify for the exception, as determined by CMS, using normal communication channels such as listservs and the CMS EPCS Program website.

We solicited comments on the proposals related to circumstances applicable for the recognized emergency and extraordinary circumstances waiver exceptions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to modify the definition of extraordinary circumstances by dropping the phrase ''other than an emergency or disaster.'' Commenters noted the policy allows prescribers to apply for a waiver for all circumstances beyond their control, even in cases where a recognized emergency is not declared. One commenter noted their belief that this policy promotes climate change resiliency by providing EPCS flexibilities during a natural disaster. Commenters also supported the alignment of policies with MIPS and other CMS programs and noted how that promotes continuity and reduces burden.

Response: We thank these commenters for their support. We agree that this policy provides the most flexibility to prescribers and reduces burden by aligning with other CMS programs.

Comment: A few commenters supported our proposal for CMS to review emergency situations and offer blanket exceptions by region on a case-by-case basis using FEMA-designated emergencies and HHS-declared public health emergencies as a baseline because it aligns with MIPS program policies.

Response: We agree that it is important that we have flexibility in establishing exceptions for recognized emergencies and that it is desirable to align the CMS EPCS Program with other CMS programs where practicable and appropriate.

Comment: One commenter did not support the proposal for CMS to identify the emergencies and disasters that would trigger the recognized emergency exception. The commenter noted that CMS did not provide any examples of when such emergencies may not be applicable, and the commenter was also concerned that disconnecting emergency and disaster declarations from the recognized emergency exception may lead to confusion.

Response: As discussed earlier in this section, we will review each emergency situation on a case-by-case basis and will generally look to events designated as a FEMA major disaster or a public health emergency declared by the Secretary. Further, by permitting prescribers to request a waiver regardless of whether we trigger the recognized emergency exception, we are providing prescribers greater certainty that, regardless of whether we recognize an emergency under the exception at § 423.160(a)(5)(ii), a prescriber can still request a waiver identifying the extraordinary circumstance preventing the prescriber from complying with the CMS EPCS Program requirements.

Finally, we believe our proposal will reduce confusion rather than increase confusion by aligning with other CMS programs. One potential example for this policy is the multi-year public health emergency related to COVID–19 that ended May 11, 2023. Some prescribers may continue to be affected by the emergency in calendar year 2023, while others are not. Under the policy we are finalizing, we would have the ability to make an assessment if the recognized emergency applies for the measurement year for the entire nation and align this assessment, if appropriate, to other programs. After consideration of public comments, we are finalizing these policies as proposed.

c. Duration of Recognized Emergency Exceptions

In the CY 2022 PFS final rule (86 FR 65367), we clarified that the recognized emergency exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring. In an effort to continue aligning the CMS EPCS Program with the Quality Payment Program, we proposed that, as a default, prescribers impacted by the CMS EPCS Program recognized emergency exception at § 423.160(a)(5)(iii) (which we codified at § 423.160(a)(5)(ii), as described in the regulation text in this rule) would be excepted for the entire measurement year, and not just for the duration of the emergency. We believe this would protect prescribers who may not be able to monitor their compliance status over multiple periods of time.

We solicited comments on the proposed duration for exceptions due to recognized emergencies.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that any prescriber impacted by a recognized emergency exception would be excepted for the whole measurement year instead of the length of the emergency. One commenter noted that they believed this would help reduce administrative burden for practices.

Response: We thank the commenters for their support. We agree this proposal will reduce administrative burden.

After consideration of public comments, we are finalizing this policy as proposed.

d. Duration and Timing of Extraordinary Circumstances Waiver Exception

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized an attestation process for prescribers to request a waiver.[438] In the CY 2024 PFS proposed rule (88 FR 52535), we did not propose any modifications on the information needed to request a waiver, but we proposed the timeframe that would be covered by a waiver that is authorized under the CMS EPCS Program and the timing of waiver requests.

Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, refers to a waiver or a renewal thereof for a period of time, not to exceed 1 year, as determined by the Secretary. We proposed that approved waivers for the CMS EPCS Program would apply to the entire measurement year. Prescribers who receive a waiver and continue to experience exceptional circumstances that extend beyond December 31 of a measurement year would be required to complete a new waiver application for the subsequent measurement year.

In the CY 2022 PFS proposed rule (86 FR 39332), we signaled that we would include more information about the waiver process in subsequent rulemaking. One issue that was not clearly defined is the timing of when a prescriber can request a waiver. In the CY 2022 PFS final rule (86 FR 65370), we finalized that we would notify prescribers that they are violating the EPCS requirement with information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. In the CY 2024 PFS proposed rule (88 FR 52535), we proposed that a prescriber

[438] The waiver application is currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10834, and the proposed collection comment request appeared in the March 10, 2023 **Federal Register** (88 FR 15037).

has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers would apply to prescriptions written by a prescriber for the entire measurement year, and the waiver would expire on December 31 of the applicable measurement year.

We solicited comments on the proposed waiver duration and the proposal for the timing and process of applying for a waiver in cases of extraordinary circumstances.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to apply the extraordinary circumstance exception for the entire measurement year and for prescribers to reapply if the emergency goes beyond the measurement year. Commenters noted this reduces burden.

Response: We agree this policy reduces burden.

Comment: One commenter requested clarification regarding how CMS will determine the length of an extraordinary circumstance for which a prescriber requests a waiver, especially if it occurs close to the end of the year, given that a granted exception would apply for the full measurement year. The commenter noted it is critical for providers to understand this information when CMS grants a waiver in response to an application to avoid inadvertent noncompliance.

Response: We realize that prescribers will not be able to apply for waivers until after the measurement period has ended and this may result in the prescriber not being able to modify their behavior based on the denial of a waiver. As part of the waiver request process, we provide an opportunity for a prescriber to describe the reasons for non-compliance. If the waiver is not accepted, there is an opportunity for educational outreach.

We also hope to minimize inadvertent non-compliance by allowing prescribers to apply for a waiver after they know their compliance status for the year. In some cases, we believe prescribers who experience an extraordinary circumstance may still be compliant because, even with the extraordinary circumstance, they were able to achieve the 70 percent compliance threshold.

After consideration of public comments, we are finalizing these policies as proposed.

6. Actions for Non-Compliance

In the CY 2022 PFS final rule (86 FR 65370), we limited compliance actions with respect to compliance from January 1, 2023 through December 31, 2023, to a non-compliance notice sent to prescribers who are violating the CMS EPCS Program requirement. In the CY 2023 PFS final rule (87 FR 70013), we extended the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 EPCS Program implementation year (January 1, 2024 through December 31, 2024). The content of the notices will remain unchanged and continue to consist of a notice to prescribers that they are violating the CMS EPCS Program requirements, information about how they can come into compliance, the benefits of EPCS, and a link to the CMS EPCS Program dashboard where the prescriber may request a waiver and provide information as to why they are not conducting EPCS.

We proposed to continue the practice of issuing a prescriber a notice of non-compliance as a non-compliance action for subsequent measurement years. As stated in the CY 2023 PFS final rule (87 FR 70013), we believe prescriber use of EPCS encourages the use of interoperable technology, produces a verifiable and traceable history, prevents fraud and abuse, and reduces burden. We believe that continuing to send non-compliance notices would support increased EPCS adherence and encourage increased EPCS adoption rates, which could be more effective than imposing more restrictive non-compliance actions or penalties that may increase burden on prescribers.

In the CY 2023 PFS proposed rule (87 FR 46240 through 46241), we solicited ideas of possible non-compliance actions with the goal of identifying one that would be operationally feasible (for example, can be accomplished without requiring modifications to the data available through the PDE file) and support the nation's ongoing fight against drug abuse and diversion without adding administrative burden to prescribers or hindering beneficiary access to needed medications. We did not receive a large number of comments. However, we did receive one comment specifically noting that non-compliance alone is not a definitive indicator of fraud, waste, or abuse. We agree with the commenter that non-compliance alone is not a definitive indicator of fraud, waste, or abuse; however, we maintain that one risk to public safety is potential fraud, waste, and abuse and intend that a prescriber's non-compliance under the CMS EPCS program may be considered in our processes for assessing potential fraud, waste, and abuse. We may use this information in our processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present. At this time, we believe the risk of fraud, waste, or abuse can be mitigated without the need for further penalties for CMS EPCS program non-compliance. Literature suggests a correlation between use of EPCS and reduction in fraud, waste, and abuse related to opioid prescriptions.[439] [440] Prescriber use of EPCS is directly related to improving prescription security, decreasing prescription forgery, and reducing the overall chance of fraud and alteration associated with paper prescribing.[441] Also notable are studies demonstrating reductions in opioid overdoses when EPCS use is increased and general findings that e-prescribing can improve coordination of care, reduce fraud and abuse, and contribute to public health safety.

Although we did not propose further non-compliance actions beyond the extension of sending notices at this time, we will continue to evaluate compliance and prescriber performance under the CMS EPCS Program and will consider whether to propose changes in future years. We solicited comments on our proposal to continue the action of sending notice to prescribers who are identified as non-compliant.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to send non-compliance notices to prescribers who do not meet the CMS EPCS Program requirements in subsequent years without imposing additional penalties. Several commenters noted that continuing to send the notices would promote increased EPCS adoption, especially for those who require additional time to update their technological abilities, and any added provider penalties for non-compliance

[439] Abuok, Rahi, and David Powell. ''Can Electronic Prescribing Mandates Reduce Opioid-Related Overdoses?'' Science Direct, JOURNAL of ECONOMICS & HUMAN BIOLOGY, Elsevier B.V., 14 Apr. 2021, *https://doi.org/10.1016/j.ehb.2021.101000.*

[440] Achar, Suraj, et al. ''Adoption and Increased Use of Electronic Prescribing of Controlled Substances.'' *Journal of Medical Regulation,* Federation of State Medical Boards, 27 Aug. 2021, *https://doi.org/10.30770/2572–1852–107.2.8.*

[441] Achar, Suraj, et al. ''Adoption and Increased Use of Electronic Prescribing of Controlled Substances.'' *Journal of Medical Regulation,* Federation of State Medical Boards, 27 Aug. 2021, *https://doi.org/10.30770/2572–1852–107.2.8.*

beyond the notice and education could be counterproductive. A few commenters noted that CMS should not impose restrictions, penalties, or other limitations that may interfere with beneficiary access and instead should work with practices to support compliance efforts.

Response: We agree that continuing to send non-compliance notices in subsequent years will encourage adoption and compliance without adding prescriber burden or restricting patient access.

Comment: A few commenters agreed with CMS's belief that public safety concerns related to fraud, waste and abuse for prescribers who do not use EPCS can be mitigated without additional penalties in the CMS EPCS Program.

Response: We agree with commenters. We believe that considering a prescriber's non-compliance under the CMS EPCS program in our processes for assessing potential fraud, waste, and abuse could help identify prescribers who may be avoiding CMS EPCS Program compliance for harmful reasons. We believe doing so promotes proper prescribing patterns.

Comment: A few commenters did not support the proposal to issue a notice of non-compliance as a non-compliance action for the CMS EPCS program requirement in subsequent measurement years; these commenters expressed concerns that additional penalty mechanisms would be needed in addition to the notice in order to increase prescriber adoption and compliance in the CMS EPCS program. One commenter noted that stronger compliance actions might be needed to increase prescriber compliance in the future, but did not provide specific suggestions. One commenter specifically supported further consideration of corrective action plans, public notice of noncompliance, and referral to applicable state regulators. One commenter suggested that the CMS EPCS requirement be connected to the Promoting Interoperability performance category under the MIPS program. Another commenter suggested that CMS consider offering incentives as a future mechanism for those who comply, as a method to encourage implementation. A few commenters acknowledged CMS' authority to refer non-compliant prescribers to other enforcement agencies for investigation. One commenter recommended that CMS provide a ''series of escalating notices'' that would allow prescribers appropriate time to correct non-compliance.

Response: We considered multiple actions for CMS EPCS Program non-compliance but believe continuing to provide non-compliant prescribers with notices, along with using CMS EPCS Program non-compliance information in our processes for identifying fraud, waste, and abuse, is sufficient incentive to encourage EPCS adoption. We will continue to evaluate previously considered actions for non-compliance and their applicability for the future as we evaluate and monitor CMS EPCS Program compliance in subsequent years. We considered the use of corrective action plans, public notice of non-compliant prescribers, referral to state regulators, and believed these options to be logistically complex for the value they would bring. We also considered alignment with existing MIPS reporting options and other financial incentives but do not believe those are feasible at the present time.

We will send notices of non-compliance for each measurement year a prescriber is non-compliant and will provide educational opportunities to support prescribers in becoming compliant. We plan to monitor CMS EPCS program compliance rates and may revisit the use of further non-compliance actions in future rulemaking.

After consideration of public comments, we are finalizing this policy as proposed.

N. Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414 subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments to the base rate and/or mileage rate, which are discussed in the next section of this final rule.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted July 15, 2009) (MIPPA), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Most recently, division FF, section 4103 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, December 29, 2022) amended section 1834(l)(13) of the Act to extend the payment add-ons through December 31, 2024. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2025. In the CY 2024 PFS proposed rule (88 FR 52536), we proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072) and the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial

application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary.

We received one comment regarding this proposal. The following is the summary of the comment we received and our response.

Comment: One commenter supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are critically important to ground ambulance services.

Response: We appreciate the commenter's support of these provisions.

After consideration of the public comment that we received, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, division FF, section 4103 of the CAA, 2023 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2024. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2025 where transportation originates in a qualified rural area. Accordingly, in the CY 2024 PFS proposed rule (88 FR 52536), we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072) and the CY 2019 PFS final rule with comment period (83 FR 59682)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2024, and does not require any substantive exercise of discretion on the part of the Secretary.

We received one comment regarding this proposal. The following is the summary of the comment we received and our response.

Comment: One commenter supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are critically important to ground ambulance services.

Response: We appreciate the commenter's support of these provisions.

After consideration of the public comment that we received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

3. Medicare Ground Ambulance Data Collection System

a. Background

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers (ground ambulance organizations) to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Section 1834(l)(17)(B)(i) of the Act required the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act required that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Division P, section 311 of the CAA, 2022 (Pub. L. 117–103) amended section 1834(l)(17)(F)(i) of the Act to delay the deadline for MedPAC to submit its report to Congress on the ground ambulance data collection system study until the second June 15th following the date the Secretary transmits data for the first representative sample of ground ambulance organizations. Section 1834(l)(17)(I) of the Act states that the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) does not apply to the collection of information required under section 1834(l)(17) of the Act.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance organizations at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. We also finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. We refer the reader to our CY 2020 PFS final rule (84 FR 62864 through 62897) for

more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

In the CY 2022 PFS final rule (86 FR 65306 through 65317), we finalized a number of updates to the Medicare Ground Ambulance Data Collection System, including: (1) a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in Year 3; (2) aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and a notice that the data collected will be publicly available beginning in 2024; and (3) revisions to the Medicare Ground Ambulance Data Collection Instrument that include better accounting for labor hours across different categories of personnel and better distinguishing between accrual and cost basis accounting methodologies. We refer the reader to our CY 2022 PFS final rule (86 FR 65306 through 65317) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

In the CY 2023 PFS final rule (87 FR 70014) we finalized a series of changes to the Medicare Ground Ambulance Data Collection System. First, we finalized our proposal to update our regulations at § 414.626(d)(1) and (e)(2) to provide the necessary flexibility to specify how ground ambulance organizations should submit hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational. Second, we finalized our proposed changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument to reduce burden on respondents, improve data quality, or both. We refer the reader to our CY 2023 PFS final rule (87 FR 70014) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

b. Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2022 PFS final rule (86 FR 65307) and the CY 2023 PFS Final Rule (87 FR 70014), we made several changes to the instrument instructions and questions to improve clarity and reduce burden for respondents. A printable version of the current instrument instructions and questions is available in English and Spanish on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Ground-Ambulance-Services-Data-Collection-System*.

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via four primary channels. First, we receive email and other written communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers and the GADCS User Guide to commonly asked questions. These documents are available on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ambulancefeeschedule/ground-ambulance-services-data-collection-system*. Through review of questions and feedback, we identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document, the GADCS User Guide, or to other resources. Second, we answer questions live from interested parties during webinars, dedicated question and answer sessions, and other educational sessions. As with the emailed questions described above, live question and answer exchanges sometimes identify opportunities for clarifying instrument language. Third, we have begun analyzing initial data responses submitted via the GADCS portal by selected organizations in Year 1 and Year 2. Findings from this initial analysis, including inconsistent response patterns, unusual combinations of responses across questions, and investigation of outlier results were helpful to identify some additional opportunities for clarification. Fourth, we continue to identify opportunities to clarify instructions and correct a small number of typos through the final development and launch of the web-based GADCS.

Based on information that we received via the four sources described above, we proposed in CY 2024 PFS proposed rule (88 FR 52537), the following further changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aimed to reduce burden on respondents, improve data quality, or both.

1. Addressing Partial-Year Responses

Ground ambulance organizations selected to participate in the GADCS that are in operation for only part of their continuous, 12-month data collection period are, following the GADCS instructions, still required to collect and report data. However, there is not a field for these organizations to report that they were in operation, and therefore collecting data, for less than a full 12-month period via the GADCS. In these cases, we would not know that the costs, revenue, and utilization reported by these partial-year organizations are comparatively smaller than those reported by similar organizations in operation for an entire 12-month period. As a result, some statistics from analyses of GADCS data, for example total annual expenditures per ground ambulance organization, would be biased downward.

To address this limitation, we proposed in the CY 2024 PFS proposed rule (88 FR 52538) to add a response option to Section 2 (Organizational Characteristics), Question 1 which asks whether the selected national provider identifier (NPI) linked to the organization was used to bill Medicare for ground ambulance services during its data collection period. The current response options are ''Yes (1)'' and ''No (0)''. We proposed to split the existing ''Yes (1)'' response into two separate responses, one reading ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' and ''Yes, but for only part of the organization's continuous, 12-month data collection period (2).'' The ''No (0)'' response would not change. Respondents from organizations that billed for ground ambulance services during part of, but not all of, its continuous, 12-month data collection period, would select ''Yes, but for only part of the organization's continuous, 12-month data collection period (2)''. Those that did so would be prompted to enter the date they started and/or stopped operations during the continuous, 12-month data collection period in a pop-up box, followed by an instruction to proceed through the remainder of the GADCS reporting process.

Organizations selecting ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' would proceed through the

rest of the GADCS reporting process as would respondents answering ''Yes (1)'' to this question currently. Organizations selecting ''No (0)'' would, as is currently the case, be prompted with several follow-up questions which result in either: outreach to the GADCS helpdesk for assistance if the listed NPI does not match their organization, or if they answer that none of the scenarios in the follow-up questions apply or to the completion of the organization's data reporting requirement.

This approach allows CMS to understand when reported costs, revenue, and utilization are measured over a period of time less than a full 12 months and, if necessary, to adjust partial-year responses so that they are more comparable to most responses that will cover a continuous full 12-month data collection period. Furthermore, we believe this approach will reduce confusion and burden for organizations in operation for only part of their 12-month data collection periods.

We solicited comments on this proposal to address partial-year responses.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters stated their overall support for our proposals to the Medicare Ground Ambulance Data Collection Instrument in the CY 2024 PFS proposed rule. The commenters appreciated CMS' efforts to educate, as well as to listen to input from interested parties and revise the data collection instrument based on this feedback.

Response: We appreciate the commenters' support of our proposals.

After consideration of the public comments we received, we are finalizing our proposal to add the ability to address partial- year responses as proposed.

2. Programming Logic for Hospitals and Other Medicare Providers of Services

Section 2 of the GADCS printable instrument includes a programming note after Question 9 reading: ''For the remainder of the data collection instrument, instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that answer Section 2, Question 7= ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b.'' The intent of this programming note is to ensure questions in Section 7 (Labor Costs) present instructions and response fields appropriate to organizations with staff having both ground ambulance and fire, police, or other public safety responsibilities. In other words, a for-profit, ground ambulance-only organization should not be asked whether they have ground ambulance staff with fire, police, or other public safety responsibilities, while a fire department-based ground ambulance organization should.

Section 2, Question 8 asks whether organizations reporting to be fire department-based (response ''a'' in Section 2, Question 7), police or other public safety department-based (response ''b'' in Section 2, Question 7), or hospital or other Medicare provider of services-based (response ''d'' in Section 2, Question 7) share operational costs between ground ambulance and the respective other reported function. A programming note for Section 2, Question 8 states that the question should be asked of organizations responding a, b, or d to Section 2, Question 7. As a result, hospitals and other Medicare provider of services-based organizations responding ''d'' in Section 2, Question 7 are presented with Section 2, Question 8, and many may respond ''Yes'' to Section 2, Question 8. As discussed above, answering ''Yes'' to Section 2, Question 8 triggers the appearance of table columns in Section 7, Question 1 related to fire, police, and other public safety staff (''Section 2, Question 7= ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b).

As a result of these programming notes, many hospital-based organizations answering ''d'' to Section 2, Question 7 and ''Yes'' to Section 2, Question 8, and any options other than ''a'' or ''b'' in Section 2, Question 9 will see columns for fire, police, and other public safety staff in Section 7, Question 1, which was not intended. We believe that no ground ambulance organizations with this response pattern will have fire, police, or other public safety staff to report via the GADCS. Furthermore, we are concerned that this will result in confusion for hospital-based organizations.

In the CY 2024 PFS proposed rule (88 FR 52538), we proposed to change the programming note after Section 2, Question 9 to read as follows: ''. . .instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that: (A) answer Section 2, Question 7= ''a'' or ''b'' AND answering Question 8 = Yes (1); OR, (B) answer Question 9 = Yes (1) to one or both of ''a'' or ''b''.'' This change to the programming logic will result in provider-based ground ambulance organizations seeing only two columns in Section 7, Question 1, one for paid and the other, if applicable, for volunteer staff, and not columns specific to staff with fire, police, or other public safety responsibilities.

We solicited comments on this proposal to change the programming note after Section 2, Question 9 in the GADCS printable instrument.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters stated their overall support for our proposals to the Medicare Ground Ambulance Data Collection Instrument in the CY 2024 PFS proposed rule. The commenters appreciated CMS' efforts to educate, as well as to listen to input from interested parties and revise the data collection instrument based on this feedback.

Response: We appreciate the commenters' support of our proposals.

After consideration of the public comments we received, we are finalizing our proposal to change the programming note after Section 2, Question 9 in the GADCS printable instrument as proposed.

3. Typos and Technical Corrections

In the CY 2024 PFS proposed rule (88 FR 52538), we proposed to make four corrections to the GADCS printable instrument.

- Section 2, Question 1a.ii is missing the word ''period'' after ''data collection'' in the text. Therefore, we proposed the question to read as: ''The NPI was in operation during the data collection period but was not used during the data collection to bill Medicare for ground ambulance services.''
- Section 2, Question 3 in the printable instrument questions ''What is the name of your organization? For the remainder of the instrument, the term ''organization'' refers to the NPI for which we are requesting data. (enter name)'' while the web-based GADCS asks ''Is [ORGANIZATION NAME] the name of your organization? For the remainder of the instrument, the term 'organization' refers to the NPI for which we are requesting data. Yes (1)/ No (0).'' The web-based GADCS asks the question in this way because organization name is pre-populated in the system and not entered directly. We proposed to change the language in the printable instrument to match the text in the web-based GADCS for consistency.

• Section 9.1 (Ground Ambulance Vehicle Costs), Question 5 current wording states ''Do not report ground ambulance acquisition costs related to an annual depreciation expense for the same ambulance'' which does not make sense. We proposed Question 5 to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground ambulance.''

• Section 9.2 (Other Vehicle Costs (Non Ambulance)), Question 5 current wording includes the same error as noted above for Section 9.1, Question 5, and also mistakenly refers to ground ambulances rather than non-ambulance vehicles: ''Do not report non-ambulance vehicle acquisition costs related to an annual depreciation expense for the same ground ambulance.'' We proposed to change the question to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground non-ambulance vehicle.''

We solicited comments on these proposals related to GADCS typos and technical corrections.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters stated their overall support for our proposals to the Medicare Ground Ambulance Data Collection Instrument in the CY 2024 PFS proposed rule.

Response: We appreciate the commenters' support of our proposals.

After consideration of the public comments we received, we are finalizing our typos and technical corrections as proposed.

O. Hospice: Changes to the Hospice Conditions of Participation

1. Background and Statutory Authority

We have broad statutory authority for most provider and supplier types to establish health and safety regulations, which includes the authority to establish health and safety requirements that advance health equity for underserved communities. Certain statutes explicitly give CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program. Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248) (TEFRA), added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd)(2)(G) of the Act, the Secretary established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to the hospice as an entity, as well as to the services furnished to each individual under hospice care. Under section 1861(dd), the Secretary is responsible for ensuring that the CoPs and their enforcement, are adequate to protect the health and safety of the individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

The Consolidated Appropriations Act of 2023 (Pub. L. 117–328) (CAA 2023), was signed into law on December 29, 2022. Division FF, section 4121 of the CAA 2023 establishes a new Medicare benefit category for marriage and family therapist (MFT) services and mental health counselor (MHC) services furnished by and directly billed by MFTs and MHCs, respectively. Section 4121(b)(2) of CAA 2023 specifically adds these services to covered hospice care services under section 1861(dd)(2)(B)(i)(III) of the Act. To implement division FF, section 4121 of the CAA 2023, we proposed to modify the requirements for the hospice CoPs at § 418.56 ''*Interdisciplinary group, care planning and coordination of service,*'' and § 418.114 ''*Personnel qualifications.*'' This statutorily-required modification allows MFTs and MHCs to serve as members of the interdisciplinary group (IDG). Specifically, the CAA 2023 revised section 1861(dd) of the Act to state that the hospice interdisciplinary group is required to include a social worker, MFT, or MHC. In addition, we proposed to modify the hospice personnel qualification at § 418.114(c) to also include qualifications for an MFT and an MHC.

2. Summary of the Hospice Proposed Provisions, Public Comments, and Responses to Comments

In this section, we discuss the public comments received on the inclusion of an MFT and MHC as part of the IDG for hospice care and personnel requirements. We received a total of 13 unique comments from patient advocacy groups, national associations, and individuals with a personal or professional interest in this proposed rule. Overall, commenters were generally supportive of the addition of the MFT and MHC to the hospice IDG. Several of the comments sought additional information and clarification on the implementation of these proposals. In addition, many comments expressed burden concerns related to staffing shortages and highlighted the challenges rural areas experience with limited access to behavioral health professionals. A few commenters believed CMS misinterpreted the Statute and that the proposed provisions do not align with congressional intent.

The following is a summary of the comments we received, our responses, and the policies we are finalizing for hospices.

a. General Comments

Comment: A commenter asked if an MFT and MHC will be able to admit a hospice patient, stating that social workers are able to admit patients. They stated that because (based on the commenter's understanding) social workers can admit a hospice patient, the MFT and MHC should also be able to do the same. Further, a commenter asked if the hospice MSW would supervise the MFT and MHC.

Response: We thank the commenter for the question regarding admitting a patient to hospice. We believe the commenter is referring to the hospice's initial visit with the patient. The initial and comprehensive assessment requirements for hospices have not changed and can be found at § 418.54. Specifically, at § 418.54(a), we require the hospice registered nurse to complete an initial assessment within 48 hours after the election of hospice care in accordance with § 418.24 (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.) There are no requirements in the assessment CoPs that require the social worker (SW) to be included in the initial assessment visit. However, we understand that many hospices utilize both the nurse and the SW for the initial assessment. Therefore, it would be within the individual hospice's purview to allow for the MFT or MHC to accompany the nurse to complete the initial assessment.

There are no regulatory requirements for the supervision of the MFT and MHC other than what is referenced in the *Condition of participation: Interdisciplinary group, care planning, and coordination of services,* § 418.56(a)(1). The role of the IDG is to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement; ''Interdisciplinary group members must provide the care and services offered by the hospice, and the

group, in its entirety, must supervise the care and services.''[442]

Comment: A commenter asked for clarification on the billing requirements for MFTs and MHCs, and if CMS will communicate this through a change request. In addition, the commenter asked if this information will be communicated in the Physicians Fee Schedule final rule or in a hospice final rule. The commenter recommended that this information be included in the 2024 hospice final rule to ensure that the target audience is aware of these proposals and for continuity. Lastly, a commenter asked for additional clarification regarding the language in this proposed rule, specifically, ''Division FF, Section 4121 of the CAA 2023 and the establishment of a new Medicare benefit category for MFT and MHC services furnished and directly billed by MFTs and MHCs respectively.''

Response: The referenced language in the CAA 2023 refers to the establishment of MFT and MHC as providers under Medicare. This rule set forth certain requirements for MFT and MHC enrollment, qualifications, and billing as Part B providers. However, the billing of these services under Part B does not apply to hospices. Hospices are paid at a daily rate for each patient based on the patient's level of care. Similar to other hospice services, the services of MFTs and MHCs are included in that daily rate. There are no separate billing provisions for MFT and MHC services, and an MFT or MHC cannot independently bill Medicare for services rendered to a hospice patient.

While we understand publishing the proposed rule and finalizing these requirements in a hospice rule may have been more apparent to the hospice industry, due to the hospice wage index publication dates and the CAA 2023 implementation requirements; it was determined that the CY 2024 PFS rule was the best rulemaking vehicle to propose and finalize the CAA requirements. Therefore, all the hospice CoP information and requirements related to MHCs and MFTs are published in this final rule, and there are no plans to republish this information in a separate hospice rule.

Comment: One commenter stated that it was their understanding that the MFT and MHC appear to be missing from other applicable regulations, specifically that MFTs and MHCs are not listed as medical social service providers in the way in which social workers are listed at §§ 418.64 and 418.202. One commenter suggested that the MFT and MHC be added to medical social services, or that the mention of the SW be removed from this provision.

Response: We thank this commenter for their feedback. While the social worker is a member of core services, a MFT and MHC are not. The CAA 2023 did not modify the Statute to include the MFT or MHC under medical social services. The Hospice Benefit Policy Manual defines medical social services as, ''services which contribute meaningfully to the treatment of a patient's condition. Such services include, but are not limited to: Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment, and adjustment to care in the facility; Appropriate action to obtain case work services to assist in resolving problems in these areas; and Assessment of the relationship of the patient's medical and nursing requirements to their home situation, financial resources, and the community resources available to them in making the decision regarding their discharge.'' [443] In addition, the hospice 2008 final rule entitled, ''Medicare and Medicaid Programs: Hospice Conditions of Participation'' (73 FR 32088) stated, ''It is essential that the individuals providing medical social services to hospice patients be qualified to provide these services.''[444] Section § 418.114 addresses the personnel qualifications that social workers must meet in order ''to provide services to hospice patients.'' Longstanding CMS regulations and policies across multiple provide types including hospice, home health agencies, and hospitals considers medical social services, also referred to as social services, to be linked directly to the scope of practice and duties of the social worker.[445] [446] [447] For example, Chapter 9 of the Medicare Benefit Policy Manual, ''Coverage of Hospice Services Under Hospital Insurance,'' states that ''Medical social services must be provided by a person who meets the criteria given in the Conditions of Participation at § 418.114(b)(3).'' [448] Section § 418.114(b)(3) defines a ''social worker'' as, a person who has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or has a baccalaureate in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and has 1 year of social work experience in a healthcare setting; or Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before December 2, 2008, and is not required to be supervised by a MSW.[449] Therefore, it would not be appropriate to add MFT and MHC to the medical social service requirement.

Comment: Multiple commenters expressed concern over the staffing shortages and lack of mental health professionals in certain areas of the country, including rural areas. Specifically, commenters stated that rural areas may not have access to MFTs and MHCs and asked how hospices should address this access issue. A commenter also asked if hospices will be able to contract these professionals for remote visits and if this would still meet the intent of the regulation. The commenter expressed concern over transporting the patient to these professionals due to their illness and explained that they were unaware of MFTs or MHCs making home visits.

Response: We acknowledge the presence of staffing shortages and recognize the importance of increasing the presence of and access to behavioral health professionals. We are aware that hospices in rural areas experience challenges in recruiting and retaining staff and that there is a shortage of behavioral health providers. We also recognize the value of telehealth services in improving access to health care services. However, the final rule, ''Medicare Program; FY 2024 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice Quality Reporting Program Requirements, and Hospice Certifying Physician Provider Enrollment Requirements'' published August 2, 2023, (88 FR 51164) clarifies that the hospice regulations at § 418.204 were amended on an interim basis during the COVID–19 Public Health Emergency (PHE). This amendment of the requirements allows for a waiver for hospices to provide services via

[442] *https://www.govinfo.gov/content/pkg/FR-2008-06-05/pdf/08-1305.pdf.*

[443] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c01.pdf.*

[444] *https://www.federalregister.gov/documents/2008/06/05/08-1305/medicare-and-medicaid-programs-hospice-conditions-of-participation.*

[445] *www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c09.pdf.*

[446] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

[447] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-409/subpart-E/section-409.45.*

[448] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-418.*

[449] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-418.*

telecommunications if it was feasible and appropriate to ensure that Medicare patients could continue receiving services that were reasonable and necessary for the palliation and management of a patient's terminal illness and related conditions without jeopardizing the patient's health and or the health of those who are providing such services during the COVID–19 PHE. This amendment only authorized the Secretary to extend this flexibility through December 31, 2024. Additionally, the authors of the Hospice Wage Index Final Rule note that the hospice benefit is best when provided in person and stress the importance of in-person services.[450]

Comment: A commenter expressed support for the IDG changes and suggested that CMS should allow PAs and NPs to substitute in the place of a physician as a required member of the IDG.

Response: We appreciate the commenters support on the IDG provision. We note that the IDG member requirements at § 418.56(a)(1) are statutorily-mandated at section 1861(dd)(2)(B)(i) of the Act. Therefore, there would need to be a change in the law for CMS to amend the hospice regulations in the manner suggested by the commenter.

Comment: One commenter sought additional information regarding HCPCS codes, quality reporting programs, and the hospice cost report. Specifically, this commenter asked if CMS will add HCPCS codes to hospice claims for identification of visits made by MFTs and MHCs. They also asked if there were plans to include MFT and MHC visits in the hospice quality reporting program. Lastly, this commenter asked how hospices should record MFT and MHC visits in the hospice cost report.

Response: We thank this commenter for their thoughtful questions. However, these topics are outside the scope of the CoPs. We will consider this feedback and share it with our CMS colleagues so that it may be taken into consideration in future rulemaking.

b. § 418.56 Condition of Participation: Interdisciplinary Group, Care Planning, and Coordination of Services

At § 418.56(a)(1)(iii) we proposed to require that the IDG must include a social worker (SW), MFT, or MHC depending on the preferences and needs of the patient. Section 4121 of the CAA 2023 specifically modified the statute to require the hospice interdisciplinary team to include one SW, MFT, or MHC. However, we emphasized that each hospice patient and family are different in their needs and goals. We explained how the services SWs, MFTs, and MHCs provide are not interchangeable, and that each offers unique support that may be valuable to the patient and family based on the situation. Therefore, it is important for the hospice to assess and determine what care and services best support the needs of the patient. This information would be included in the individualized patient plan of care in accordance with § 418.56(c), as well as which discipline(s) (SW, MFT, or MHC) will be caring for the hospice patient. We note that the IDG must develop an individualized plan of care for each patient that is based on the needs of the patient, so we expect that the needs of the patient will be addressed regardless of whether a SW, MFT, of MHC serves on the IDG.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concern that CMS was misinterpreting the statute and that the proposed provisions do not align with congressional intent. Specifically, the commenters noted that they do not believe that the patient preferences and needs of the of the patient should drive the IDG membership. These commenters pointed out that the provision in the CAA 2023 was meant to be optional, allowing the choice of which practitioner will sit on the IDG. They stated that making it mandatory would create a significant burden for hospices and be difficult to comply with. Commenters emphasized the use of the word ''or'' in the amended language of the CAA 2023 indicates that the hospice IDG includes at least one SW, one MFT, or one MHC, not all three disciplines. The hospice community interpreted the language in the CAA to mean that hospices have the choice of using a SW, MFT, or MHC, and would not be required to employ or contract with a MFT or MHC. One commenter urged CMS to underscore that it is not a requirement to make them available, even when counseling services are in the plan of care. The commenters emphasized that requiring every hospice to add an MFT or MHC would deprive beneficiaries of access to hospice care. Commenters explained that the statute indicates the disciplines from which a hospice must choose IDG members to, ''provide or supervise the provision of,'' covered hospice services. The commenters noted that the statute does not address the needs and preferences of the patient, and one commenter expressed their belief that CMS was exceeding their statutory authority by adding ''depending on the preferences and needs of the patient'' to this requirement. They explained that their interpretation on the use of this language would require the hospice to have all three disciplines as part of the IDG and that this would eliminate the intended flexibility for hospices to choose the IDG members. They also noted that regulations implementing the statutory language regarding IDG membership have not been connected to patient needs and preferences in the past. Commenters stated it will be necessary to revise the proposed provisions to accurately and completely implement this statutory amendment.

Response: The hospice IDG will only be required to include one SW, one MFT, or one MHC. The hospice is not required to include all three of these professions as members of the IDG. We note that the hospice may choose (although is not required) to select more than one of these professions to serve as member(s) of the IDG. The MFT or MHC must be hired as a direct employee which would include the options of hiring full time, part time or per diem. This may alleviate some of the staffing challenges that hospices may experience by allowing more flexibility in the recruitment and hiring process. In addition, the 2008 hospice final rule (73 FR 32088) implemented section 946 of the MMA (Medicare Modernization Act).[451] In accordance with section 946 of the MMA, a hospice (the primary hospice) may enter into arrangements with another Medicare-certified hospice to obtain core hospice services. The MMA provided that this could be done under extraordinary or other nonroutine circumstances. The Act specifically states ''substantially all'' in recognition of the fact that there are times when hospices must contract for core services. Section 1861(dd)(5)(D) of the Act identifies the circumstances in which hospices are permitted to contract for core services as those that are ''extraordinary'' or otherwise ''nonroutine'' such as unanticipated periods of high patient loads, temporary staffing shortages, and travel of a patient outside of the hospice's service area. The provision at § 418.64(d) requires counseling services to be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the

[450] *https://www.federalregister.gov/documents/2023/08/02/2023-16116/medicare-program-fy-2024-hospice-wage-index-and-payment-rate-update-hospice-conditions-of.*

[451] *https://www.federalregister.gov/documents/2008/06/05/08-1305/medicare-and-medicaid-programs-hospice-conditions-of-participation.*

terminal illness, related conditions, and the dying process. We believe the MFT and MHC primarily provide counseling services and that counseling services are considered core services of the hospice. The ''extraordinary circumstance'' provision is generally a short-term temporary event that was unanticipated. This may allow hospices the flexibility to contract for the MFT or MHC during temporary staffing shortages. If a hospice chooses to contract with another Medicare-certified hospice or a non-hospice entity, the contracting hospice or non-hospice entity must maintain professional management responsibility for the services provided, in accordance with § 418.100(e). During a survey to determine the hospice's compliance with the CoPs, the hospice should be able to explain why it is using the ''extradentary circumstance'' to mitigate the staffing shortages and how it is working towards hiring direct staff. The survey process for Medicare and Medicaid participating hospices provides an opportunity for them to demonstrate compliance with all of the applicable CoPs. The methods used by CMS to determine compliance with the hospice regulations include surveys conducted by a State survey agency and surveys conducted by AOs that have deeming authority for Medicare and Medicaid participating hospices. Currently, the professionals (physician, registered nurse, social worker, pastoral or other counselor) that comprise the IDG are responsible for providing and supervising the provision of the care and services for each patient. The CAA 2023 has now provided hospices with the option to select between multiple professionals. In the past, the IDG structure did not require hospices to distinguish between different disciplines, each with their own unique scope of practice, when determining IDG membership. As stated earlier, and commenters agreed, the services provided by SWs, MFTs, and MHCs are not interchangeable. Each offers unique support that may be valuable to the patient and family based on the situation. For example, a SW may assist the patient and their family with issues regarding finances or connecting the family to valuable community resources. Conversely, therapy and counseling services traditionally may help patients cope with mental distress.

We believe it is important for the hospice IDG to consider the patients' assessed needs to ensure IDG member, whether it be a SW, MFT or MHC, have the appropriate knowledge and scope of practice to share and recommend care options related to the services that patient is receiving or may need. We agree the hospice has the choice to select either a SW, MFT or MHC. We also understand that hospice may have IDG team members pre-selected to serve on specific teams, and it may be administratively impractical to change a member based on the needs of one patient. Therefore, we are not finalizing the requirement that the SW, MFT, or MHC be a member of the IDG ''based on the needs and preferences of the patient.'' While we are modifying the proposed requirement, we stress that hospices have always had the option to have non-IDG staff that provide care for the patient to attend the IDG meetings to share patient status, issues/concerns, and recommendations. For example, if the patient is receiving care and services from a SW and MFT, and the MFT is the designated member of the IDG; the SW could attend the IDG meeting and provide the IDG team with updates related to social work services. Additionally, if the patient is receiving volunteer services, the volunteer may attend the IDG meeting to share information that will assist with informing the plan of care.

The provisions at § 418.56(e) requires the hospice to develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures. The provision also requires the hospice IDG to maintain responsibility for directing, coordinating, and supervising the care and services provided; ensure that the care and services are provided in accordance with the plan of care (which is based on the needs of the patient); ensure that the care and services provided are based on all assessments of the patient and family needs, and to provide for and to ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.[452] The hospice model has always been based on an interdisciplinary care model, which requires frequent communication between care disciplines across settings, as well as between the hospice, the patient and the family. The hospice relies on communication between and integration of providers to effectively plan and furnish care to patients and families. Over time, hospices have developed methods within their policies and procedures to ensure that all members of a patient's care team receive timely information about patients. Therefore, we expect that the hospices' ''system of communication'' would include how information is communicated and shared during the IDG meetings; ensuring pertinent patient care information from each discipline caring for each patient are communicated with the IDG, according to the hospices own policies.

Comment: Several commenters shared their support for the inclusion of the MFT and MHC in the interdisciplinary group and in the personnel qualifications. A few commenters stated they appreciate CMS' acknowledgment of the importance of collaborative decision-making between provider, client, and family in providing the best care aligned to that patient's needs and preferences. Beneficiaries' access to robust care provider options to meet their needs is pivotal in providing quality care, during what can be a particularly difficult time, and help to decrease distress. Another commenter supported the proposed changes and suggested that additional information regarding implementing these provisions be included in the State Operations Manual/interpretive guidance. This commenter also sought guidance on whether the hospice would need to document their decision-making process in selecting which practitioner (MFT, MHC, or SW) will serve as a member of the IDG, as they consider the patient's needs and preferences. The commenter stated that this could lead to an additional administrative burden.

Response: We thank the commenters for their support of these new proposals. Additional information regarding the implementation and execution of these proposals will be provided in the hospice interpretive guidance, which will be published following the publication of this final rule. It is important for the hospice to assess and determine, along with the input from the patient and family, which care and services are most appropriate/ensure the health and safety of the patient. Therefore, we expect that during the care planning process, the hospice IDG would consider the patient's needs and preferences will provide services to meet the needs of the patient. As stated earlier, the information from the patient's assessment would be included in the individualized patient plan of care, as well as which professional(s) (SW, MFT or MHC) will be caring for the hospice patient.

Comment: Several commenters found the language ''at least one social worker, MFT, or MHC'' in the proposed rule unclear. This language led these commenters to seek clarification regarding whether the hospice IDG must

[452] *https://www.federalregister.gov/documents/2008/06/05/08-1305/medicare-and-medicaid-programs-hospice-conditions-of-participation.*

include a SW and MFT, SW and MHC, all three professionals, or just one of these professionals. Additionally, a few comments shared that it was their interpretation that the addition of the MFT and MHC was optional, not mandatory.

Response: The statutory language of division FF, section 4121 of the CAA 2023 states that section 1861(dd)(2)(B)(i)(III) of the Act (42 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by inserting ', marriage and family therapist, or mental health counselor' after social worker,'' and that, ''The amendments made by this section shall apply with respect to services furnished on or after January 1, 2024.'' This language clarifies that hospices have the ability to discern which professional to choose to serve as a member of the IDG. The language ''at least'' was used in the proposed rule to qualify that there must be, at minimum, one of these three professionals who serve as members of the IDG. As previously discussed, we emphasize the hospice interdisciplinary care model, which relies on communication between and integration of providers to effectively plan and furnish care to patients and families.

Comment: Many commenters concurred with CMS that the needs, preferences, and goals of each hospice patient and family should be considered when determining which professional (SW, MFT, or MHC) should serve on a hospice IDG. Commenters also noted that grief and bereavement counseling that hospice patients and their families may need should be from a counselor with a master's or higher degree and should be distinguished from the case management services provided by social workers on a hospice interdisciplinary team. Further, the commenter stated these different types of supportive services may both be needed, and hospice programs should be encouraged to ensure access to both, to the extent possible.

Response: We appreciated the commenters support on this provision. We note that bereavement counseling is out of scope for this rule and is a separate requirement in the hospice CoPs at § 418.64(d)(1). The bereavement counseling provision requires the hospice to have an organized bereavement program furnished under the supervision of a qualified professional with experience or education in grief or loss counseling. We note the commenters recommendations and will consider this for future rulemaking.

Comment: One commenter noted that MFT and MHC services may potentially be needed more often in areas with larger populations.

Response: We thank the commenter for providing insight into areas that will benefit from our proposed provisions. We believe all populations, including areas with larger populations, may benefit from MFT and MHC services.

Comment: We received one comment that discussed that the MFT and MHC are not defined as ''non-core services'' like physical therapy, occupational therapy, and speech-language pathology, which are defined at § 418.70. The commenter noted that these ''non-core'' services have clearly defined expectations for hospices in contracting and providing services, including waivers for when the professionals are not available in a hospice's service area.

Response: We are aware that hospices in rural areas experience challenges in recruiting and retaining staff and that there is a shortage of behavioral health providers. Hospices have the option to directly employee MFTs and MHCs full time, part time or per diem, which provides additional flexibility to the hospice in their recruitment and hiring practices. This may help to hire the most qualified professionals, as well as increase employee retention. Further, § 418.74 allows hospice to waive the requirement to provide physical therapy, occupational therapy, speech-language pathology, and dietary counseling 24 hours a day for hospices located in non-urbanized areas. This waiver does not eliminate the requirement that the hospice must provide these services, it waives the requirement to provide the services 24 hours a day. At this time, we are not proposing revisions to these ''non-core services'' CoPs but will consider this for future rulemaking.

Comment: Several commenters were concerned about the enforcement of these provisions. These commenters asked if there would be consequences if the hospice is unable to comply with these regulations.

Response: We acknowledge that there is an increased need for behavioral and mental health services. However, we understand that many regions, particularly rural areas, may not be able to fulfill this need. We will follow the standard survey and enforcement process and additional information regarding the implementation of these provisions will be available in interpretative guidance that will be published following the publication of this final rule.

After consideration of public comments on this provision, we are finalizing the proposed requirements with modification at § 418.56 by removing the phrase ''depending on the preferences and needs of the patient.'' We believe this modification will provide additional flexibility for the hospice to choose the members of the IDG while also utilizing the hospice's system of communication (§ 418.56(e)) to ensure information is communicated during the IDG meetings, according to the hospices own policies.

The inclusion of an MFT or MHC as members of the hospice IDG helps to provide hospices with greater flexibility in IDG membership in meeting the mental health needs of their patients. The provisions support our responsibility to protect patient health and safety by encouraging the patients' and their family members to act as active participants in decision-making processes. We believe that this action strengthens our response to the need for increased access to behavioral and mental health services.

b. Personnel Qualifications (§ 418.114)

With the introduction of MFT and MHC into the hospice CoPs, it is important to also include these new disciplines into the personnel qualifications at § 418.114. Currently the requirement at § 418.114 establishes the requirements for several disciplines that work in hospices including but not limited to social worker, registered nurse and the therapist. We proposed to add both MFT and MHC to the provider requirements under 42 CFR subpart B, Medical and Other Health Services at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the Medical and Other Health Services requirements, we proposed to add both MFT and MHC to the requirements as new standards at § 418.114(c)(3) and (4) and reference the new requirements at §§ 410.53 and 410.54, respectively.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters shared their support for the inclusion of the MFT and MHC in the personnel qualifications.

Response: We thank this commenter for their support for the inclusion of MFT and MHC in the hospice personnel requirements. We believe this provision will help support the introduction of MFTs and MHCs to hospice.

Comment: One commenter that suggested that the MFT and MHC should be cited at § 418.114(a) instead of the proposed § 418.114(c). This commenter clarified that this change is needed to ensure that MFTs and MHCs

can effectively serve as hospice providers.

Response: We thank the commenter for bringing this to our attention and we agree that it would be more appropriate for the MFT and MHC personnel requirements to be located at a different regulation citation to accurately reflect the licensure requirements for these professions. However, we believe it is more appropriate to redesignate the proposed personnel requirements at § 418.114(b)(9) and (10) with the personnel qualifications for certain disciplines in order to reflect the State licensure requirements that the MFT and MHC have. We have collaborated with our colleagues to accurately align the personnel requirements for the MFT and MHC with the proposed definitions for these professions at §§ 410.53 and 410.54.

Comment: One commenter noted that States define MFTs and MHCs differently, and that this may result in hospices being unable to utilize MFTs and MHCs in some States.

Response: We refer to the definitions of the MFT and MHC at §§ 410.53 and 410.54. If State requirements for MFT and MHC are stricter than our Federal requirements, then those stricter State requirements would take precedence. If State requirements are less stringent than Federal requirements, then the Federal requirements will take precedence. We believe that the scope of this final rule are the minimum health and safety requirements with which facilities could reasonably be expected to comply.

After consideration of the public comments we received, we are finalizing this provision with modification by redesignating the personnel qualifications at § 418.114(c)(3) and (4) to § 418.114(b)(9) and (10) referencing requirements at §§ 410.53 and 410.54, respectively. The inclusion of an MFT and MHC in the personnel requirements will clarify for hospices the qualifications required for MFT and MHC.

P. Request for Information: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

1. Background

The Clinical Laboratory Improvement Advisory Committee (CLIAC), CMS, interested parties, and State Agency (SA) surveyors have identified areas in the CLIA requirements that may need updating.

a. Histopathology

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578, October 31, 1988) regulations related to histopathology have not been updated since 1992. The current Histopathology requirements may not represent new innovations and technology performed in laboratories.

(1) Slide Preparation and Staining

Facilities only collecting or preparing specimens (or both) or only serving as a mailing service but not performing testing are not considered laboratories [453]. Slide staining and tissue processing have not been subject to the CLIA regulations. However, we received inquiries from interested parties stating that slide staining and tissue processing are an essential part of the testing process for histopathology. Absent these steps, the tissue cannot be prepared, mounted onto a slide, or accurately evaluated by a pathologist to make an assessment for diagnosis.

Slide staining in histopathology includes routine Hematoxylin and Eosin (H&E) staining, special stains, and immunohistochemical (IHC) stains. Routine slide staining in histopathology provides simple cellular identification and requires minimal steps with solutions, dyes, and clearing reagents (for example, Hematoxylin & Eosin stains, Giemsa stain). An individual trained under the supervision of a qualified technical supervisor can perform these staining techniques. An independent facility (for example, a processing center, that performs slide staining) is not required to hold a CLIA certificate. IHC stains are complex stains designed to identify specific antigens and targets within the cells. These targets can include ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) specific reactivity. The U.S. Food and Drug Administration (FDA) has categorized instruments that perform automated IHC staining as high complexity. Therefore, individuals that perform IHC staining in a CLIA certified laboratory (for example, histotechnicians, histotechnologists, and pathology assistants) must meet the personnel requirements for facilities carrying out high complexity testing. The facility must also hold a CLIA certificate in the subspecialty of testing performed.

(2) Gross Tissue Examination Review

Testing in histopathology includes both gross tissue examination (macroscopic) and the microscopic evaluation of the stained slide(s) with evaluation and diagnostic interpretations, and the reporting of diagnostic findings by qualified personnel. Gross examination means the manipulation, orientation, and selection of the desired representative pieces of excised tissue from the total specimen received. This includes the physical examination and description, color, weight, measurements, and other characteristics of the tissue. Selected portions of the tissue are placed into a tissue cassette, subjected to a fixative, processed and infiltrated with paraffin wax, placed onto a slide(s), and stained before being reviewed and evaluated by a technical supervisor.

The CLIA State Operations Manual (SOM), Appendix C (''Interpretive Guidelines'')[454] for 42 CFR 493.1489(b)(7) state that gross examinations may be performed by individuals qualified under § 493.1489 as delegated by the technical supervisor. The technical supervisor is not required to provide on-site supervision, but is responsible for the review, accuracy, and confirmation of the macroscopic gross examination in the patient report. The documentation of the review of the results of the macroscopic gross examination by the technical supervisor must be included in the signed microscopic examination report, as required at § 493.1273(d). The CLIA regulations do not cover the acceptable timeframe in which the review of the gross tissue examination must be completed. The discussion surrounding the review of the gross tissue examination includes CLIA's oversight at this phase of the histopathology testing process. CLIA supports an acceptable timeframe to permit a pathologist to review the tissue specimen prepared during the gross examination by a qualified technical supervisor. This review can be delegated by the technical supervisor to a qualified individual. Gross examination is a critical part of the tissue analysis process to ensure subsequent pathology tests are accurate and reliable. The review of the gross tissue is important to protect the patient's specimen identification during the testing process.

b. Cytology

(1) CLIA Statute and Regulations

CLIA revised section 353 of the Public Health Service Act (42 U.S.C 263a) to authorize the regulation of all clinical

[453] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2.*

[454] CLIA Interpretive Guidelines: *https://www.cms.gov/regulations-and-guidance/legislation/clia/interpretive_guidelines_for_laboratories.*

laboratories. Section 353(4)(B)(vi) of the Public Health Service Act requires that all cytological screening be done on the premises of a laboratory that is certified under this section.

The CLIA regulations for cytology state that cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology at § 493.1274(a).

(2) Clinical Laboratory Improvement Amendments (CLIA) Guidance for Temporary Testing Sites Under the Multiple Site Exception [455], CMS Policy Memo (QSO–22–13–CLIA)

The intent of the CLIA program is to ensure that test results provided to individuals and their healthcare providers are accurate, timely, and reliable. During the COVID–19 public health emergency (PHE), we issued memo QSO–22–13–CLIA that informed interested parties that we exercised enforcement discretion to allow pathologists the ability to examine histopathology and cytology slides/images remotely, under the following conditions:

- The primary laboratory's CLIA certificate must include the specialty of pathology with the subspecialties of histopathology and cytology, as appropriate.
- The remote location complies with other applicable Federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- The primary laboratory's written procedure manuals for tests, assays, and examinations are available to the pathologists at the remote location.
- Retention time for histopathology slides (10 years), specimen blocks (2 years), preserved tissue remnants (until a diagnosis was made), and cytology slides (5 years) were maintained.
- The use of equipment, supplies and reagents, and similar items needed at the remote location are not allowed to be permanently stored on site.

Under the memorandum, QSO–22–13–CLIA, the remote location could allow pathologists the opportunity to examine histopathology and cytology slides during the PHE.

Pathologists that held a current CLIA certificate were exempt from this enforcement discretion. The pathology community has expressed their desire to make this enforcement discretion a permanent provision after the end of the PHE for COVID–19.

c. Clinical Cytogenetics

We require any testing facility that meets the CLIA regulatory definition of a ''laboratory'' (per § 493.2, *Definitions* [456]) to have a CLIA certificate. A laboratory may choose to outsource a test or a portion of their test procedure because it lacks the equipment, personnel with the expertise in the subject, or is considered more cost-efficient. The CLIA regulations at § 493.1242(c) require the laboratory to only refer a test (for example, reflex, confirmatory, or distributive testing) to another laboratory that is CLIA certified or to a laboratory meeting equivalent requirements as determined by CMS. Therefore, each laboratory or testing facility that performs clinical testing must have its own CLIA certificate and comply with the regulations for the complexity of the testing it performs.

Clinical cytogenetics testing is generally categorized as a CLIA high complexity test. A cytogenetics test may be conducted at one facility or involve a testing workflow model in which one facility performs the analytical bench testing activities (for example, sample processing, extraction, chemical reaction, slide preparation, imaging) and another facility conducts the non-bench testing activities (for example, review of images, analysis, interpretation or reporting of the results). When any part of a test is performed by more than one facility, this testing model is considered distributive testing. CLIA defines distributive testing under § 493.2, *Definitions,* as ''laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.'' Therefore, any facility performing clinical cytogenetics testing activities must be CLIA certified and meet high complexity testing requirements.

During the PHE for COVID–19, we exercised enforcement discretion regarding clinical cytogenetics distributive testing models. Under the enforcement discretion, we allowed clinical cytogenetics personnel the opportunity to examine clinical cytogenetics digital images (that is, non-bench testing activities) at a remote testing location without obtaining a separate CLIA certificate for the remote site under certain conditions. Some interested parties have requested we make this enforcement discretion permanent. Changes to the current CLIA regulations would be necessary to allow the examination of clinical cytogenetics images at a different, remote location from the primary CLIA-certified site without a separate CLIA certificate. Please note that a remote location not associated with or covered by a primary CLIA-certified laboratory would be required to obtain its own CLIA certificate. The primary site laboratory director would be responsible for the overall operation and administration of the laboratory including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently; for assuring compliance with applicable regulations in their primary laboratory; and for the supervision of the personnel reviewing digital laboratory data, digital results, and digital images remotely.

2. Solicitation of Public Comments

We solicited comments on the following areas of CLIA: Histopathology; Cytology; and Clinical cytogenetics. The topics listed in this RFI are areas that CMS, CDC, interested parties, and SA surveyors have identified that may potentially be used by CMS for future rulemaking.

a. Histopathology

We solicited comments on the following:

- Whether, and how, CLIA should provide oversight of histopathology preparation and processing of tissue samples for slide staining, specifically related to guidance for routine histopathology slide staining and complex IHC staining.
- What criteria (for example, training programs, on-the-job training, experience, or academic degree) would interested parties recommend for personnel performing high complexity automated IHC staining?
- How does the categorization of automated staining systems impact personnel who are currently performing this task but do not meet the qualifications for performing high complexity testing?
- What is an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue?

[455] QSO–22–13–CLIA: *https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-guidance-temporary-testing-sites-under-multiple-site.*

[456] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2.*

• What education and experience or training requirements should be required for individuals to qualify as a general supervisor (GS) for histopathology? If qualified, what is an acceptable timeframe for the GS to review and evaluate gross examinations under the specialty of histopathology?

• What education and professional experience, or training requirements should be required for individuals performing gross tissue examination that have an associate degree from a histotechnician program or a PA who has training from an accredited program and is certified as a PA?

b. Histopathology and Cytology Testing at Remote Locations

We solicited comments on the following:

• How should ''remote testing location'' be defined?

• How should the CLIA regulations be revised to allow pathologists to examine histopathology and cytology slides/images at a remote testing location?

• What conditions (including, location(s)) should apply for a pathologist to examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification?

• Under what conditions should a primary location cease permitting testing at the remote location?

• How should the remote location be included on the final patient report?

• How should CMS, SAs, or Accreditation Organizations perform onsite surveys at remote locations?

c. Clinical Cytogenetics

We solicited comments on the following:

• Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?

• Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?

• What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?

• What ''conditions'' or ''criteria'' would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

We thank the commenters for their submissions. We received 52 comments.

Commentors were in favor of updating the CLIA '88 regulations in Histopathology, Cytology, and Clinical cytogenetics to reflect advancements in technology and current laboratory practices. We will consider the input received as we continue to evaluate possible future changes to the CLIA regulations.

Q. Changes to the Basic Health Program Regulations

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act or ACA), provides States with the option to operate a Basic Health Program (BHP). In the States that elect to operate a BHP, the State's BHP makes affordable health benefits coverage available for lawfully present individuals under age 65 with household incomes between 133 and 200 percent of the Federal poverty level (or in the case of a lawfully present non-citizen, ineligible for Medicaid or the Children's Health Insurance Program (CHIP) due to immigration status, whose household income is between zero and 200 percent of the FPL) who are not eligible for Medicaid, CHIP, or other minimum essential coverage. As of the date of this final rule, only New York and Minnesota have implemented a BHP.

Federal funding for BHP is based on 95 percent of the value of the premium tax credits (PTC) and cost sharing reduction (CSR) subsidies that BHP enrollees would have received had they instead enrolled in Qualified Health Plans (QHPs) through the Exchange in accordance with section 1331(d)(3)(A)(i) of the ACA. These funds are paid to trusts established by the States and dedicated to the BHP, and the States then administer the payments to BHP standard health plans within the BHP. Under section 1331(d)(2) of the ACA, Federal funding for the BHP can only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within the State.

1. Allowing States To Suspend a BHP

Current regulations require States to operate a BHP under a certified Blueprint approved by CMS, and to operate the BHP as long as their approved certified Blueprint is in place. Under 42 CFR 600.140, a State may terminate its BHP, which requires that the BHP trust fund balance be refunded to the Federal government. The regulations do not contemplate ''suspending'' a BHP, and, as such, in the CY 2024 PFS proposed rule, we proposed to give a State the option of temporarily suspending its BHP program, while retaining funds that were accrued prior to suspending the program in the BHP trust fund for a limited period of time. Specifically, we proposed at § 600.140(b)(1) that States wishing to suspend their BHP program must submit an application to HHS. Under proposed § 600.140(b)(1), States could also seek approval to extend a BHP suspension previously approved by HHS. In § 600.140(b)(1)(vi), we proposed that the application must be submitted at least 9 months in advance of the proposed effective date of the suspension or extension. However, for States seeking to suspend a BHP in the first plan year that begins following publication of a final rule adopting this proposal, we proposed that States must submit an application within 30 days of the publication of such a final rule and HHS would approve or deny such application as expeditiously as possible. We proposed in § 600.140(b)(2) that a suspension application would need to be approved prior to the effective date of suspension, except in the case of a State seeking to suspend a BHP in the first plan year that begins following publication of a final rule adopting this proposal.

The proposed substantive requirements for the suspension application are described in proposed § 600.140(b)(1)(i) through (v). Under the proposed requirements, for the period of suspension, BHP enrollees must receive comparable coverage that is as comprehensive and affordable as, or more comprehensive and affordable than, BHP coverage during the period of suspension. Therefore, in § 600.140(b)(1)(i) through (iii), we proposed to require that the suspension and extension application demonstrates that the benefits that would be provided to individuals that meet the BHP eligibility criteria are at least equivalent to the benefits offered in the State's BHP. We proposed that the cost sharing and premiums that would be charged to such individuals under the new coverage option could not exceed the amounts charged under the BHP to reduce the risk that these individuals are harmed by the transition to other coverage.

Finally, in developing our proposal we believed that the suspension period should not result in individuals losing coverage solely due to a change in eligibility criteria for the program. Therefore, we proposed in § 600.140(b)(1)(iv) that a State must demonstrate in its application that the eligibility criteria for coverage during

the suspension would not more restrictive than the criteria described in § 600.305.

We believed that the suspension period should be long enough to allow the State to evaluate the alternative coverage provided to BHP-eligible individuals but should not be indefinite. Therefore, we proposed in § 600.140(b)(1)(v) that a State could request a suspension of up to 5 years in an initial suspension application, after which a State could request an extension of up to 5 additional years. Additional extension periods would not be allowed. We proposed at § 600.140(b)(7) that at least 9 months before the end of the suspension period, a State would be required to submit a transition plan to HHS that explains how the State would reinstate its BHP, or terminate the program under § 600.140(a) of the current regulations.

Under proposed § 600.140(b)(1)(vii), States requesting an extension of a previously-approved BHP suspension also would need to provide an evaluation of the alternative coverage in its application.

If individuals and/or standard health plans would experience a change in the terms of the coverage, including receiving additional benefits or being charged different cost sharing amounts, in § 600.140(b)(3), we proposed to require that the State provide notice to them at least 90 days prior to the effective date of the suspension. The notices would need to include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State, and meet the accessibility and readability standards at 45 CFR 155.230(b).

We proposed to require in § 600.140(b)(4) that States that suspend their BHP must submit the data necessary to complete the BHP payment reconciliation process within 12 months of the effective date of the suspension. We believed that 12 months was a reasonable amount of time for a State to submit the actual enrollment data for the periods it was operating a BHP.

We proposed in § 600.140(b)(6) that while the State is not providing BHP coverage, any accrued interest on the trust fund would have to be remitted to HHS on an annual basis in the form and manner set out by HHS.

States currently submit the balance of their trust fund and any interest accrued through the BHP annual report described in § 600.170. We proposed revisions to §§ 600.140(b) and 600.170(a) to require States that suspend their BHP continue to submit an annual report in order to document the interest earned and to provide assurance that the coverage provided to BHP-eligible individuals meets the standards discussed previously in this section.

If a State does not meet the proposed requirements (that is, completing the financial reconciliation process, remitting interest on the trust fund, continuing to meet the standards that the alternative coverage provides coverage as comprehensive and affordable as the BHP, and submitting the required information in its annual report), we proposed in § 600.140(d), redesignated as § 600.140(c) in this final rule, that the Secretary could withdraw approval of the suspension. We received four public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported allowing States to suspend their BHP, with some commenters mentioning specific changes they would like to see which are discussed later in this section. One commenter noted that flexibility to suspend a BHP while maintaining the trust fund may encourage more States to consider implementing a BHP.

Response: We appreciate the commenters support of our proposal, and for reasons discussed below, we are finalizing the regulation changes as proposed, with only minor modifications.

Comment: One commenter suggested that CMS require States to outline in the application for suspension a plan to notify physicians who provide care to BHP enrollees about the suspension; share information with physician practices and other clinicians and facilities about how and where patients will receive or can seek alternative comprehensive, affordable coverage; and work with physician practices to minimize any resulting administrative burden.

Response: We appreciate this commenter's suggestion. While we will not be requiring States to provide a specific plan to notify physicians who provide care to BHP enrollees about the suspension in the suspension application, we anticipate informally asking States for how they will notify providers, including physicians, of this change. We will encourage States to communicate any changes that may impact patient care networks to providers. We proposed and are finalizing a requirement that would apply if individuals and/or standard health plans will experience a change in the terms of the coverage during the suspension, including receiving additional benefits or being charged different cost sharing amounts, States would be required to provide notice to them at least 90 days prior to the effective date of the suspension. We also proposed and are finalizing that BHP enrollees must receive comparable coverage that is as comprehensive and affordable as, or more comprehensive and affordable than, BHP coverage during the period of suspension. Therefore, as individuals will be receiving coverage that is as comprehensive and affordable as the BHP coverage, and will have been notified at least 90 days prior to the effective date of the suspension of any changes, we do not believe it necessary to require that States explicitly provide information to physicians regarding where individuals can receive alternative care.

Comment: One commenter specifically requested that CMS require that the Secretary must approve an application for the suspension of BHP submitted by the State.

Response: We proposed in § 600.140(b)(2) that the State could not implement the suspension or extension of the suspension without prior approval by the Secretary, unless the State is proposing to suspend their BHP in the first plan year following publication of such a final rule. Additionally, for States seeking to suspend a BHP in the first plan year that begins following publication of a final rule adopting this proposal, we proposed that States must submit an application within 30 days of the publication of such a final rule and that HHS would approve or deny such application as expeditiously as possible. We are finalizing this requirement as proposed, with minor modifications.

We are finalizing the requirement that a State cannot implement the suspension or extension of the suspension without prior approval by the Secretary unless the State is proposing to suspend their BHP in 2024. This is a minor change from the proposed regulation, which stated that a State cannot implement a suspension or extension of a suspension without prior approval by the Secretary, unless the State is proposing to suspend their BHP in the first plan year after this rule is finalized. We are finalizing that, for States proposing to suspend their BHP in 2024, the suspension application must be submitted within 30 days of the effective date of this final rule. This is a minor change from the proposed regulation, which stated that a State proposing to suspend their BHP in the first plan year after this rule is finalized, must submit their suspension

application within 30 days of publication of the final rule.

Comment: One commenter specifically requested that CMS establish requirements for States to ensure safeguards are in place for individuals that are enrolled in BHP. Another commenter noted support for the proposal to ensure formerly BHP-eligible consumers are not subject to more restrictive eligibility rules under an alternative coverage plan while the BHP is suspended.

Response: We share the commenters' desire to ensure there are safeguards for individuals that are enrolled in BHP. We proposed in § 600.140(b)(1)(i) through (iii), that, during the period of suspension, former BHP enrollees should receive coverage that is as comprehensive and affordable as, or more comprehensive and affordable than, BHP coverage during the period of suspension. Specifically, we proposed to require that the suspension and any suspension extension applications demonstrate that the benefits that will be provided to individuals who meet the BHP eligibility criteria are at least equivalent to the benefits offered in the State's BHP. We also proposed that the cost sharing and premiums that will be charged to such individuals under the new coverage option do not exceed the amounts charged under the BHP to reduce the risk that these individuals are harmed by the transition to other coverage. We are finalizing these requirements as proposed.

Comment: One commenter suggested that States be allowed to suspend their BHP beyond 10 years, if the circumstances in States could reasonably justify longer suspension periods, subject to CMS approval.

Response: We appreciate the commenter's suggestion, but we believe that our proposal to allow a suspension for 5 years with a one-time extension of an additional 5 years, is sufficient time for a State to evaluate whether or not it should resume its BHP. As discussed in the proposed PFS rule, we chose 5 years for the initial approval period because this aligns with the duration of initial waivers and demonstration projects approved under section 1332 of the ACA and section 1115 of the Act. We believe these are the most likely authorities under which States could seek to provide alternative coverage to BHP enrollees. Similarly, we chose 5 years for the extension period because it aligns with the duration of typical extensions or amendment periods under section 1332 waiver and section 1115 demonstration projects.

Comment: One commenter suggested that if a State proposes to suspend its BHP and implement a section 1332 waiver, that the State be allowed to leverage relevant parts of their section 1332 waiver application and actuarial and economic analysis to provide the necessary supporting evidence for their BHP suspension application since aspects of the 1332 application serve a similar purpose.

Response: We believe it is likely a State would be able to use relevant parts of its section 1332 waiver application and actuarial and economic analysis to provide supporting evidence for the BHP suspension application. As discussed in the CY 2024 PFS proposed rule, to determine that the cost sharing required of individuals under the new coverage option does not exceed the BHP cost sharing levels, we proposed at § 600.140(b)(1)(ii) to require that the actuarial value of the new coverage option must meet or exceed the actuarial value of the BHP standard health plans in effect immediately prior to the suspension period. If there are multiple health plans being offered under the new coverage option and/or multiple standard health plans in effect in the State, we proposed that the median actuarial value of the health plans offered under the new coverage option must meet or exceed the median actuarial value of the BHP standard health plans. To the extent this information is required for the State's 1332 waiver application, it could also be utilized for the suspension application and be submitted as part of the suspension application.

Comment: One commenter recommended that States be required to submit only the sections of the BHP Annual Report pertaining to financial management and audit findings while the BHP is suspended.

Response: In the CY 2023 PFS proposed rule, we proposed to add a new paragraph § 600.170(a)(2) to require that States that have suspended their BHP under § 600.140(b) submit an annual report that includes (1) the balance of the BHP trust fund and any interest accrued on that balance; (2) an assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 continues to meet the standards described in § 600.140(b)(1)(i) through (iii); and (3) any additional information specified by the Secretary at least 120 days prior to the date that the annual report is due. We believe it is important for States to continue to provide assurances that any coverage changes under the alternative program continue to meet the BHP suspension requirements.

Comment: One commenter requested that States be allowed to use BHP trust funds for the duration of the suspension on, at a minimum, the same uses that were permissible when BHP-eligible consumers were still enrolled in the BHP, and not the alternative coverage program.

Response: As discussed in the CY 2024 PFS proposed rule, under section 1331(d)(2) of the ACA and current regulations at § 600.705(c), Federal funding for BHP can only be used to reduce the premiums and cost-sharing, or to provide additional benefits, for BHP-eligible individuals enrolled in standard health plans within the State. When a State suspends its BHP, individuals will no longer be enrolled in standard health plans. Therefore, Federal funding is not available for costs associated with providing new coverage after the transition has occurred.

After consideration of public comments, we are finalizing the requirements for a suspension of a State's BHP as proposed, with minor changes. We are removing proposed paragraph § 600.140(c), because it was duplicative of the requirement in proposed § 600.140(b)(2). As such, proposed paragraph § 600.140(d) is redesignated to § 600.140(c) in this final rule.

We are finalizing the requirement that a State cannot implement the suspension or extension of the suspension without prior approval by the Secretary unless the State is proposing to suspend their BHP in 2024. This is a minor change from the proposed regulation, which stated that a State cannot implement a suspension or extension of a suspension without prior approval by the Secretary, unless the State is proposing to suspend their BHP in the first plan year after this rule is finalized. We are finalizing that for States proposing to suspend their BHP in 2024, the suspension application must be submitted within 30 days of the effective date of this final rule. This is a minor change from the proposed regulation, which stated that a State proposing to suspend their BHP in the first plan year after this rule is finalized must submit their suspension application within 30 days of publication of the final rule.

2. Submission and Review of BHP Blueprints

In developing the BHP proposals included in the proposed rule, we determined that additional parameters were necessary to ensure effective and efficient operation of the BHPs and HHS review of a revised Blueprint, consistent with section 1331(a)(1) of the ACA. Therefore, we proposed changes to § 600.125 to establish timeframes and

procedures for the submission and review of BHP Blueprints, similar to the Medicaid and CHIP State plan amendment (SPA) submission and review processes. We noted that these proposed timeframes only apply to the submission and review of revised Blueprints; we did not propose changes to the timeframes for the submission and review of an initial Blueprint, set forth in current regulations at § 600.120, in the event additional States seek to establish BHPs.

Additionally, we believed States needed flexibility to receive approval of a retroactive effective date for changes to their BHP Blueprint, similar to flexibilities allowed under regulations at §§ 430.20(b) and 457.60 for the submission of Medicaid and CHIP SPAs. We noted, that in the event that a State implements a change to its BHP Blueprint that is ultimately disapproved by HHS, the State could be required to implement a corrective action plan under § 600.715.

Specifically, under existing regulations at § 600.125(a), States must submit a revised Blueprint whenever they seek to make significant change(s) that alter program operations the BHP benefit package, enrollment, disenrollment and verification policies described in its certified BHP Blueprint. Under the proposed revisions to § 600.125(a), we would broaden the circumstances requiring submission of a revised Blueprint to include States' significant changes that alter any core program operations under § 600.145(f). States also would be required to submit a revised Blueprint to HHS whenever necessary to reflect changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in their certified Blueprint. States would continue to be required to submit a revised Blueprint to make changes to the BHP benefit package or to enrollment, disenrollment, and verification policies described in the certified Blueprint, as currently required under § 600.125(a).

At § 600.125, we also proposed to redesignate paragraph (b) as paragraph (d) and to add new paragraph (b) to provide that the effective date of a revised Blueprint may be as early as, but not earlier than, the first day of the quarter in which an approvable revision is submitted to HHS. This policy mirrors the standards for submission of a Medicaid SPA at § 430.20(b). The current regulations do not specify as to when a revised Blueprint is considered received by HHS. We believe that it is reasonable to consider a revised Blueprint to be received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes indicated in track changes. In the event a State is unable to submit a revised Blueprint electronically, due to a disaster or other event outside of the State's control, we proposed that CMS could consider other modes of submission on a case-by-case basis. Under current regulations at § 600.125(b), redesignated at § 600.125(d) in the proposed rule, the State is responsible for continuing to operate under the terms of the existing certified Blueprint until the State adopts a revised Blueprint, the State terminates or suspends the BHP, or the Secretary withdraws certification for the BHP.

We also proposed to redesignate paragraph (c) of current § 600.125 as paragraph (g) and to add a new paragraph (c) to create clear timelines for HHS's review, approval, and disapproval of revised Blueprints similar to the timelines currently applicable to CHIP SPAs under § 457.150. Under proposed § 600.125(c)(1), a revised Blueprint would be deemed approved unless HHS, within 90 days after receipt of the revised Blueprint, sends the State written notice of disapproval or written notice of additional information HHS needs in order to make a final determination. If HHS requests additional information, the 90-day review period would be stopped and would resume the day after HHS receives all of the requested additional information from the State. Under proposed paragraph (c)(2), if 90 days from the date a Blueprint revision is received does not fall on a business day, the 90-day review period would end on the next business day. Under proposed paragraph (c)(3), HHS may send written requests for additional information as many times as needed to obtain all information necessary to certify the revised Blueprint. This mirrors the process used by CHIP, of having one 90-day review period that can start and stop multiple times with a request for additional information and response. This process differs from Medicaid, which has a 90-day review period that can be stopped once by a request for additional information, followed by a second 90-day review period when the State responds. At paragraph (c), we proposed that HHS may disapprove a Blueprint amendment if the Secretary determines that the Blueprint revision is not consistent with section 1331 of the ACA or the regulations set forth in this part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

Once a Blueprint is approved, current § 600.125(b) specifies that the State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless a revised Blueprint that seeks to make significant change(s) is certified, as described in paragraph (c), except during a public health emergency. We proposed to revise paragraph (b) of § 600.125, redesignated as paragraph (d) in this rulemaking, redesignated as paragraph (d) in this rulemaking, to provide that the State must continue to operate under the terms of an existing certified Blueprint until the State adopts a revised Blueprint, terminates the BHP following the procedures described in § 600.140(a), suspends the BHP following the procedures described in § 600.140(b), or the Secretary withdraws certification of the BHP under § 600.142.

Finally, we proposed to apply some of the existing parameters for initial Blueprint submissions to Blueprint revisions. In paragraph (e), we proposed that a State may withdraw the proposed revised Blueprint during HHS review if the State has not yet implemented the proposed changes and provides written notice to HHS. This proposal mirrors current § 600.130 for initial BHP Blueprints. In paragraph (f), we proposed that HHS will accept a State's request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against standards for certification if requested. This proposal mirrors current § 600.135(c) for initial BHP Blueprints.

Under current § 600.135, HHS must act on all initial BHP Blueprint certification and revision requests in a timely matter. Because we proposed to specify timeframes for the submission and review of revised BHP Blueprints under § 600.125, we proposed to revise § 600.135 to apply only to the submission of initial BHP Blueprints. Specifically, we proposed to revise the title to clearly state that this section is applicable to only initial Blueprints and to remove the reference to BHP Blueprint revisions in paragraph (a).

For a full discussion of this proposal, please see the CY 2024 PFS proposed rule (88 FR 52545).

We received one public comment on these proposals.

Comment: The commenter supported the proposed regulations allowing for retroactive approval of Blueprint revisions and aligning the review process for Blueprint revisions more closely with that for Medicaid State plan amendments. This commenter stated the changes would provide States

with further clarity regarding the review process for revising Blueprints as well as more flexibility to implement changes to their BHPs.

Response: We appreciate this commenter's support and are finalizing the regulation changes as proposed.

3. BHP Notices

Under current § 600.330, States must provide written notice to beneficiaries conveying final determination of eligibility or ineligibility. The regulation does not require States to provide those notices in a manner that is accessible to individuals with disabilities or limited English proficiency (LEP). Therefore, we proposed to add paragraph (f) to § 600.330 to require that BHP eligibility notices be written in plain language and be provided in a manner which ensures that eligible individuals with LEP are provided with meaningful language access and individuals with disabilities are provided with effective communication.

For a full discussion of this proposal, please see the CY 2024 PFS proposed rule (88 FR 52546).

We received one public comment on this proposal.

Comment: One commenter supported the proposed changes requiring that eligibility notices be written in plain language.

Response: We appreciate this commenter's support and are finalizing our regulations as proposed.

4. BHP Appeals

Under current § 600.335(b), individuals must be given the opportunity to appeal BHP eligibility determinations through the appeals rules of the State's Medicaid program or the Exchange, as indicated in the State's Blueprint. Current BHP and Exchange regulations do not provide for appeals of health services matters. Therefore, we proposed in paragraph (b) to remove the option for States to conduct their BHP appeals process according to Exchange rules. In paragraph (b)(2), we proposed to require States to provide individuals an opportunity to appeal a delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service, after individuals exhaust appeals or grievances through the BHP standard health plans. Because current BHP regulations do not include provisions related to the appeal of health services matters, these appeals are not currently included in the list of core operations of a BHP in § 600.145. Therefore, in proposed § 600.145(f)(2), we included appeals of health services matters as specified in § 600.335 as a core operation of a BHP.

For a full discussion of these proposal, please see the CY 2024 PFS proposed rule (88 FR 52546).

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal changes to the regulations for appeals of health care services.

Response: We appreciate this commenter's support and are finalizing our regulations as proposed, with one modification described later in this section.

Comment: One commenter requested clarification on whether an appellant must exhaust utilization review and external appeals before filing a health service appeal through the proposed BHP appeal process.

Response: As stated in the preamble of the proposed rule, individuals must first exhaust appeals or grievances through the BHP standard health plans prior to appealing to the State. We have added this requirement to the regulation text, to provide further clarify this requirement.

Comment: One commenter requested that States be permitted flexibility to establish the health service appeals process in a manner that takes individual States' needs into account, such as being able to choose the department that will oversee the appeals.

Response: We appreciate the comment and agree that individual States' needs should be taken into account, including being able to choose the department that will oversee the appeals. We have revised § 600.335(b) and added § 600.335(c) to specify that subject to HHS approval, a State may request to follow an appeals process for BHP eligibility determinations and health service matters that differs from the State's Medicaid program. We specify that the State must demonstrate in its request that the BHP agency has oversight of any entity delegated the authority to administer appeals and provide a clear description of the responsibilities and functions delegated to such an entity. In addition, the State must ensure that the agency to which eligibility determinations or appeals decisions are delegated: complies with all relevant Federal and State law, regulations, and policies; and informs applicants and beneficiaries how they can directly contact and obtain information from the agency.

We expect this request to be submitted via a Blueprint revision. In determining whether the BHP agency has sufficient oversight, CMS will consider whether:

- The delegated agency has been provided sufficient training to make appeals decisions and apply BHP laws and policies correctly;
- The responsibilities of the delegated agency have been clearly articulated, including the scope of review, whether the delegated entity has final decision making authority, and how the delegated entity coordinates with the BHP agency regarding processing requests and other functions necessary to conduct appeals;
- A written agreement is in place between the delegated entity and the BHP agency regarding the responsibilities of the delegated entity; and
- A process has been established to monitor the accuracy and quality of decisions made by the delegated entity.

Comment: One commenter requested that the effective date for the requirement to follow the Medicaid process for appeals of health services matters be extended into the future by 3–5 years.

Response: We believe that by allowing a State to request to follow an appeals process for health service matters that differs from the State's Medicaid program, as discussed previously in this section, that the effective date of the policy does not need to be extended.

After consideration of public comments, we are finalizing this proposal as proposed, with one change as described previously in this section. We have revised § 600.335(b) and added § 600.335(c) to specify that subject to HHS approval, a State may request to follow an appeals process for BHP eligibility determinations and health service matters that differs from the State's Medicaid program.

R. Updates to the Definitions of Certified Electronic Health Record Technology

1. Background

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted February 17, 2009) (ARRA), authorized incentive payments to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (ONC Health IT Certification Program) to provide for the certification of health information technology (IT),

including EHRs. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary pursuant to section 3004 of the Public Health Service Act. The ONC Health IT Certification Program supports the use of certified health IT under the programs that we administer, including, but not limited to, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced Alternative Payment Models (Advanced APMs). While these programs continue to require the use of CEHRT, the use of certified health IT has expanded to other government and non-government programs.

For CY 2019 and subsequent years, the definitions of CEHRT for the Promoting Interoperability Programs at § 495.4, the Quality Payment Program at § 414.1305, and the Shared Savings Program at § 425.20 require the use of EHR technology that meets the 2015 Edition Base EHR definition at 45 CFR 170.102 and is certified to 2015 Edition health IT certification criteria under the ONC Health IT Certification Program. In addition, the CEHRT definitions in our regulations for these programs require technology to be certified to certain specific 2015 Edition health IT certification criteria, as specified in each of the definitions, including criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program, and criteria necessary to report on applicable objectives and measures specified under the MIPS Promoting Interoperability performance category under the Quality Payment Program. Prior Editions of health IT certification criteria were associated with ''stages'' of the EHR Incentive Programs (now the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category), which linked new and updated functionality in certified health IT to significant revisions to the objectives and measures in the programs.

In the CY 2021 PFS final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria (2015 Edition Cures Update), as finalized in the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Cures Act) final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Medicare Promoting Interoperability Program, the MIPS Promoting Interoperability performance category, and Advanced APMs may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022 date established in the ONC interim final rule, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency (85 FR 70064), for health IT developers to make updated certified health IT available (85 FR 84815 through 84825). After this date, health care providers were required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period beginning with CY 2023.

In the ONC ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' proposed rule (88 FR 23746 through 23917) (hereafter referred to as ''ONC HTI–1 proposed rule''), which appeared in the **Federal Register** on April 18, 2023, ONC proposed to discontinue the year themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules (88 FR 23758). In the proposed rule, ONC noted public comments stating that the continued use and reference to the 2015 Edition inaccurately implies an age and outdatedness to the certification criteria ONC has adopted. Given these concerns, ONC stated that it believes there should be a single set of certification criteria, which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health IT development timelines (88 FR 23750).

ONC further stated its belief that maintaining a single set of ''ONC Certification Criteria for Health IT'' would create more stability for the ONC Health IT Certification Program and for Federal partners who reference the ONC Health IT Certification Program, as well as make it easier for developers of certified health IT to maintain their product certificates over time (88 FR 23759). ONC stated this proposal to remove ''editions'' from the ONC Health IT Certification Program would also help users of certified health IT identify which certification criteria are necessary for their participation in programs, such as the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program's MIPS Promoting Interoperability performance category and Advanced APMs (88 FR 23760). For example, users would only need to know that their Health IT Module is certified to 45 CFR 170.315(b)(3), electronic prescribing, for successful participation in the MIPS Promoting Interoperability performance category related to electronic prescribing, as compared to the current state, where they must also know if the Health IT Module supports electronic prescribing as part of the 2014 Edition Certification Criteria or the 2015 Edition Certification Criteria, or 2015 Edition Cures Update Certification Criteria. To implement this approach, ONC has proposed to rename all criteria within the ONC Health IT Certification Program simply as ''ONC Certification Criteria for Health IT,'' proposing associated changes to the regulations at 45 CFR part 170 (88 FR 23759).

Similar to ONC's proposal to move away from ''editions'' and toward incremental changes to its certification criteria, we also have focused in recent years on implementing incremental changes to individual measures under, but not limited to, the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced APMs. We expect to continue to prioritize incremental changes in future years to reduce burden on participants in these programs (including eligible hospitals and CAHs and MIPS eligible clinicians), and build on the established base of available certified health IT capabilities. We believe our approach is consistent with the strategy discussed in the ONC HTI–1 proposed rule, in which ONC proposes to pursue a framework for the ONC Health IT Certification Program that focuses on incremental updates to a single set of certification criteria.

2. Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program and the Quality Payment Program

a. Background and Previously Finalized Certification Requirements

In consideration of the updates made to the 2015 Edition certification criteria as described in the CY 2021 PFS final rule (85 FR 84815 through 84828), we finalized that health care providers participating in the Medicare Promoting

Interoperability Program and eligible clinicians participating in the Quality Payment Program must use certified health IT that satisfies the definitions of CEHRT at §§ 495.4 and 414.1305, respectively, and is certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria, as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We explained this included technology used to meet the 2015 Edition Base EHR definition at 45 CFR 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and technology certified to the criteria necessary to report on applicable objectives and measures. In this final rule, we are finalizing revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program (on which the Shared Savings Program's definition of CEHRT at § 425.20 also relies) to support the proposed transition from the historical state of year themed ''editions'' to the ''edition-less state'' in the ONC HTI–1 proposed rule.

We included Table IX.F.-04 in the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2024 Rates final rule (88 FR 59278 through 59279), which includes some, but not all, certification criteria for the Medicare Promoting Interoperability Program's measures and eCQMs for eligible hospitals and CAHs, and Table 57 in section IV.A.4.f.(4)(e)(iv) of this final rule, which includes some, but not all, certification criteria for measures under the MIPS Promoting Interoperability performance category. These tables are only applicable for the measures under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and do not include all of the updated certification criteria included in the CEHRT definition as discussed in the CY 2021 PFS proposed rule (85 FR 50265 through 50270). For further discussion on the complete list of changes to the certification criteria under the CEHRT definition, we refer readers to the ONC 21st Century Cures Act final rule (85 FR 25667), the CY 2021 PFS proposed rule (85 FR 50265), and the CY 2021 PFS final rule (85 FR 84818 through 84825).

b. Revisions to Certified Electronic Health Record Technology Definitions in Regulatory Text

We proposed to revise the definitions of CEHRT in §§ 495.4 and 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program respectively (88 FR 52547 through 52548) so these definitions would be consistent with the ''edition-less'' approach to health IT certification as proposed in the ONC HTI–1 proposed rule, should the ONC proposal be finalized. First, for references to the ''2015 Edition Base EHR definition'' defined at 45 CFR 170.102, we proposed to add a reference to the revised name ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if ONC's definition is finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759, 23905). Next, we proposed to replace our references to ''2015 Edition health IT certification criteria,'' with ''ONC health IT certification criteria'' and to add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We are finalizing these proposals as proposed. By revising our regulations to account for ONC's proposed discontinuation of references to the ''2015 Edition,'' and pointing to the regulations at 45 CFR 170.102 and 170.315, we believe these changes will ensure the CEHRT definitions do not need to be updated to reflect modified terminology unless ONC changes the location of these certification criteria.

While these proposed revisions will allow us to maintain more permanent cross-references to ONC's regulations and terminology, we recognize that ONC has historically updated, and will likely in the future continue to update over time, the underlying certification criteria contained in 45 CFR 170.315.

Previously under the year-themed ''editions'' construct, we periodically revised the language in our regulatory CEHRT definitions to refer to a new Edition in order to incorporate ONC's updates to health IT certification criteria. Then, in the CY 2021 PFS final rule (85 FR 84818 through 84825), to incorporate ONC's updates to certification criteria in its 2015 Edition Cures Update, which ONC finalized under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), we did not revise the language of the CEHRT definitions for the Medicare Promoting Interoperability Program and the Quality Payment Program. Instead, we finalized that technology used to satisfy the CEHRT definitions must be certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria as finalized in the ONC 21st Century Cures Act final rule.

Consistent with ONC's proposal to move away from year-themed ''editions,'' and to further simplify our regulatory approach, we proposed revisions to our definitions of CEHRT to ensure we would not necessarily be required to update our regulatory text each time ONC proposed or finalized any updates to its definition of Base EHR or certification criteria.

We proposed to establish that any certification criteria adopted or updated in 45 CFR 170.315 would be applicable for the CEHRT definitions in our programs' regulations at §§ 495.4 and 414.1305, if ONC's applicable regulations are referenced directly in our CEHRT definitions. We stated that if finalized, this proposal would allow the CEHRT definitions in our regulations to automatically incorporate ONC's updates to relevant certification criteria without pursuing additional rulemaking.

In the proposed rule, we stated that any update to a certification criterion finalized by ONC would not necessarily be immediately required for use in CEHRT for our Medicare Promoting Interoperability Program, Quality Payment Program, and Shared Savings Program. We remind readers that ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet ONC's new or updated certification criteria to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers who may participate in programs that require use of CEHRT (88 FR 23761). We also noted that CMS will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of certified health IT.

We believe this approach will provide us with more flexibility to finalize updates and is more consistent with the incremental approach to revising measures and technology requirements described above. Moreover, this additional flexibility will allow eligible hospitals, CAHs, and eligible clinicians

to adopt, implement, and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need to wait for us to first amend the regulations at §§ 495.4 and 414.1305 through separate rulemaking.

In summary, we proposed to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305 (88 FR 52548). Specifically, we proposed to add a reference to the revised name of ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if that rule is finalized, the revised name of ''Base EHR definition'' is applicable for the CEHRT definitions going forward (88 FR 23759). We also proposed to replace our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria'' and add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We proposed to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR 170.315 ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, which we are finalizing as proposed, will ensure that updates to the definition at 45 CFR 170.102 and updates to applicable health IT certification criteria in 45 CFR 170.315 will be incorporated into the CEHRT definitions, without additional regulatory action by CMS.

Finally, we noted that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize its proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT.

We solicited comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to revise and streamline the CEHRT definitions and the proposed cross-references for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305, with ONC's regulations and terminology. Some commenters supported the alignment because disparate definitions for the same terms across different health IT and other health care regulations can cause confusion and administrative burdens to ensure compliance. Some commenters agreed with the proposal and approach to offer flexibility to clinicians and hospitals to adopt and implement ONC's updated certification criteria as they become available without having to wait on CMS to amend related regulations. Commenters also agreed with our assertion that CMS will determine when to incorporate any new or revised measures requiring new ONC Health IT Certification Program certification criteria—taking into account implementation timelines and readiness.

Response: We agree that the revisions will help to reduce potential confusion by clarifying references to certification criteria under the ONC Health IT Certification Program. We believe these revisions are consistent with the strategy described in the ONC HTI–1 proposed rule to move away from year-themed ''editions,'' including updates to the Base EHR definition and establishment of a single set of ONC health IT certification criteria (88 FR 52547). We believe this alignment, whether or not ONC finalizes its proposals, will simplify participation and reduce confusion for CMS program participants. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of any new health IT certification criteria.

Comment: Some commenters requested more information regarding specific requirements to meet the ONC health IT certification criteria. One commenter recommended that CMS work with ONC to educate providers on the certification process to convey what providers need to know, actions to take now and in future years, and the anticipated costs associated with adopting and implementing certified EHR technology. Another commenter suggested that CMS ensure proper disclosures and plain language be included from EHR vendors to avoid confusion regarding EHR updates so that medical groups remain fully aware of whether the products they are using meet the CMS requirements. Another commenter recommended that CMS work with ONC to ensure health IT developers support awareness of proposed policies that impact healthcare providers.

Response: We thank commenters for their suggestion to work with ONC in development of educational materials for providers so they better understand the certification process. We also appreciate the need to help users of ONC-certified products understand whether those products meet the definition of CEHRT, as well as the need to ensure clear and concise communications when describing the certification status of their products. We note that ONC maintains the Certified Health IT Product List (*https://chpl.healthit.gov/*), which is a comprehensive source of information for all health IT products certified by the ONC Health IT Certification Program. We may take these recommendations into consideration as we engage in continued educational activities. We will also work with ONC to explore the role health IT developers can play in effectively communicating policy changes to healthcare providers.

Comment: Other commenters expressed concern that the proposal would create financial and clinician burden in terms of implementation without providing clear or defined advantages and benefits. One commenter noted that many EHR developers charge physicians for ''upgrades'' and software updates to support new certified ''editions'' of the ONC health IT certification criteria. These fees often signify a required change in EHR versions to support federal reporting requirements, therefore, leaving it up to the EHR developer to ''provide'' ongoing certified EHRs to physicians. This results in the EHR developer charging physicians for updates without sufficiently communicating why the update is necessary, which could result in the physician declining the update to save money without realizing this action could result in the physician not possessing certified health IT necessary for participation in CMS' programs. To address this, the commenter recommended a joint ONC–CMS educational campaign to clearly communicate to physicians what an EHR developer's ''provided product'' means and what declining the product means for the EHR's ability to support provider participation in Federal programs. The commenter also expressed concern that shifting the responsibility to the physician, rather than requiring explicit use of a specific certified ''edition'' of ONC health IT certification criteria, as ONC and CMS have required for years, will disadvantage physicians.

Response: We understand that financial and other implementation burden for providers may be associated with updates to certified health IT products required for participation in CMS programs. We note that ONC's focus on moving to incremental updates from the large-scale updates associated with year-themed Editions is intended in part to help mitigate the burden

associated with updates. We also appreciate the recommendation to have joint educational resources that underscore the importance of having health IT products that meet the CEHRT definition, and we may take this into consideration as we engage in continued educational activities. Additionally, we agree it is important to support the broader adoption and use of interoperable certified health IT, and we refer readers to several existing resources and technical assistance information that HHS disseminates to support the broader care continuum.[457] [458] [459] We do not believe that this approach will disadvantage health care providers, relative to our prior focus on year-themed Editions. Rather, we believe this approach will simplify compliance and reduce the burden on healthcare providers who were previously required to ascertain the requirements and complete a large-scale update from one Edition to the next every few years. For a given capability required under the Medicare Promoting Interoperability Program or the Quality Payment Program, a health care provider will only need to know that their health IT product is certified to the appropriate criterion or criteria at 45 CFR 170.315, rather than the appropriate Edition. As previously mentioned, ONC maintains the Certified Health IT Product List (*https://chpl.healthit.gov/*), which is a comprehensive and authoritative listing of all certified Health IT Modules that have been successfully tested and certified by the ONC Health IT Certification program. We believe this will also help healthcare providers to have confidence that their health IT is kept up to date as their developer supports compliance with the ONC Health IT Certification Program requirements.

Comment: One commenter expressed concern with the updates providers would need to implement for criteria that are part of the CEHRT definition, such as those under the Base EHR definition. Specifically, the commenter noted since the CEHRT definition (both current and revised in this rule) directly references the Base EHR definition at 45 CFR 170.102, any such criteria would be updated as part of the Base EHR definition as of a date defined by ONC, and therefore, also updated automatically as part of the CEHRT definition given that direct citation. The commenter urged CMS to revise the CEHRT definition in a way that clarifies a date by which such new or revised criteria would become effective for purposes of Medicare Promoting Interoperability Program and the Quality Payment Program, for instance, by codifying a standard delay of 12 months from ONC's own effective dates intended for applicability for developers. One commenter recommended the timelines related to CEHRT definitions and requirements in this proposed rule not be effective any sooner than 24 months following the publication of the final rule. One commenter recommended that CMS set a date by which it expects all EHRs to achieve certification, requesting that CMS afford EHR vendors and health care providers a transition period of 3 to 5 years to develop, adopt, and integrate certified products. Other commenters requested the proposed timelines be clarified and delayed or extended, and prioritization be given to reducing provider burden across the whole healthcare continuum when implementing provisions of the 21st Century Cures Act and updating ONC's Health IT Certification Program.

Response: As noted by the commenter, under this final policy, technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR 170.315 ''as adopted and updated by ONC.'' As a result, updates to the definition at 45 CFR 170.102 of a ''Base EHR'' and updates to applicable health IT certification criteria in 45 CFR 170.315 would be incorporated into the CEHRT definitions of our programs, without additional regulatory action by CMS. ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet new or updated certification criteria in order to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers (88 FR 23761). We decline to finalize separate effective dates in the CEHRT definitions for the use of updated certified health IT products within the Medicare Promoting Interoperability Program or the Quality Payment Program, as recommended by commenters. We believe that emphasizing the timelines ONC adopts through notice and comment rulemaking for health IT developers to update and provide certified technology to their customers will reduce burden on participants in the Medicare Promoting Interoperability Program and the Quality Payment Program. Conversely, we believe that developing separate deadlines for program participants to ensure their technology has been appropriately updated would increase the regulatory burden for participants. As stated in the CY 2024 PFS proposed rule (88 FR 52548), we will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of certified health IT.

Finally, we refer readers to ONC's HTI–1 proposed rule, which includes two important proposals to further ensure that developers of certified health IT have certified products available for their customers to implement by specific dates. First, ONC proposes across several certification criteria,[460] and across several standards that are incorporated into certification criteria,[461] an expiration date after which a certification criterion and standard would no longer be available for certification under the ONC Health IT Certification Program.[462] Second, ONC proposes a new requirement (88 FR 23828 through 23830) as part of the Assurances Condition and Maintenance of Certification requirements in 45 CFR 170.402(b)(3) that would require a health IT developer to (1) update their products to the most recently adopted capabilities and standards included in a revised certification criterion and (2) provide to its customers such updated products by dates specified according to the revised criterion or standard.[463]

[457] *https://www.healthit.gov/topic/health-it-health-care-settings/long-term-and-post-acute-care.*

[458] *https://www.healthit.gov/topic/behavioral-health.*

[459] *https://www.healthit.gov/sites/default/files/page/2020-07/Care%20Continuum%20Tipsheet.pdf.*

[460] For example, ONC proposed in 45 CFR 170.315(f)(5) that a Health IT Module must conform to the revised requirements of the electronic case reporting certification criterion on an after December 31, 2024 (88 FR 23769 through 23774).

[461] For example, ONC proposed that adoption of the United States Core Data for Interoperability (USCDI) version 1 standard in 45 CFR 170.213(a) would expire on January 1, 2025 (88 FR 23764).

[462] See also 45 CFR 170.315(a)(9)(vi) where ONC proposed that adoption of the CDS criterion for purposes of the ONC Health IT Certification Program expires on January 1, 2025 (88 FR 23782).

[463] For example, several new standards were proposed for the standardized API for patient and population level services certification criterion in 45 CFR 170.315(g)(10), and under the proposed Assurances requirements in 45 CFR 170.402(b)(3) a developer of certified health IT with a Health IT Module certified to 45 CFR 170.315(g)(10) would

Continued

After consideration of public comments, we are finalizing our proposals to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305, to add a reference to the revised name of ''Base EHR definition''; to replace our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria''; and to add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315.

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

Medicare coverage for the Annual Wellness Visit (AWV) under Part B is primarily described in statute at section 1861(hhh) of the Act, and in regulation at 42 CFR 410.15. In the CY 2024 PFS proposed rule (88 FR 52262), we proposed to exercise our authority in section 1861(hhh)(2)(I) of the Act to add other elements to the AWV by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We noted that the proposed new SDOH Risk Assessment would enhance patient-centered care and support effective administration of an AWV. There are no deductible requirements or Part B coinsurance for the AWV. See §§ 410.160(b)(12) and 410.152(l)(13). Our proposal built upon our separate proposal described earlier to establish a stand-alone G code (G0136) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit (see section II.E. of this final rule).

1. Background

The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention plan. The AWV also includes an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html.*

It is estimated [464] that around 50 percent of an individual's health is directly related to SDOH, which is defined by Healthy People 2030 [465] as, ''The conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' Healthy People 2030 also defines the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. These parameters include factors like housing, food and nutrition access, and transportation needs. Given the large impact on health these factors have, the health care system broadly has been working to take these factors into account when providing care and rendering services.

Several Federal agencies, including the CDC, AHRQ, ACL, ACF, SAMHSA, HRSA, ONC, and ASPE are developing policies and implementation frameworks to better address the impact SDOH has on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity.[466] At CMS, addressing SDOH is an essential piece of the CMS Framework for Health Equity,[467] and it is tied in heavily with the CMS Strategic Pillar to advance equity. SDOH was also a foundational concept with the CMS Innovation Center Accountable Health Communities (AHC) Model that ended in 2022. Given the importance of and focus surrounding SDOH and enhancing equity, CMS is exploring ways to recognize and quantify practitioner work currently being done in this area, and to provide support to enable practitioners to assess and intervene when SDOH is relevant to the assessment, prevention and treatment plan of a Medicare patient.

CMS tested the AHC Model between 2017 and 2022. One element of the model test was the development and application of the AHC Health-Related Social Needs (HRSN) Screening Tool, which helps providers to identify patients' SDOH related needs, including housing instability, food insecurity, family and community support and mental health. Additional information on the AHC model is available on the CMS website at *(https://innovation.cms.gov/innovation-models/ahcm).*

We have heard from many health care professionals and beneficiary groups that there are barriers to completing the AWV, including, but not limited to, language and communication, differences in cultural perspectives and expectations regarding engagement with the healthcare system. We described in the PFS proposed rule that we increasingly understand the importance that SDOH be considered in an assessment of patient histories, patient risk, and in informing medical decision making, prevention, diagnosis, care and treatment.

In February 2018, Health Affairs published an article titled, ''Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit,'' which described findings from a statistical study of Medicare primary care providers and AWV's from 2011 to 2015. The article states, ''One of our most striking results was that while underserved patients were less likely to receive an annual wellness visit regardless of where they sought care, practices in rural areas and those caring for underserved and sicker populations were less likely to provide such visits to any of their patients—which suggests these practices may face resource constraints or have priorities that compete with adoption of the visit.'' [468]

In August 2022, the Journal of the American Geriatrics Society published an article titled, ''Medicare's annual wellness visit: 10 years of opportunities gained and lost.'' The article expresses the concern, ''currently AWVs are a 'one size fits all','' approach. This uniform approach does not sufficiently take into consideration the medical, psychological, functional, racial, cultural and socio-economic diversity of older adults. Updated AWVs should be tailored to meet the needs and priorities of older adults receiving them.'' It goes on to recommend, ''Medicare AWVs should include screening and

need to update their products to use the newer standards and provide those updated products to its customers by dates specified in 45 CFR 170 subpart B. In the case of 45 CFR 170.315(g)(10), by January 1, 2025 (88 FR 23828 through 23830).

[464] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[465] *https://health.gov/healthypeople.*

[466] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[467] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[468] Ganguli I, Souza J, McWilliams JM, Mehrotra A. Practices Caring For The Underserved Are Less Likely To Adopt Medicare's Annual Wellness Visit. Health Aff (Millwood). 2018 Feb;37(2):283–291. doi: 10.1377/hlthaff.2017.1130. PMID: 29401035; PMCID: PMC6080307.

counseling for social determinants of health as a means of mitigating the growing disparities in health and longevity for underserved older adults.'' [469]

2. Statutory and Regulatory Authority

Section 4103 of The Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) expanded Medicare coverage by adding the AWV benefit at section 1861(hhh) of the Act, effective for services furnished on or after January 1, 2011. We subsequently implemented the AWV in CMS regulations at § 410.15. The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an IPPE or AWV within the past 12 months. Section 1861(hhh)(2) of the Act describes a number of elements included in the AWV and section 1861(hhh)(2)(I) of the Act authorizes the addition of any other element determined appropriate by the Secretary.

Section 410.15(a) requires that the first AWV include the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.
- Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.
- Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

We noted in the PFS proposed rule that § 410.15(a) requires that a subsequent AWVs include the following:

- Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).
- An update of the individual's medical and family history.
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.
- Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care

[469] Coll PP, Batsis JA, Friedman SM, Flaherty E. Medicare's annual wellness visit: 10 years of opportunities gained and lost. J Am Geriatr Soc. 2022 Oct;70(10):2786–2792. doi: 10.1111/jgs.18007. Epub 2022 Aug 17. PMID: 35978538.

preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

In the CY 2016 PFS final rule (80 FR 70885), we included ACP as an optional element (at beneficiary discretion) within the AWV. We stated in the final rule we added ACP as a voluntary, separately payable element of the AWV. We provided the instruction that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV (80 FR 70958). We also added this policy to the regulatory text at § 410.15(a).

3. Proposal

In the CY 2024 PFS proposed rule (88 FR 52262), we proposed to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment. We recognized that, for some patients, identification and consideration of SDOH is critical to furnishing a fully informed health assessment and personalized prevention plan in the AWV. Interested parties had reported that the current elements of the AWV may not directly or adequately identify those SDOH challenges. We proposed that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. We proposed that the SDOH Risk Assessment service include the administration of a standardized, evidence-based SDOH risk assessment tool, furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We stated that services that are culturally and linguistically appropriate are critical to providing effective, equitable, understandable, and respectful quality care that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs of each patient. We recognized that patients with SDOH risks and challenges may often also experience communication barriers of various kinds when interacting with the health care system. We further noted that we believe that the SDOH Risk Assessment would only be effective in informing the greater AWV (including the health assessment and personalized prevention plan) when furnished in a manner that is intelligible and appropriate to the individualized characteristics and circumstances of the patient. Additional information on culturally and linguistically appropriate services in healthcare can be found at (*https://thinkculturalhealth.hhs.gov/clas*). In addition, we described our belief that the SDOH Risk Assessment Tool would be most effective and actionable when furnished in a setting with staff-assisted supports in place to ensure follow-up for health-related social needs associated to the visit. We also encouraged partnerships with community-based organizations such as Area Agencies on Aging to help address identified social needs. We proposed that the SDOH Risk Assessment be furnished as part of the same visit and on the same date of service as the AWV, so as to inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments and prevention services education and planning. We suggested our proposal would directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, in support of the existing AWV. In addition, we expressed our hope that our proposal would help spread general awareness among health professionals about the importance of providing cultural and linguistically appropriate services, which in turn will encourage clinicians to adopt language services and technologies to achieve high quality communication between the practitioner and patient. Our goal was the development of a personalized prevention plan that takes SDOH into account and is truly tailored to the individual patient. We solicited comments on our proposal, including whether a SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

We recognized in the PFS proposed rule that SDOH risk assessments are an emerging and evolving tool in healthcare and so we did not restrict our proposal to a specific list of approved assessments. In selecting an evidence-based tool, we encourage clinicians to explore the many widely adopted and validated tools available, including the CMS Accountable Health Communities [470] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool,[471] and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[472] We also encouraged clinicians, where feasible, to select screening instruments that maximize opportunities to collect and analyze standardized, quantifiable, and actionable data. For instance, clinicians were encouraged to utilize screening instruments where questions and responses are computable and mapped to health IT vocabulary standards (that is, have available LOINC® coding terminology), to ensure that data captured through assessments is interoperable and can be shared, analyzed and evaluated across the care continuum.

Our proposal built upon our separate proposal described earlier in the PFS proposed rule to establish a stand-alone G code (G01365) for SDOH Risk Assessment furnished in conjunction with an E/M visit. See section II.E. of this final rule for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. We indicated that once the rule was final, CMS would issue public guidance in the Medicare Learning Network, the Medicare & You Handbook, and other policy and payment instructions in the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual on the CMS website.

CMS has worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from

[470] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[471] *https://www.nachc.org/research-and-data/prapare/.*

[472] CMS–10825.

coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients by recommending the assessment of SDOH through position or discussion papers,[473] [474] [475] organizational strategic plans,[476] and provider training modules,[477] among others. We have discussed how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally performed by physicians and other health professionals in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. Practitioners are expending resources to obtain information from the patient about health-related social needs, and to formulate diagnosis and treatment plans that take these needs into account as part of a person-centered care plan for the treatment of medical problems. This work currently is reported and paid for, in part, under the PFS under E/M visit codes, and we believe as such, is undervalued and not optimized to allow the health professional and patient to benefit from the full value of a dedicated SDOH assessment and have that assessment immediately inform the health assessment and prevention planning services in the AWV.

We proposed that Medicare would pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (beneficiary cost sharing would not be applicable) when this risk assessment is furnished to a Medicare beneficiary as an optional element within an AWV (as part of the same visit with the same date of service as the AWV). Our proposal was analogous to our approach to the ACP service, which is an optional service for which beneficiary cost sharing is not applicable when furnished as part of the same visit and on the same date of service as the AWV. Beneficiary cost sharing (coinsurance and deductible) is not applicable to the AWV and, because the SDOH Risk Assessment will be an optional element within the AWV, there will not be any beneficiary cost sharing for the SDOH Risk Assessment either. See §§ 410.160(b)(12) and 410.152(l)(13). We noted that beneficiary cost sharing would apply to the SDOH Risk Assessment if furnished in conjunction with another service (outside of the AWV) that is subject to beneficiary cost sharing. We proposed that the SDOH Risk Assessment would be optional for both the health professional and the beneficiary to empower clinicians and patients to employ this assessment only when appropriate and desired.

We proposed to add regulatory text at § 410.15 that will include the new SDOH Risk Assessment service as an optional element within the AWV, at the discretion of the health professional and beneficiary. Furthermore, we proposed to add regulatory text that the SDOH Risk Assessment be standardized, evidence-based, and furnished in a manner that all communication with the patient be appropriate for the beneficiary's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We solicited comments on our proposal.

Because we had previously received feedback from interested parties that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit, we also solicited comments on this issue for consideration in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Overall, public commenters expressed broad support and approval of our proposal to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment and no applicable beneficiary cost sharing. Many commenters agreed with our position described in the PFS proposed rule that, for some patients, a Social Determinates of Health Risk Assessment would be critical to furnishing a fully informed Health Risk Assessment and Personalized Prevention Plan in the Annual Wellness Visit, and thus, an appropriate additional, optional element in the AWV.

Response: We thank the commenters for their support of our proposal to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment and no applicable beneficiary cost sharing.

Comment: Many commenters expressed agreement with our proposal to make the SDOH Risk Assessment optional for the patient and clinician. A few comments disagreed with our proposal that the SDOH Risk Assessment be optional for the provider and beneficiary and, instead, the commenters recommended that the SDOH Risk Assessment be a mandatory additional element in the AWV.

Response: We disagree with the commenters' recommendation that the SDOH Risk Assessment should be a mandatory element of the AWV at this time. We recognize that a SDOH Risk Assessment is an emerging tool in healthcare and that some clinicians and patients may be reluctant to collect and share sensitive information about health-related social needs until this tool becomes more established and familiar. We are not adopting the recommendation by public commenters that the SDOH Risk Assessment be a mandatory element of the AWV, but we may consider it in future rulemaking.

Comment: We received a few comments requesting clarification on the type of clinician that would be eligible to furnish the SDOH Risk Assessment as an additional element of the AWV.

Response: We clarify in the PFS final rule that as an additional element of the AWV, the clinicians identified within the definition of ''Health Professional'' (42 CFR 410.15(a)) as eligible to furnish to AWV would also be eligible to furnish the SDOH Risk Assessment as an additional element of the AWV. This would include a physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); and a medical professional (including a registered nurse, a licensed clinical social worker, a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in § 410.32(b)(3)(ii)) of a physician.

Comment: A few commenters requested clarification on the eligibility of the beneficiary and frequency limitations of the SDOH Risk Assessment as an additional element in the AWV.

[473] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[474] *https://doi.org/10.7326/M17-2441.*

[475] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[476] *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf.*

[477] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

Response: We clarify the PFS final rule that as an additional element of the AWV, the SDOH Risk assessment would be subject to the same limitations on coverage for the AWV described at § 410.15(c). Specifically, the beneficiary must be eligible for an AWV and have not had either an initial preventive physical examination or an AWV within the past 12 months. We note earlier in our final rule in section II.E. that the SDOH Risk Assessment may also be furnished in conjunction with an E/M visit, though in this instance different frequency limitations and other conditions of payment would apply, and Part B coinsurance and deductible would be applicable.

Comment: Numerous commenters requested clarification on whether elements of the AWV, including the health risk assessment described at § 410.15(a), and the SDOH Risk Assessment described in the PFS proposed rule, could be initiated by the patient prior to the date of the AWV, and if so, whether it would fit within the requirement of the PFS proposed rule that it be furnished on the same date of service and as part of the same visit as the AWV.

Response: We clarify in the PFS final rule that in some cases, for various reasons, elements of the AWV may be initiated and furnished over a period of multiple days. In these situations, the date of service that should be reported on the claim is the date of service on which the entirety of the AWV (including applicable additional elements) (based on CPT code description) is completed. For example, there could be a scenario where a patient would provide their input for a SDOH Risk Assessment through an online portal on a Monday and the health professional interprets the patient's SDOH Risk Assessment input and applies that information toward the establishment or update of a personalized prevention plan as part of the remainder of the AWV on a Tuesday. In this scenario, the date of service for both the SDOH Risk Assessment and the AWV would be the date of service on which the entirety of the AWV is completed. We further clarify that medical record documentation should reflect that the service began on one day and was completed on another day (the date of service reported on the claim). If documentation is requested, medical records for both days should be submitted. In scenarios where elements of the AWV are initiated on one day and completed on another day, the services are to be billed based on the time involved as described by CPT code and the date of service the entire AWV is completed. This clarification is consistent with our implementing regulations for the health risk assessment element of the AWV, which allow that the health risk assessment may be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter (§ 410.15(a) ''Health risk assessment''). This clarification is consistent with prior CMS guidance on coding and billing date of service on professional Medicare claims. See MLN article # SE17023.[478]

Comment: Numerous commenters requested clarification on implications of our proposal for Federal Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). First, commenters requested clarification on whether FQHCs and RHCs would be eligible to furnish the SDOH Risk Assessment as an additional element of the AWV. Second, many commenters also requested clarification on coding and payment calculations and mechanics for the SDOH Risk Assessment as an additional element of the AWV in relation to the FQHC and RHC bundled payment mechanisms.

Response: First, we clarify in the PFS final rule that as FQHCs and RHCs are currently eligible to furnish the AWV, they will also be eligible to furnish a SDOH Risk Assessment as an additional element of the AWV. Second, regarding comments requesting clarification on payment calculations and mechanics for the SDOH Risk Assessment within the AWV in relation to the bundled payment mechanisms of the FQHC Prospective Payment System and the RHC facility-specific all-inclusive rate (AIR), see section III.B. of this final rule for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service in regards to FQHCs and RHCs.

Comment: One commenter requested that CMS add screening for chronic kidney disease and rare kidney disease as additional elements in the AWV.

Response: While adding screening for chronic kidney disease and rare kidney disease as additional elements in the AWV is out of scope for this rule, we will take it into consideration for possible future rulemaking.

After consideration of public comments, we are finalizing our proposal made in the CY 2024 PFS proposed rule to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment and no applicable beneficiary cost sharing. We are also finalizing corresponding updates to regulatory text as proposed.

IV. Updates to the Quality Payment Program

A. CY 2024 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule outlines changes to the Quality Payment Program starting January 1, 2024, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on our measurement efforts and refining how clinicians would be able to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2024 performance period/2026 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a payment incentive program, by which the Medicare program rewards clinicians who provide high-value, high-quality services in a cost-efficient manner. The Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined in 42 CFR at 414.1305) are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to our established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In

[478] CMS website: *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017-transmittals-items/se17023.*

calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for CY 2024 performance period/2026 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold we have established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. The actual amount paid to the MIPS eligible clinician in MIPS payment year, once the MIPS payment adjustment factor is applied, is subject to further calculations such as application of the scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the CY 2023 performance year receive a 3.5 percent APM Incentive Payment in the 2025 payment year, and, beginning with the CY 2024 performance year (payment year 2026), a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

Participation in the Quality Payment Program (defined as clinicians with a final score greater than 0, including both those who submitted data and those who did not submit data) decreased slightly to 97.59 percent in the sixth year (CY 2022 performance period/2024 MIPS payment year) with 609,148 MIPS eligible clinicians receiving a final score other than zero out of 624,209 MIPS total eligible clinicians. In the CY 2021 performance period/2023 MIPS payment year, all 698,859 MIPS eligible clinicians received a final score other than zero. Therefore, participation rates in MIPS decreased slightly between the CY 2021 and CY 2022 MIPS performance periods.

In addition, 78.76 percent of MIPS eligible clinicians received a positive payment adjustment for the CY 2024 MIPS payment year based on their performance in the CY 2022 performance period. Please note that results for the CY 2022 performance period/CY 2024 MIPS payment year described herein are subject to change as a result of the targeted review process which began on August 10, 2023, and will conclude on October 9, 2023. For more information on the targeted review process for the CY 2022 performance period/2024 MIPS payment year, please see our targeted review guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2511/2022MIPSTargetedReviewGuide.pdf.*

Regarding performance in Advanced APMs, for the CY 2022 QP Performance Period, 384,105 eligible clinicians (TIN–NPIs) earned Qualifying APM Participant (QP) status while another 2,528 eligible clinicians earned partial QP status.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with implementing MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the seventh year of the Quality Payment Program, we are finalizing the updates set forth in this section of this final rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

In developing and putting forth these proposed and final policies, we intend to continue our efforts to align the Quality Payment Program with broader CMS initiatives, such as the establishment of the Universal Foundation (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*) and the CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy*). These initiatives unify strategic efforts across our programs, including the Quality Payment Program, to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures.

The vision for the CMS National Quality Strategy is to shape a resilient, high-value American health care system to achieve high-quality, safe, equitable, and accessible care for all. This strategy aims to promote the highest quality outcomes and safest care for all individuals. It also focuses on a person-centered approach as individuals journey across the continuum of care, care settings, and across payer types. The goals of this strategy incorporate lessons learned from the COVID–19 public health emergency (PHE) to inform both short- and long-term direction for our health care system.

The Universal Foundation moves toward a building-block approach to advance the overall vision of the National Quality Strategy and increase alignment across CMS quality programs by capturing measures that are meaningful, broadly applicable, and capable of being digitally reported and stratified, to identify and track disparities over time. The Universal Foundation seeks to improve health outcomes, reduce provider burden, improve standardization of measurement, and promote interoperability by prioritizing measures to transition to interoperable digital data.

The implementation of MVPs aligns with many of the objectives and goals the CMS National Quality Strategy and the Universal Foundation strive to achieve. For example, to align implementation of the measures in the Universal Foundation across MIPS and APMs, we are finalizing as proposed the updates to consolidate the Promoting Wellness and Managing Chronic Conditions MVPs into the Value in Primary Care MVP to align with the adult Universal Foundation measure set. We also explored the expansion of the APM Performance Pathway (APP) reported by clinicians in the Shared

Savings Program and Advanced APMs to include the primary care universal measure set in the future. In our continued strategy to incentivize improved equity as well as advancing value, in Performance Year 2023, the Shared Savings Program will implement an upside-only adjustment to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857).

To support our goal to accelerate interoperability, we are finalizing with modification our proposal to align the Shared Savings Program CEHRT requirement with the MIPS Promoting Interoperability performance category's requirements. We also are finalizing as proposed to modify our certified electronic health record (EHR) technology (CEHRT) use criterion for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology. Moreover, we are finalizing as proposed the expansion of our portfolio of available MVPs for the CY 2024 performance period and remain committed to our goal of ensuring more meaningful participation in the Quality Payment Program through MVPs.

b. Summary of Major Provisions

(1) Transforming the Quality Payment Program

The CMS National Quality Strategy addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. This vision is supported by the alignment of policies and quality measures in MIPS and APMs within the Quality Payment Program. Priorities for the Quality Payment Program include: achieving more equitable outcomes; utilizing clinically relevant measures for specialty performance that inform clinicians and beneficiaries; enhancing quality, patient safety, and efficiency through use of CEHRT; reducing burden and simplifying quality performance reporting; articulating meaningful outcomes, promoting alignment where possible, and moving to all digital reporting.

The Quality Payment Program allows eligible clinicians to engage in patient-centered care via two tracks: MIPS and APMs. We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care. To this end, we are implementing MVPs to allow clinicians to report on measures that are directly relevant to their clinical practice. MVPs provide more clinically relevant performance measurement, engage more specialists in performance measurement, and reduce barriers to APM participation. CMS has recently laid out multiple steps intended to fulfill the potential of APMs. The CMS Innovation Center strategy refresh acknowledges that whole person care requires the depth and scope of services that includes both primary and specialty care and aims to provide ACOs with tools to better engage specialists, test ways to better link primary and specialty care upstream in the patient journey, and further movement into value-based care.[479]

(2) Major MIPS Provisions

We requested comment on how the Quality Payment Program can facilitate continuous improvement of Medicare beneficiaries' healthcare and best build on existing CMS Innovation Center model policies and Medicare programs, such as the Medicare Shared Savings Program. We sought feedback on how we might modify our policies, requirements, and performance standards to encourage clinicians to continuously improve the quality of care, particularly for clinicians with little room for improvement in MIPS.

(a) MIPS Value Pathways Development and Maintenance

In an effort to promote high-quality, safe, and equitable care and to implement the vision outlined in the CMS National Quality Strategy, we are finalizing as proposed five new MVPs around the topics of: Women's Health; Infectious Disease, Including Hepatitis C and HIV; Mental Health and Substance Use Disorder; Quality Care for Ear, Nose, and Throat (ENT); and Rehabilitative Support for Musculoskeletal Care. In addition, we are finalizing as proposed MVP maintenance updates to our MVP inventory that are in alignment with the MVP development criteria, and in consideration of the feedback from interested parties we have received through the maintenance process.

(b) Subgroup Reporting

We are finalizing our proposal to codify previously finalized subgroup policies in the preamble to regulation text. Additionally, we are finalizing updates to previously finalized subgroup policies to help guide clinicians and groups to meaningfully participate in MVPs through subgroup reporting. Specifically, we are finalizing to eliminate the policy allowing a subgroup to submit a separate reweighting application request independent of its affiliated group, to not calculate the facility-based score for a subgroup, to assign the affiliated group's complex patient bonus score for subgroups under final score calculation, and to allow subgroups to submit a targeted review request.

(c) MIPS Performance Category Measures and Activities

(i) Quality Performance Category

We proposed six modifications to the quality performance category. First, we are finalizing the proposal to expand the definition of the collection type to include Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). Second, we are finalizing the proposal to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT. Third, we are finalizing the proposal to establish the data submission criteria for Medicare CQMs. Fourth, we are finalizing the proposal to require the administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish translation. Fifth, we are finalizing the proposal to maintain the data completeness criteria threshold to at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and not finalizing the proposal to increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year. Sixth, we are finalizing, with modification, the proposal to establish the data completeness criteria threshold for Medicare CQMs to at least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, and not finalizing the proposal to increase the data completeness criteria threshold for Medicare CQMs to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year. Finally, we are finalizing, with modification, the proposal to establish a measure set inventory of 198 MIPS quality measures.

(ii) Cost Performance Category

We are finalizing our proposal to add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year: Depression,

[479] CMMI Strategy Refresh. October 20, 2021. *https://innovation.cms.gov/strategic-direction-whitepaper.*

Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related Conditions. We are also finalizing our proposal to use a 20-episode case minimum for each of these new measures, and to clarify our policy regarding case minimums for cost measures, as codified at § 414.1350(c). Additionally, we are finalizing our proposal to remove the Simple Pneumonia with Hospitalization episode-based measure beginning with the CY 2024 performance period/2026 MIPS payment year. Lastly, we are finalizing our proposal to update the operational list of care episode and patient condition groups and codes to add all five new measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

(iii) Improvement Activities Performance Category

We are finalizing as proposed to add five new, modify one existing, and remove three existing improvement activities from the Inventory. The new and modified activities help fill gaps we have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. Four of the new activities relate to CMS Health Equity, Increase All Forms of Accessibility to Health Care Services and Coverage. We are also finalizing the removal of three improvement activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the inventory offers flexibility and choice without potentially causing burden with too many activities to choose from.

(iv) Promoting Interoperability Performance Category

We are finalizing as proposed five policy modifications for the Promoting Interoperability performance category. Specifically, we are finalizing to: (1) lengthen the performance period for this category from 90 days to 180 days; (2) modify one of the exclusions for the Query of Prescription Drug Monitoring Program (PDMP) measure; (3) provide a technical update to the e-Prescribing measure's description to ensure it clearly reflects our previously finalized policy; (4) modify the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guide measure to require MIPS eligible clinicians to affirmatively attest to completion of the self-assessment of their implementation of safety practices; and (5) continue to reweight this performance category at zero percent for clinical social workers for the CY 2024 performance period/2026 MIPS payment year. In section III.R of this final rule, we are finalizing the revision of our regulatory definition of CEHRT for the MIPS Promoting Interoperability performance category to be more flexible in reflecting any changes the Office of the National Coordinator for Health Information Technology (ONC) may make to its Base EHR definition, certification criteria, and other standards for health information technology.

(d) MIPS Final Scoring Methodology

(i) Performance Category Scores

We are finalizing as proposed updates to our scoring flexibilities policy. We are finalizing to update the criteria by which we assess the scoring impacts of coding changes and apply our scoring flexibilities.

(ii) Cost Improvement Scoring

We are finalizing as proposed with modification two amendments to the cost improvement scoring methodology that was established in the CY 2018 Quality Payment Program final rule. First, we are finalizing to change improvement scoring from a measure-level to a category-level method and to remove the statistical significance requirement and amend the cost improvement scoring calculation, with a modification to amend the final step of the cost improvement scoring calculation. Second, we are finalizing that the maximum cost improvement score is zero percentage points for the CY 2020 through CY 2024 MIPS payment years, and one percentage point beginning with the 2025 MIPS payment year.

(e) MIPS Payment Adjustments

We are not finalizing our proposed policy to identify the ''prior period'' by which we will establish the performance threshold as three performance periods, instead of a single prior performance period, beginning with the CY 2024 performance period/2026 MIPS payment year. To determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year, we are finalizing that we will use the CY 2017 performance period/2019 MIPS payment year. Based on the mean final score from that prior period, we are finalizing the performance threshold as 75 points for the CY 2024 performance period/2026 MIPS payment year and codifying this policy at § 414.1405(b)(9)(iii).

(f) MIPS Targeted Review

We are finalizing as proposed to add virtual groups and subgroups as being eligible to submit a request for targeted review. We are finalizing to codify this addition at § 414.1385(a).

In addition, we are finalizing as proposed an amendment at § 414.1385(a)(2) with respect to the timeline for MIPS eligible clinicians, virtual groups, subgroups, groups, and APM entities to request a targeted review of our calculation of their MIPS payment adjustment factor(s). Specifically, we are finalizing an amendment to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. This will modify the current time period to submit a request for targeted review, which is 60 days beginning on the day that CMS makes available the MIPS payment adjustment factors for the MIPS payment year.

We also are finalizing to amend § 414.1385(a)(5). Specifically, we are finalizing an amendment to require that, if CMS requests additional information under the targeted review process, then that additional information must be provided to and received by CMS within 15 days of receipt of such request. This will modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt of such request.

(g) Third Party Intermediaries

In this final rule, in addition to codifying previously finalized policies and proposing to make technical updates for clarity, we are finalizing proposals to: (1) Add requirements for third party intermediaries to obtain documentation of their authority to submit on behalf of a MIPS eligible clinician; (2) Specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that the information contained in the qualified posting about them is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting to increase flexibility for measures supported; (6) Specify requirements for a transition plan for QCDRs and qualified registries withdrawing from the program; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed

throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Allow CMS to terminate third party intermediaries that are on remedial action for 2 consecutive years; (14) Specify the process for publicly posting remedial action; and (15) Specify the criteria for audits.

(h) Public Reporting on Compare Tools

In an effort to expand the information available to patients and caregivers when choosing a doctor or clinician, we are finalizing our proposals to modify existing policies for public reporting on individual clinician and group profile pages, including:

- The telehealth indicator, such that, we would use the most recent CMS coding policies at the time the information is updated to identify the telehealth services provided on clinician profile pages instead of only using specific Place of Service (POS) and claims modifier codes.
- Utilization data, such that we have additional procedure code grouping flexibility; can address procedure volume limitations and provide a more complete scope of a clinician's experience by adding Medicare Advantage (MA) data to procedure counts; and align the data in the Provider Data Catalog (PDC) with the procedural groupings shown on profile pages.

Additionally, we solicited feedback from interested parties through a request for information on ways to publicly report data submitted on measures under the MIPS cost performance category on the Compare tool.

(3) Major APM Provisions

(a) APM Performance Pathway

In section IV.A.4.e. of the proposed rule, we are finalizing as proposed to include the Medicare Clinical Quality Measure (Medicare CQM) for Accountable Care Organizations Participating in the Medicare Shared Savings Program collection type in the APM Performance Pathway (APP) measure set.

(b) Overview of the APM Incentive

In section IV.A.4.m. of the proposed rule, we are not finalizing our proposal to end the use of APM Entity-level QP determinations and instead make all QP determinations at the individual eligible clinician level. We also are not finalizing our proposal to modify the ''sixth criterion'' under the definition of ''attribution-eligible beneficiary,'' which is listed at § 414.1305.[480] Specifically, we are not finalizing our proposal to include as attribution-eligible any beneficiary who has received a covered professional service furnished by the NPI for the purpose of making QP determinations. We are finalizing our proposal to amend § 414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with amendments made by the CAA, 2023. Relatedly, we are finalizing our proposal to amend § 414.1450 to reflect the statutory APM Incentive Payment amount for the 2025 payment year (performance year 2023) of 3.5 percent of the eligible clinician's estimated aggregate payments for covered professional services in accordance with amendments made by the CAA, 2023. As described in the proposed rule (88 FR 52601 through 52603), we are finalizing as proposed an amendment § 414.1385 to adjust the Targeted Review period to address operational challenges that have arisen ahead of the required transition beginning for payment year 2026 (performance year 2024) from the APM Incentive Payment to the higher PFS payment rate for QPs (calculated using the differentially higher ''qualifying APM conversion factor).

(c) Advanced APMs

In section IV.A.4.n. of the proposed rule, we are finalizing as proposed our proposal to modify the CEHRT use criterion for Advanced APMs to provide greater flexibility for APMs to tailor CEHRT use requirements to the APM and its participants. We also had proposed to amend the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i) effective beginning for CY 2024 to remove the 75 percent CEHRT use threshold, and to instead specify that the APM must require all APM participants to use CEHRT as defined in a proposed revised definition of CEHRT under § 414.1305. We are finalizing this proposal with a modification in the effective date, to retain the 75 percent CEHRT use threshold in CY 2024 and instead remove that threshold effective beginning for CY 2025. We also finalizing our proposal to amend the Other-Payer Advanced APM CEHRT use criterion at § 414.1420(b) to conform to the proposed changes at § 414.1415(a)(1)(i).

2. Definitions

At § 414.1305, we are finalizing as proposed to revise the definitions of the following terms:

- Certified Electronic Health Record Technology (CEHRT); and
- Collection type.
- Qualified posting

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. Transforming the Quality Payment Program

a. Advancing CMS National Quality Strategy Goals

(1) Increasing Alignment Across Value-Based Programs

The CMS National Quality Strategy [481] addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. One of the CMS National Quality Strategy goals is to improve quality and health outcomes across the health care journey through implementation of a ''Universal Foundation'' of impactful measures across all CMS quality and value-based programs.[482] Adoption of the Universal Foundation [483] [484] will focus clinician attention on specific quality measures,

[480] Currently, there are six criteria required for a beneficiary to be an ''attribution-eligible beneficiary'' during the QP Performance Period, which can be found at § 414.1305. The sixth criterion provides that an ''attribution-eligible beneficiary'' must have ''a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and/or other services.''

[481] The National Quality Strategy: A Person-Centered Approach to Improving Quality . . . , *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[482] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[483] Aligning Quality Measures across CMS. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundationhttps://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

[484] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

reduce burden, help identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

We identified adult and pediatric measures for the Universal Foundation to be used across CMS programs and populations, including the Quality Payment Program, to the extent they are applicable. The Quality Payment Program measure inventory already includes quality measures in the adult core set from the Universal Foundation. In addition, we are finalizing our proposal in the CY 2024 PFS proposed rule (88 FR 52558 through 52559 and 88 FR 53193 through 53197) to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP that aligns with the adult Universal Core set of quality measures at section IV.A.4.b. and Appendix 3: MVP Inventory, Table B.11 of this final rule. We also finalizing our policy, proposed in the CY 2024 PFS proposed rule (88 FR 52426 through 52428) to expand the APM Performance Pathway (APP) reported by clinicians in the Medicare Shared Savings Program (Shared Savings Program) to include Medicare Clinical Quality Measure (Medicare CQM) collection types, at section III.G.2.c. of this final rule.

(2) Advancing Health Equity

We also articulated a detailed strategy to advance health equity and accountability in order to design, implement, and operationalize policies to support health for all people served by our programs, eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and provide the care and support that our beneficiaries need to thrive.[485] Specifically, the CMS Office of Minority Health released the *CMS Framework for Health Equity,*[486] which updates the CMS Equity Plan with an enhanced and more comprehensive 10-year approach to further embed health equity across CMS programs including Medicare, Medicaid, Children's Health Insurance Program, and the Health Insurance Marketplaces. The CMS Office of Minority Health also released ''Paving the Way to Equity: A Progress Report'' [487] in 2021, which describes the CMS Equity Plan for Medicare and progress from 2015 to 2021.

In accordance with our health equity strategy, both MVPs and APMs share a goal of incenting improved equity as well as advancing value (87 FR 70035). For example, beginning in Performance Year 2023 the Shared Savings Program will implement an upside-only Health Equity Adjustment (HEA) to an ACO's MIPS Quality performance category score to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857, also see HEA proposal at 88 FR 52429 through 52430). We are finalizing the technical clarifications to our previously finalized HEA policy at section III.G.2.d. of this final rule.

(3) Accelerating Interoperability

The CMS National Quality Strategy also calls for supporting the transition to a digital and data driven health care system. The CMS National Quality Strategy proposed to achieve this through the development of requirements for sharing, receipt, and use of digital data, including digital quality measures.[488] We believe that, as clinicians strive to make improvements in patient care, clinicians should demonstrate increasingly more advanced and innovative uses of health information technology. In the CY 2024 PFS proposed rule (88 FR 52433 through 52437), we proposed to require individual clinicians, or the ACO as an APM Entity, participating in the Shared Savings Program ACO to report the measures in the MIPS Promoting Interoperability performance category beginning with the CY 2024 performance year. We refer readers to section III.G.2.h.(2) of this final rule, where we finalize these proposals with modification, delaying the implementation of the MIPS Promoting Interoperability performance category reporting requirements for the Shared Savings Program until the CY 2025 performance year. Additionally, in the CY 2024 PFS proposed rule (88 FR 52625 through 52628), we proposed to modify the CEHRT use criterion for Advanced APMs to provide flexibility for APMs to adopt CEHRT use requirements that are clinically relevant to models and their participants, emphasizing the importance of interoperability and health information technology. We refer readers to section IV.A.4.n.(3) of this final rule where we finalize with modification the CEHRT use criterion for Advanced APMs. We believe these policies, in addition to ongoing efforts to build CMS infrastructure and develop technical solutions, are an important step towards evolving our health information technology ecosystem.

b. Quality Payment Program Vision and Goals

(1) Emphasizing the Importance of Value-Based Care

The Quality Payment Program was designed and implemented to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations (81 FR 77010). In the Advanced APM track of the Quality Payment Program, APM entities and eligible clinicians take responsibility for improving the quality of care, care coordination and health outcomes for a group of beneficiaries through participation in Advanced APMs.[489] Advanced APMs can ensure that beneficiaries get the right care at the right time by reducing fragmentation between clinicians, which can reduce unnecessary duplication of services and preventable medical errors.[490] Advanced APMs also support our goal that all Traditional Medicare beneficiaries be in a care relationship with clinicians accountable for quality and total cost of care by 2030, as outlined by the CMS Innovation Center strategy refresh.[491]

Our ongoing alignment of the Shared Savings Program and the Quality Payment Program supports new as well as long term participation in ACOs for clinicians choosing to participate in accountable care relationships. In the CY 2021 PFS final rule, we finalized the Alternative Payment Model (APM) Performance Pathway (APP) under

[485] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[486] CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[487] CMS, Paving the Way to Equity: A Progress Report (2015–2021) *https://www.cms.gov/sites/default/files/2021–01/Paving%20the%20Way%20to%20Equity%20CMS%20OMH%20Progress%20Report.pdf.*

[488] CMS National Quality Strategy. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy.*

[489] Medicare Value-Based Care Strategy: Alignment, Growth and Equity. The Medicare Value-Based Care Strategy: Alignment, Growth, And Equity. Health Affairs, Jacobs, Fowler, Fleisher, and Seshamani. *https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity.*

[490] CMS Announces Increase in 2023 in Accountable Care Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship. *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable.*

[491] Innovation Center Strategy Refresh. *https://innovation.cms.gov/strategic-direction-whitepaper.*

MIPS, in part, to reduce reporting burden, and create new scoring opportunities for MIPS eligible clinicians participating in MIPS APMs (85 FR 84720).

(2) MVP Reporting in the Quality Payment Program

We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care practice. To this end, we are implementing MVPs to allow for clinicians to report on measures that are directly relevant to their clinical practice. Rather than selecting individual measures and activities from a large inventory to report under each of the siloed MIPS performance categories under traditional MIPS, eligible clinicians who select an MVP (for example, the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP) can select from a smaller, cohesive set of measures and activities focused on the clinician's performance in rendering care for their specialty or clinical condition.

We also developed the MVP framework with the intention of supporting clinicians in their journey of continuous performance improvement and reducing barriers to APM participation as clinicians and practices prepare to take on, and successfully manage financial risk (84 FR 62946 through 62949).

c. Promoting Continuous Improvement in MIPS

For MIPS, we developed policies and methodologies to assess clinicians' performance, and to support performance improvement across four performance categories (quality, cost, improvement activities, and Promoting Interoperability) in accordance with section 1848(q)(1)(A)(i) and (ii) of the Act. We believe we should evaluate our policies, requirements, and standards for MIPS periodically to determine if we need to raise the bar in order to foster the availability of opportunities for continuous performance improvement. We are considering how we can implement future policies to support continuous improvement for clinicians who consistently perform well in MIPS. One challenge we face is that, after a clinician has achieved high performance scores on the same measures and activities year over year, there may be little or no room for the clinician to improve their performance. Another challenge is that some MIPS eligible clinicians choose measures and activities for which they are already performing well, rather than measures and activities where they would be required to implement changes in their workflow, clinical care, or practices in order to achieve a positive payment adjustment. This selection practice, to repeatedly choose the same measures and activities for which the clinician is confident they will perform well, can mean that the clinician has less incentive to transform the way that care is delivered and continuously improve quality of the care they provide. For these reasons, we are considering modifying our policies in the future to encourage clinicians who have consistently been high performers in MIPS to continuously improve various areas of their clinical practice, including implementing more rigorous standards under MIPS and supporting participation in an APM.

We were interested in feedback on approaches to modifying our policies, requirements, and standards under MIPS, while remaining cognizant of the burden any changes may place on MIPS eligible clinicians. Section 1848(q)(1)(A) and (5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for applicable measures and activities in each performance category applicable to the MIPS eligible clinician for a performance period. We were particularly interested in how we can balance the impact of any policy changes on MIPS eligible clinicians who have become accustomed to our current program requirements with the benefit of potential modifications that foster clinicians' continuous improvement. For example, we could increase reporting requirements in traditional MIPS and MVPs, or we could require that specific measures be reported, instead of allowing choice of measures, once MVPs are mandatory to encourage improvement for clinicians with continuously perform well under MIPS.

d. Request for Feedback

We solicited comments on how we can modify our policies under the Quality Payment Program to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries. Such modifications for MIPS may include requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities.

In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation request for information is exempt from the PRA.

We requested public comment on specifically the following questions:

- What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?
- Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?
- Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?
- Should we consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?
- What changes to policies should CMS consider to assess continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?
- We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?
- While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

We thank submitters for their responses to this request for information. We may consider the information we received and use it to inform future rulemaking.

4. MVP Development, Maintenance, and Scoring

a. Development of New MIPS Value Pathways (MVPs)

In the CY 2024 PFS proposed rule (88 FR 52558), we discuss the detailed MVP development process. Through our development processes for new MVPs (85 FR 84849 through 84856, 87 FR 70035 through 70037), we aim to

gradually develop new MVPs that are relevant and meaningful for all clinicians who participate in MIPs. We proposed the inclusion of five new MVPs (88 FR 52558) and (88 FR 53146 through 53166):

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorders;
- Quality Care for the Treatment of Ear, Nose, and Throat (ENT) Disorders; and
- Rehabilitative Support for Musculoskeletal Care.

We referred readers to Appendix 3: MVP Inventory, of this final rule for discussion of each proposed new MVP, the public comments received, and our responses.

b. MVP Maintenance on Previously Finalized MVPs

In the CY 2024 PFS proposed rule (88 FR 52558 through 52559) we discuss the MVP maintenance process and refer readers to the proposed rule for those details.

In the CY 2024 PFS proposed final rule (88 FR 53167 through 88 FR 53197), we proposed modifications to our 12 previously finalized MVPs for the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854), feedback received through the MVP maintenance process, and based off the removals of certain improvement activities from the improvement activities inventory, as well as the addition of other relevant existing quality measures for MVP participants to select from. In addition, through the MVP maintenance process, we proposed to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP, that aligns with the Adult Universal Core Set, as described in the journal article, ''*Aligning Quality Measures across CMS- The Universal Foundation*'' (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*).

We refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications of the established MVPs, the public comments received, and our responses.

c. Scoring MVP Performance

In the CY 2022 PFS final rule, we finalized policies for MVP scoring that took effect beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we intend to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further our goals for the MVP framework (86 FR 65419).

We refer readers to the CY 2024 PFS proposed rule for policies we proposed regarding MIPS scoring flexibilities in the quality performance category scoring (88 FR 52592 through 52593); for the change to scoring improvement in the cost performance category (88 FR 52593 through 52596); for the improvement activity ''IA_MVP, Practice-wide quality improvement in the MIPS Value Pathway Program (MVP)'' in the improvement activities performance category (88 FR 52577 through 52578 and 88 FR 53133 through 53134); and for the policies for the Promoting Interoperability performance category (88 FR 52578 through 52590), including modifications of the SAFER Guide Measure's requirements and the Query of Prescription Drug Monitoring Program (PDMP) measure's exclusion, a technical update to the e-Prescribing measure, an increase in the length of the performance period from 90 continuous days to 180 continuous day, and continuation of our reweighting policy of the performance category for clinical social workers.

In addition, we refer readers to the CY 2024 PFS proposed rule for policies we proposed regarding subgroups, including reweighting proposals, addition of subgroups to our Targeted Review policies, and a clarification regarding the scoring of facility-based clinicians at the subgroup level (88 FR 52559 through 52562).

Finally, we refer readers to the CY 2024 PFS proposed rule for policies we proposed regarding Targeted Review process, including the addition of virtual groups to our Targeted Review policies (88 FR 52601 through 52603).

In this final rule, we are finalizing these policies as proposed. For a discussion of our finalized policies and the public comments received, please refer to section IV.A.4.g.(1)(c)(i) of this final rule for our discussion on MIPS scoring flexibilities in the quality performance category scoring; section IV.A.4.g.(1)(d)(i) in this final rule for our finalized updates to scoring improvement in the cost performance category; section IV.A.4.f.(3) and Appendix 2: Improvement Activities of this final rule for the finalized new improvement activity; section IV.A.4.f.(4) in this final rule for the finalized policies for the Promoting Interoperability performance category, section IV.A.4.d. of this final rule for finalized policies regarding subgroups, and section IV.A.4.d.(4). for finalized policies regarding Targeted Review process.

d. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized the option for clinicians to participate as subgroups for reporting MIPS value pathways (MVPs) beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We referred readers to Title 42 of CFR at §§ 414.1318 and 414.1365, the CY 2022 PFS final rule (86 FR 65398 through 65405), and the CY 2023 PFS final rule (87 FR 70038 through 70045) for additional details on previously finalized subgroup policies.

In the CY 2024 PFS proposed rule, we proposed to: (1) update the subgroup policy for reweighting of MVP performance categories at § 414.1365(e)(2) (88 FR 52559 and 52560); (2) update the facility-based scoring and complex patient bonus for subgroups under final score calculation at § 414.1365(e)(3) and (4) (88 FR 52560 and 52561); (3) update the targeted review policy for subgroups at § 414.1385 (88 FR 52561); and (4) codify in our regulations the subgroup policies finalized in previous years' rules (88 FR 52561 and 52562).

(2) Subgroup Reweighting

In the CY 2022 PFS final rule (86 FR 65425 through 65426), we finalized at § 414.1365(e)(2)(ii) that for an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. Additionally, we finalized that if reweighting is not applied to an affiliated group, then the subgroup may receive reweighting under the circumstances described at §§ 414.1365(e)(2)(ii)(A) and (B). In establishing this policy, we noted our concern about extreme and uncontrollable circumstances (EUC) that would impact only the subgroup (fire or natural disaster at a specific practice location) and does not affect the entire affiliated group. We also finalized that if a subgroup submits data for a performance category which was reweighted, the subgroup data

submission will void the reweighting applied to the performance category.

Upon further consideration of the previously finalized policy, we identified technical constraints that affect our ability to implement the policy. Specifically, we are concerned that the time necessary to adjudicate reconsideration requests for both a subgroup and its affiliated group may deprive the subgroup of knowledge of its reweighting status during a significant portion of the relevant performance period and undermine its ability to plan data submission needs accordingly.

There may be instances when a subgroup and its affiliated group have separate reasons to submit reweighting applications. Those separate applications may request the reweighting of different performance categories. Under § 414.1380(c)(2), clinicians, groups, and APM Entities submit reweighting applications annually on a rolling basis throughout the performance period, or a date specified by CMS. However, the requirement in § 414.1365(e)(2)(ii) that any reweighting applied to a subgroup's affiliated group is also applied to the subgroup means that when a subgroup and its affiliated group both submit reweighting applications, the subgroup will not know its reweighting status until CMS makes a determination regarding the group's reweighting application. Depending on when the group submitted its reweighting request, this may not happen until after the close of the performance period for which the reweighting application was made.

We believe the uncertainty created for a subgroup by not knowing its reweighting status until later in the performance period would disrupt its ability to best plan for the measures and activities on which it will be scored. We recognize that there may be instances when only the subgroup is affected by an extreme and uncontrollable circumstance (natural disaster, fire, hurricane, etc.) and would want to request its own reweighting, independent of the affiliated group. However, we believe that the need for a subgroup to know of its data submission requirements outweighs the benefit of being able to request its own reweighting independent of the affiliated group.

Separately, there are certain special status designations (non-patient facing, small practice, etc.) that automatically qualify a group for reweighting of the Promoting Interoperability performance category. A subgroup can learn about its affiliated group's special status designation as described in the second paragraph under the definition of MIPS determination period at § 414.1305. Given that subgroup eligibility and special status determinations are made at the group level, we believe that applying an affiliated group's reweighting to a subgroup and removing the ability of a subgroup to submit a separate reweighting application, would enable subgroups to receive their reweighting status and identify their data submission obligations in a timely manner. Therefore, we proposed to revise § 414.1365(e)(2)(ii) to limit the reweighting applied to a subgroup to that which is also applied to its affiliated group beginning with the CY 2024 performance period/2026 MIPS payment year.

In order to operationalize the previously established policy, we intend to implement a manual process for reviewing subgroup reweighting applications for the CY 2023 performance period/2025 MIPS payment year. We considered also using the manual process for reviewing subgroup reweighting applications in future performance periods. However, we are concerned that manually reconciling the reweighting requests would delay the approval of the reweighting requests received from a subgroup. Additionally, we are concerned that it may create confusion for a subgroup to determine whether a performance category has been reweighted and its potential impact on subgroup data submission, specifically in instances when both the subgroup and its affiliated group submit a reweighting application for one or more of the MVP performance categories. For the above reasons, we would use the manual process only for the CY 2023 performance period/2025 MIPS payment year.

We acknowledge that there may be instances when an extreme and uncontrollable circumstance impacts only a subgroup and not the entire affiliated group (for example, fire or natural disaster at the subgroup's practice location). Because subgroup reporting is not mandatory at this time, we believe that in these instances, when a registered subgroup is unable to participate in MVP reporting as a subgroup, the eligible clinicians in the registered subgroup would participate in MIPS via another available reporting option. These clinicians could either participate as individuals or as a group, if its affiliated group chooses to participate in traditional MIPS, or in MVP reporting. Additionally, we established the policy in § 414.1318(b)(1) to not assign a score for a registered subgroup that did not submit data for the applicable performance period (87 FR 70045). In the scenario that the registered subgroup did not submit data, we would assign the highest of the available final scores associated with the clinician's TIN/NPI for the eligible clinicians in the subgroup (86 FR 65536 and 65537). We refer readers to the CY 2023 PFS proposed rule (87 FR 46272 through 46275) for examples that illustrate how the final score is applied for a clinician who is part of a group TIN where only some of the clinicians under that TIN choose to participate in MIPS through subgroups. We will continue to monitor subgroup participation trends and will revisit this policy in the future, as needed.

For the above reasons, we proposed (88 FR 52560) to revise § 414.1365(e)(2)(ii) to state that an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B).

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to remove the capability for a subgroup to submit its own reweighting application independent of the affiliated group.

Response: We thank the commenters for their support.

Comment: A few commenters did not support our proposal to remove the separate application reweighting request for subgroups. One commenter requested additional clarification on how the delayed reweighting review process would impact a subgroup when both the subgroup and the affiliated group requested reweighting. The commenter also shared their concerns that it is unclear how individual MIPS eligible clinicians in a subgroup affected by a natural disaster could submit MIPS data using other participation options. A commenter requested that CMS monitor the subgroup reweighting application trends and recommended that CMS consider alternate options that would permit both the subgroup and the affiliated group to submit reweighting applications. The commenter expressed concern that the proposed policy might negatively impact subgroups when subgroup reporting is mandatory.

Response: We acknowledge the commenter's concerns with removing

the separate reweighting application requests for subgroups. We previously finalized at § 414.1365(e)(2)(ii) that a subgroup will receive the same reweighting applied to the affiliated group (86 FR 65425 through 65426). If both the affiliated group and a subgroup submit reweighting applications, CMS would need to wait until it has reviewed the affiliated group's reweighting application prior to making a determination on the subgroup's reweighting request. Doing so would delay informing the subgroup's of its reweighting status, allowing it to determine its data submission needs. Additionally, there could be instances when a group could submit their reweighting application towards the end or after the end of the MIPS performance period, preventing a subgroup from submitting data for a performance period. Therefore, we believe the benefit of a subgroup determining its data submission needs early in the performance period outweighs the benefit of submitting a separate reweighting application.

In the scenario that a subgroup is affected by a natural disaster and the affiliated group is not, we note that the MIPS eligible clinicians in the subgroup will be included in the affiliated group's submission if the affiliated group submits data at the group level. If the affiliated group does not submit data, each MIPS eligible individual clinician could submit a reweighting application at the individual level. We will continue to monitor subgroup participation trends and revisit the policy in the future as we move towards mandatory subgroup reporting.

After consideration of public comments, we are finalizing our proposal to revise § 414.1365(e)(2)(ii) to provide that an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B).

(3) Subgroup Scoring Policies

(a) Facility-Based Score for Subgroups

We established policies for facility-based measurement and scoring for MIPS eligible individual clinicians and groups at § 414.1380(e). Under these standards, we calculate a MIPS eligible clinician's final facility-based score using the clinician's performance in another value-based purchasing program (83 FR 59866 through 59867). In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(3) that if an MVP Participant that is not an APM Entity and is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). We recognize that we inadvertently overlooked excluding MVP Participants that are subgroups from facility-based scoring. We noted that it was not our intent to calculate a facility-based score at the subgroup level.

In the course of implementing MVPs, we have offered clinicians and groups the opportunity to elect to report via MVPs and via traditional MIPS. If a facility-based MIPS eligible clinician participates in MVP reporting as an individual or as part of a group, we will calculate a final score for the MIPS eligible clinician based on the MVP reporting. We would not use the facility-based scores to calculate the clinician's final scores under the MVP because we currently do not have an MVP specifically focused on facility-based measurement. We believe eligible clinicians would choose to participate in MVP reporting with the intent to report on measures applicable to the scope of care provided and therefore, it would be appropriate for facility-based clinicians participating in MVP reporting to receive a score based on the data submitted for the measures and activities in an MVP. If a facility-based clinician chooses to participate in an MVP for a MIPS performance period, a facility-based score would be calculated as part of traditional MIPS. Clinicians will also receive a score for MVP reporting, that is not facility-based, and we will use the higher of the scores to determine the MIPS payment adjustment for the MIPS eligible clinicians. Subgroup reporting is limited to MVPs, and subgroup reporting is not available for clinicians reporting on measures in traditional MIPS. Therefore, we proposed (88 FR 52560) to modify the text at § 414.1365(e)(3) to state that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring a facility-based score will also be calculated in accordance with § 414.1380(e).

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to not calculate a facility-based score based for clinicians participating as a subgroup.

Response: We thank the commenters for their support.

Comment: A few commenters did not support our proposal to not calculate a facility-based score at the subgroup level and recommended CMS to calculate a facility-based score for subgroups participating in MVP reporting. The commenters shared their belief that using the higher of the facility-based or subgroup scores to determine the MIPS payment adjustment for facility-based clinicians participating in MVP reporting would align with the scoring policies for facility-based clinicians participating in traditional MIPS.

Response: Under the previously established standards for facility-based measurement and scoring for MIPS eligible individual clinicians and groups at § 414.1380(e), we calculate a MIPS eligible clinician's final facility-based score using the clinician's performance in another value-based purchasing program (83 FR 59866 through 59867). Facility-based clinicians and groups participating in traditional MIPS receive a facility-based score in the quality and cost performance categories derived from the applicable value-based purchasing score available for the facility-based clinician or group. Clinicians can choose to report on measures relevant to their scope of care by participating in subgroups and MVP reporting. It is most appropriate for CMS to assess the performance of a clinician participating in a subgroup and reporting an MVP using the measures and activities reported by the clinician's subgroup as it would allow CMS to provide feedback on the subgroup's performance based on the data submitted by the clinicians in the subgroup for the measures and activities in a MVP. We note that a facility-based clinician could still participate as a subgroup for reporting an MVP. However, we calculate the facility-based score for these clinicians based on their participation in traditional MIPS and not based on their participation as a subgroup in MVP reporting. It would defeat the purpose of MVPs to score a subgroup on a value-based purchasing program's measures that are not part of the MVP. Additionally, doing so would extend subgroup reporting of quality measures outside of MVPs to traditional MIPS, where it was never intended to be available. Our policy to not calculate a facility-based score at the subgroup level does not affect an individual facility-based clinician in a subgroup in that the clinician would also receive all the available scores from the affiliated group, including the traditional MIPS score derived from facility-based scoring. We will assign the highest of

the available final scores associated with clinician's TIN/NPI under the existing scoring hierarchy established in the CY 2022 PFS final rule (86 FR 65536 and 65537).

Comment: A few commenters recommended that CMS assign the affiliated group's facility-based score for the clinicians participating as a subgroup as it would align with the subgroup scoring policies for cost measures. One commenter requested clarification on why CMS would calculate a facility-based score for a group participating in MVP reporting but not for a subgroup.

Response: As noted in the proposed rule (88 FR 52560), if a facility-based clinician chooses to participate as a group in MVP and traditional MIPS reporting for a MIPS performance period, a facility-based score would be calculated as part of traditional MIPS and not part of their MVP reporting. As described in response to the comment above, it would not be appropriate to calculate a facility-based score for a subgroup. Also as noted above, in addition to calculating a subgroup score based on the subgroup's MVP reporting for a facility-based MIPS eligible clinician participating in a subgroup, we would also assign the MIPS eligible clinician their affiliated group's score if available, for its participation in traditional MIPS or MVP reporting as a group. We would use the higher of the group's traditional MIPS score or MVP score and the subgroup's MVP score to determine the MIPS payment adjustment for the MIPS eligible clinician in the subgroup.

After consideration of public comments, we are finalizing our proposal at § 414.1365(e)(3) to provide that a facility-based score will also be calculated in accordance with § 414.1380(e) for an MVP Participant that is not an APM Entity or a subgroup and is otherwise eligible for facility-based scoring.

(b) Complex Patient Bonus for Subgroups

In the CY 2018 Quality Payment Program final rule (82 FR 53776), we finalized at § 414.1380(c)(3)(i) that we will add a complex patient bonus to the final score of certain MIPS eligible clinicians that submit data on at least one performance category during the applicable performance period. We finalized that this complex patient bonus would be calculated on the basis of the average Hierarchical Condition Category (HCC) risk score and the dual eligible ratio for beneficiaries seen by clinicians and groups. In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(4) that a complex patient bonus will be added to the final score for an MVP Participant in accordance with § 414.1380(c)(3). We also revised § 414.1380(c)(3) to permit subgroups to receive the complex patient bonus as, in the case of subgroups, we intended to apply the bonus based on the patient population of the subgroup.

Since then, however, we have identified issues with using claims data associated with the clinicians in a subgroup that prevents us from calculating the complex patient bonus at the subgroup level. Specifically, we are unable to identify the beneficiaries seen by the clinicians in a subgroup, and therefore we cannot calculate the average HCC score and dual eligible ratio scores. At the time the relevant claims data is retrieved, the composition of the subgroup may not be known, making it impossible to calculate the required data elements for the complex patient bonus (for example, clinicians, beneficiaries that received care, etc.) at the subgroup level. Additionally, the group may have subgroups that do not collectively represent the entire group, restricting our ability to gather the beneficiary data necessary to calculate the complex patient bonus score at the subgroup level.

We recognize that we would need to retroactively modify the previously established policy at § 414.1365(e)(4) for the CY 2023 performance period/2025 MIPS payment year to address the fact that we cannot calculate the complex patient bonus at the subgroup level. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because the current rule provides for the calculation of the complex patient bonus score at the subgroup level when it would be impossible for CMS to do so. We proposed (88 FR 52560 and 52561) to add § 414.1365(e)(4)(i) to provide that for subgroups, beginning with the CY 2023 performance period/2025 MIPS payment year, the affiliated group's complex patient bonus will be added to the final score. Additionally, we proposed conforming changes in § 414.1380(c)(3)(v) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median (88 FR 52560 and 52561). Similarly, we proposed conforming changes in § 414.1380(c)(3)(vi) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, for MIPS eligible clinicians and groups, the complex patient bonus components are calculated as described under § 414.1365(c)(3)(vi) (88 FR 52561).

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to assign the affiliated group's complex patient bonus score to the subgroup as it would appropriately credit both the group and subgroup for the complexity in the care provided. One commenter recommended that CMS use the higher of the group or subgroup complex patient bonus scores, when CMS is able to calculate the complex patient bonus score at the subgroup level.

Response: We thank the commenters for their support. We will consider the commenter's recommendation to assign the higher of the affiliated group or subgroup's complex patient bonus score when CMS can calculate the complex patient bonus score at the subgroup level.

Comment: A few commenters did not support our proposal to apply the affiliated group's complex patient bonus score for a subgroup. The commenters shared their belief that CMS calculated the scores for administrative claims measures at the subgroup level and recommended that CMS could utilize the clinician information submitted during subgroup registration for attributing beneficiaries to calculate the complex patient bonus score at the subgroup level.

Response: While we have established attribution methodologies for individual clinicians (NPI level) and group (TIN level), we are unable to identify beneficiaries at the subgroup level. Therefore, it would be impossible for us to calculate the average HCC and dual eligible ratio scores at the subgroup level. We may develop a methodology for identifying beneficiaries at the subgroup level after gaining further experience with subgroup reporting, at which time, we can consider changing our complex patient bonus approach for subgroup reporting through a proposal in future rulemaking.

Regarding the commenter's concerns on beneficiary attribution and scoring of administrative claims measures at the

subgroup level, we discussed in the CY 2023 PFS final rule (87 FR 70043 through 70045) the issues related to testing the reliability and validity of administrative claims measures at the subgroup level. We have established these thresholds only at the individual and group level. Therefore, we currently do not have the capability to score the administrative claims measures at the subgroup level and would need additional time for testing these measures and calculate the complex patient bonus score at the subgroup level.

After consideration of public comments, we are finalizing our proposal to add § 414.1365(e)(4)(i) such that, for subgroups, beginning with the CY 2023 performance period/2025 MIPS payment year, the affiliated group's complex patient bonus will be added to the final score. Additionally, we are finalizing the proposed conforming changes in § 414.1380(c)(3)(v) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. We are also finalizing the proposed conforming changes in § 414.1380(c)(3)(vi) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, for MIPS eligible clinicians and groups, the complex patient bonus components are calculated as described under § 414.1365(c)(3)(vi).

(4) Targeted Review for Subgroups

We previously established at § 414.1385(a) that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77353 through 77358 and 77546). We also finalized the process to submit a targeted review application, codified at § 414.1385(a) (81 FR 77353 through 77358 and 77546). Similar to the previously established targeted review process for individual clinicians and groups, MIPS eligible clinicians who participate in MVP reporting and are scored as a subgroup may request a targeted review beginning with the CY 2023 performance period/2025 MIPS payment year. We recognize that we did not propose changes in the existing language for targeted review at § 414.1385(a) to reflect the availability of the targeted review process for subgroups.

We proposed to modify § 414.1385(a) to state that a MIPS eligible clinician, group, or subgroup may request a targeted review of the calculation of the MIPS payment adjustment factors applicable to such MIPS eligible clinician, group, or subgroup for a year (88 FR 52561). We also proposed to modify § 414.1385(a)(1) to state that a MIPS eligible clinician, group, or subgroup (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review (88 FR 52561). Additionally, we proposed to make conforming changes at § 414.1385(a)(3), (5), and (6) to remove the term ''MIPS eligible clinician or group'' and add in its place the term ''MIPS eligible clinician, group, or subgroup'' (88 FR 52561). With these proposals, a subgroup that would like to request a review of the calculation for the MIPS payment adjustment factor for MVP data submission in the CY 2023 performance period/2025 MIPS payment year may also submit a targeted review application.

In addition, we noted that we also proposed additional changes to the targeted review process overall as set forth in § 414.1385(a) (88 FR 52601 through 52603). We refer readers to section IV.A.4.j. of this final rule for further discussion on these targeted review proposals.

We requested comments on the above proposals related to targeted review for subgroups. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal allowing subgroups to submit a targeted review request. We received no other comments on this proposal.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing our proposal to modify § 414.1385(a) to state that a MIPS eligible clinician, subgroup, or group may request a targeted review of the calculation of the MIPS payment adjustment factors applicable to such MIPS eligible clinician, subgroup, or group for a year. We are also finalizing our proposal to modify § 414.1385(a)(1) to state that a MIPS eligible clinician, subgroup, or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. Additionally, we are finalizing our proposal with minor technical corrections to make conforming changes at § 414.1385(a)(3), (5), and (6) to remove the term ''MIPS eligible clinician or group'' and add in its place the term ''MIPS eligible clinician, subgroup, or group.'' As previously discussed, we refer readers to section IV.A.4.j. of this final rule for discussion of our other proposals related to targeted review and additional changes to § 414.1385(a).

(5) Codification of Previously Finalized Subgroup Policies From Preamble

We have identified that some subgroup policies were finalized in prior rulemaking but were not codified in the CFR. Additionally, we neglected to propose to include subgroups in our previously established definition of ''attestation'' in § 414.1305. We have reviewed the existing language and identified policies that should be codified. We proposed to correct these errors (88 FR 52561 and 52562).

Each of the changes to the policies described in this section must be effective beginning with the CY 2023 performance period/2025 MIPS payment year in order for MIPS Value Pathways to operate effectively. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. Here, the failure to apply the changes retroactively would be contrary to the public interest because the discrepancies remedied by the below proposals may cause undue confusion for clinicians participating as subgroups and may also create unintended errors in program implementation.

(a) Definitions

(i) Attestation

At § 414.1305, we currently define attestation to mean a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS. Beginning in the CY 2023 performance period/2025 MIPS payment year, clinicians participating as subgroups would submit data for the Promoting Interoperability and improvement activities performance categories in an MVP as described at § 414.1365(c). As described previously in this section, we proposed to adopt

this change retroactively pursuant to section 1871(e)(1)(A)(ii) of the Act. We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data through an attestation for the Promoting Interoperability and improvement activities performance categories as described in § 414.1365(c). Therefore, we proposed (88 FR 52562) to add the term ''subgroup'' and revise the definition of attestation in § 414.1305 to state that attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician, group, or subgroup may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposals to codify previously finalized policies for subgroups, including the addition of subgroups to ''attestation.''

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing the proposal to add the term ''subgroup'' and revise the definition of attestation in § 414.1305 to state that attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician, group, or subgroup may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS. This revision is effective beginning with the CY 2023 performance period/2025 MIPS payment year.

(ii) Submitter Type

At § 414.1305, we defined a submitter type to mean the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS. In accordance with the subgroup reporting requirements at § 414.1318(c), we inadvertently overlooked adding subgroups in the definition of submitter type at § 414.1305. As described previously in this section, we proposed to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii) of the Act. We believe that the failure to apply the change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data as described at § 414.1318(c). Therefore, we proposed (88 FR 52562) to add the term ''subgroup'' and revise the definition of submitter type at § 414.1305 to state that a submitter type means the MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, subgroup, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposals to codify previously finalized policies for subgroups, including the addition of subgroups to ''submitter type.''

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal to add the term ''subgroup'' and revise the definition of submitter type at § 414.1305 to state that a submitter type means the MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, subgroup, or APM Entity, as applicable, that submits data on measures and activities under MIPS. This revision is effective beginning with the CY 2023 performance period/2025 MIPS payment year.

(b) Data Submission Criteria for the Improvement Activities Performance Category

We refer readers to § 414.1360 for data submission criteria for the improvement activities performance category. In the CY 2022 PFS final rule (86 FR 65462), we finalized revisions to the data submission criteria at § 414.1360(a)(2) to allow subgroups to perform and attest to their improvement activities separately and to apply the 50 percent threshold within their subgroup. We inadvertently overlooked codifying subgroups in the regulation text at § 414.1360(a). The existing regulation text at § 414.1360(a) refers to data submission criteria in the improvement activities performance category for only MIPS eligible clinicians and groups. As described previously, we proposed to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii) of the Act. We believe that the failure to apply the change retroactively would be contrary to the public interest because it would create ambiguity in the data submission requirements established in § 414.1360(a)(2) regarding the reporting of improvement activities by subgroups. Therefore, we proposed (88 FR 52562) to revise § 414.1360(a) to state that for purposes of the transition year of MIPS and future years, MIPS eligible clinicians, groups, or subgroups must submit data on MIPS improvement activities in one of the following manners described at § 414.1360(a)(1) through (a)(1)(i).

We requested comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposals to codify previously finalized policies for subgroups

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal to revise § 414.1360(a) to state that for purposes of the transition year of MIPS and future years, MIPS eligible clinicians, groups, or subgroups must submit data on MIPS improvement activities in one of the following manners described at § 414.1360(a)(1) and (a)(1)(i). This revision is effective beginning with the CY 2023 performance period/2025 MIPS payment year.

e. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in performance year 2021, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. We also established that ACOs will be required to report quality data for purposes of the Shared Savings Program via the APP (85 FR 84722).

Under policies finalized under the CY 2023 PFS (87 FR 69858), to meet the quality performance standard under the Shared Savings Program through the 2024 performance year, we stated that ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMS and the CAHPS for MIPS survey. Beginning in the 2025 performance year and subsequent performance years, ACOs must report the three eCQMS/MIPS CQMs and the CAHPS for MIPS survey (87 FR 69858 through 69859).

(2) Provisions for the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program

As discussed in the proposed rule (88 FR 52420–3), we proposed to establish the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP measure set. The Medicare CQM collection type will be available to only ACOs participating in the Shared Savings Program. ACOs in the Shared Savings Program will have the option to report the Medicare CQM under the APP on only ''beneficiaries eligible for Medicare CQMs as defined at § 425.20'', instead of their all payer/all patient population, beginning with the 2024 performance year (88 FR 52420). The Medicare CQM also will serve as another collection type in addition to the existing eCQM/MIPS CQM option, which is an all payer/all patient collection type under the APP.

In the CY 2023 PFS final rule, we stated that we will monitor the impact of policies such as the sunsetting of the CMS Web Interface in the 2024 performance year and the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in the 2025 performance year (87 FR 69833). We also stated that we may revisit these and related issues in future rulemaking based on lessons learned as we gain more experience with ACOs reporting eCQMs/MIPS CQMs (87 FR 69833). In the proposed rule, we reiterated that we are committed to supporting ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting (88 FR 52420–3). We encouraged readers to review additional background on our proposal to include the Medicare CQM collection type in the APP measure set (88 FR 52420–3). Similarly, we now refer readers to section III.G.2.b.(2) of this final rule for additional context on finalizing this proposal.

The following is a summary of the comments we received on this proposal as outlined in this section and our responses. Related comments and responses may be found in section III.G.2.b.(2) of this final rule.

Comment: We received one comment supporting the proposal to establish the Medicare CQM collection type in the APP measure set as described in this section.

Response: We thank the commenter for their support.

Comment: Some commenters expressed confusion about our reference in the proposed rule to ''attributed Medicare fee-for-service beneficiaries who meet the definition of a 'beneficiary eligible for Medicare CQM(s)''' (88 FR 52562). In particular, commenters were concerned that our use of the word ''attributed'' may indicate a different beneficiary population for the Medicare CQM collection type than the population referenced elsewhere in the proposed rule (88 FR 52420).

Response: We agree that our use of the word ''attributed'' may have been confusing. We now clarify that our proposal to establish the Medicare CQM collection type in the APP measure set is intended to reference the same beneficiary population as that discussed in the Shared Savings Program section of the proposed rule (88 FR 52420), specifically beneficiaries eligible for Medicare CQMs as defined at § 425.20. For more discussion on this matter, please refer to section III.G.2.b.(2) of this final rule.

After consideration of public comments, we are finalizing as proposed to include the Medicare CQM collection type in the APP measure set beginning with the 2024 performance year.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We referred readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, and 87 FR respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In the CY 2024 PFS proposed rule (88 FR 52562 through 52568), we proposed to:

- Amend the definition of the term ''collection type'' to include the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).
- Amend (through technical modifications) the data submission criteria for MIPS quality measures and establish the data submission criteria for Medicare CQMs.
- Require the administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish language translation.
- Maintain the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.
- Establish data completeness criteria for Medicare CQMs.
- Modify the MIPS quality measure set as described in Appendix 1 of the CY 2024 PFS proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Definition of Collection Type

With the proposed establishment of a new collection type, the Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) specific to the APM Performance Pathway (APP) as described in the CY 2024 PFS proposed rule (88 FR 52420 through 52423), we proposed to amend the definition of the term ''collection type'' to include Medicare CQMs to account for the new collection type available only to Medicare Shared Savings Program ACOs meeting the reporting requirements of the APP. Specifically, starting with the CY 2024 performance period, we proposed to amend the definition of the term ''collection type'' in § 414.1305 to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the

CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). The Medicare CQMs collection type would serve as a transition collection type under the APP and be available as determined by CMS.

We solicited public comment on the proposal to amend the definition of the term collection type to include the Medicare CQMs as an available collection type in MIPS. The following is a summary of the public comments received.

Comment: Many commenters supported the proposal to amend the definition of the term collection type to include Medicare CQMs as an available collection type in MIPS. The commenters expressed support for the establishment of the new collection type as an available option to serve as a transitional means for Medicare Shared Savings Program ACOs to prepare for the reporting of eCQMs and MIPS CQMs under the APP.

Response: We appreciate the support from commenters.

Comment: A few commenters requested for the Medicare CQMs collection type to not be limited to Medicare Shared Savings Program ACOs meeting the reporting requirements under the APP, but expand the availability to MIPS eligible clinicians, groups, virtual groups, subgroups, and other APM Entities participating in MIPS.

Response: Due to the complex technical challenges that Medicare Shared Savings Program ACOs encounter as they prepare for the reporting of eCQMs and/or MIPS CQMs, we established the new Medicare CQMs collection type to serve as a transition collection type under the APP. While the reporting of QCDR measures, eCQMs, MIPS CQMs, and Medicare Part B claims measures under MIPS is not new, the reporting of eCQMs and/or MIPS CQMs under the APP for Medicare Shared Savings Program ACOs is new and in order to facilitate the transition to the reporting of eCQMs and/or MIPS CQMs, the availability of the Medicare CQMs as a collection type to Medicare Shared Savings Program ACOs provides a means to assist with the transition of reporting eCQMs and/or MIPS CQMs, particularly as the complex technical challenges specific to Medicare Shared Savings Program ACOs are mitigated and addressed. We do not intend to expand the availability of the Medicare CQMs collection type, serving as a transition collection type, to MIPS eligible clinicians, groups, virtual groups, subgroups, and other APM Entities participating in MIPS.

Comment: A few commenters suggested that the Medicare CQMs collection type be afforded the 7-point scoring floor for the first year of implementation and the 5-point scoring floor applied for the second year of implementation as a means for incentivizing Medicare Shared Savings Program ACOs to adopt the Medicare CQM collection type.

Response: We note that the scoring policy providing measure achievement points of a 7-point scoring floor and a 5-point scoring floor pertains to the submission of new MIPS quality measures during their first 2 years in MIPS. Specifically, under the scoring policy for new MIPS quality measures in § 414.1380(b)(1)(i)(C), the measure achievement points available for the submission of a new MIPS quality measure (having a benchmark, and meeting case minimum and data completeness requirements) in its first year of MIPS are between 7 and 10 measure achievement points and the submission of a new MIPS quality measure (having a benchmark, and meeting case minimum and data completeness requirements) in its second year of MIPS are between 5 and 10 measure achievement points. The scoring policy for new MIPS quality measures is not applicable to the establishment of a new collection type or the application of a newly available collection type to an existing MIPS quality measure. In the CY 2022 PFS final rule, we noted that such policy will not apply to measures that have existed as a MIPS quality measure but are being introduced for a new collection type (86 FR 65500). For example, if a MIPS quality measure is currently available as a MIPS CQM and it becomes newly available as an eCQM or Medicare CQM, the application of the newly available collection type to an existing MIPS quality measure would not be considered a new measure under such scoring policy.

After consideration of public comments, we are finalizing, as proposed, the proposal to amend the definition of the term collection type in § 414.1305 to include Medicare CQMs as an available collection type in MIPS.

To operationalize the implementation of the Medicare CQMs collection type, specifically the capability to distinguish between the submission of data for a Medicare CQM and a MIPS CQM to CMS, we created an identifier that reflects the Quality number associated with a quality measure (that is, Q001, Q134, and Q236) followed by the letters ''SSP.'' For the reporting of Medicare CQMs, the identifiers are as follows: 001SSP, 134SSP, and 236SSP. We note that the Medicare CQM identifiers must be included in the submission files. We refer readers to section III.G.2.b.of this final rule for a summary of public comments received regarding the implementation and operationalization of the Medicare CQMs collection type under the APP.

(c) Quality Data Submission Criteria

(i) Data Submission Criteria for Quality Measures

In the CY 2024 PFS proposed rule, we proposed technical amendments to data submission criteria for MIPS quality measures and proposed to establish data submission criteria for Medicare CQMs. The participants in MIPS have expanded from MIPS eligible clinicians and groups to virtual groups starting with the CY 2018 performance period (82 FR 53593 through 53617), APM Entities starting with the CY 2021 performance period (85 FR 84860), and subgroups starting with the CY 2023 performance period (86 FR 65392 through 65394). In order to account for the expansion of participants in MIPS and the applicability of data submission criteria for MIPS quality measures, we proposed technical amendments. We proposed technical amendments to recognize that a virtual group, subgroup, and APM Entity are able to meet the data submission requirements pertaining to the quality performance category at § 414.1325(a)(1), (c), and (d). Also, we proposed technical amendments to recognize that a virtual group and an APM Entity are able to meet the data submission requirements established at § 414.1335(a)(1)(i) and (ii) for the data submission criteria pertaining to Medicare Part B claims measures, MIPS CQMs, eCQMs, and QCDR measures. Additionally, in § 414.1335(a)(1)(ii), we proposed to modify references of MIPS eligible clinicians and groups, to refer to such clinicians and groups in the singular to ensure that § 414.1335 uniformly references the various types of MIPS participants in the singular. We made a grammatical correction to § 414.1335(a)(1)(i) to ensure subject-verb agreement. We noted that the technical amendments in § 414.1335(a)(1)(i) and (ii) are not applicable to subgroups because MIPS subgroup participation is part of the MVP framework, which has separate data submission criteria specified in § 414.1365.

We proposed technical amendments to the data submission criteria for the CAHPS for MIPS Survey measure, which will identify the CAHPS for MIPS Survey as a measure in § 414.1335(a)(3). Currently, § 414.1335(a)(3) does not reference the CAHPS for MIPS Survey as a measure, which is erroneous. Also, we proposed a revision to § 414.1335(a)(3) to recognize that a virtual group, subgroup, and APM Entity are able to administer the CAHPS for MIPS Survey in § 414.1335(a)(3)(i).

Additionally, we proposed amendments to the data submission criteria for quality performance category at § 414.1325(a)(1)(i) and (ii) in order to clarify that the data submission of MIPS quality measures specific to eCQMs must be submitted utilizing certified electronic health record technology (CEHRT). Section 1848(q)(5)(B)(ii) of the Act provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall: (1) Encourage MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of CEHRT and QCDRs; and (2) For a performance period for a year, for which a MIPS eligible clinician reports applicable measures under the quality performance category through the use of CEHRT, treat the MIPS eligible clinician as satisfying the CQMs reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year. To encourage the use of CEHRT for quality improvement and reporting on measures under the quality performance category, we established a scoring incentive for MIPS eligible clinicians who use their CEHRT systems to capture and report quality information, specifically the end-to-end electronic reporting bonus points (81 FR 77294 through 77297). We sunset the end-to-end electronic reporting bonus points starting with the CY 2022 performance period (CY 2021 performance period/2023 MIPS payment year was the last performance period in which the end-to-end electronic reporting bonus points were available (85 FR 84907 through 84908)).

With the framework for transforming MIPS through MVPs, we noted in the CY 2021 PFS final rule that we will find ways to incorporate digital measures without needing to incentivize end-to-end electronic reporting with bonus points (85 FR 84907 through 84908). In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged interested parties to consider electronically specifying their quality measures as eCQMs, to encourage MIPS eligible clinicians, groups, and virtual groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the duration of the program. Since the inception of MIPS, our intention has been to encourage the utilization of CEHRT, which encompasses the requirement of CEHRT pertaining to eCQM data submission.

With the sunset of the end-to-end electronic reporting bonus points, there is ambiguity regarding the requirement of utilizing CEHRT for the data submission of eCQMs. While the sunsetting of the end-to-end electronic reporting bonus points was merely to eliminate such bonus points, our intention was to continue the requirement of utilizing CEHRT for eCQM data submission. However, with the sunset of the end-to-end electronic reporting bonus points, there is an inadvertent absence in policy that would continue the requirement of utilizing CEHRT for eCQM data submission. As a result of such inadvertent absence of policy establishing the overarching CEHRT requirements for eCQM data submission for purposes of the quality performance category (aside from the CEHRT requirements under the end-to-end electronic reporting bonus point criteria), we are rectifying the issue by establishing the requirement to utilize CEHRT for the data submission of eCQMs. We proposed to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT in § 414.1335(a)(1). Specifically, in § 414.1335(a)(1)(i)(A) and (ii)(A), we proposed that the data submission criteria for eCQMs requires the utilization of CEHRT, as defined in § 414.1305. Furthermore, we proposed to amend the definition of CEHRT in § 414.1305(2)(ii) by broadening the applicability of the health IT certification criteria identified in 42 CFR 170.315 that are necessary to report objectives and measures specified under MIPS (would no longer be limited to the Promoting Interoperability performance category). As a result of this proposal, the health IT certification criteria identified in § 414.1305(2)(ii) would be applicable, where necessary, for any MIPS performance category, including the criteria that support eCQMs identified in § 414.1305(2)(ii)(B).

We noted that the proposal pertaining to the data submission criteria for eCQMs requiring the utilization of CEHRT will not require third party intermediaries that report eCQMs on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to obtain certification. Currently, third party intermediaries may facilitate reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for an eCQM while not having been certified to the certification criteria at 45 CFR 170.315(c)(1) through (3). However, if a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity is relying on a third party intermediary for elements of the required certification capabilities for the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the CEHRT definition applicable for their participation, then the third party intermediary will need to provide the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity with a certified Health IT Module for the needed capability or capabilities.

We noted that the definition of CEHRT in § 414.1305 references several certification criteria in the ONC Health IT Certification Program for clinical quality measurement, including: ''Clinical quality measures (CQMs)—record and export'' (45 CFR 170.315(c)(1)), as part of the 2015 Base Electronic Health Record (EHR) definition in 45 CFR 170.102; ''Clinical quality measures (CQMs)—import and calculate'' (45 CFR 170.315(c)(2)); ''Clinical quality measures (CQMs)—report'' (45 CFR 170.315(c)(3)); and, optionally, ''Clinical quality measures (CQMs)—filter'' (45 CFR 170.315(c)(4)). Under the proposal, at a minimum, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity would need to utilize technology certified to the criteria at 45 CFR 170.315(c)(1) through (3) to report on eCQMs. We reiterate that certified Health IT Modules meeting these criteria are not required to be provided by the same health IT developer; a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity may use Health IT Modules to meet the certification requirements provided by more than one developer. For example, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could use certified health IT meeting the criteria in 45 CFR 170.315(c)(1) and (c)(2) provided as part of their EHR system while a third party intermediary that supports reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could supply a Health IT Module that meets the criterion in 45 CFR 170.315(c)(3) to generate a measure report and thus, enable a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity

to meet the requirement to use CEHRT for eCQMs.

Lastly, we proposed to establish data submission criteria for the Medicare CQM collection type (as proposed under the APP in the CY 2024 PFS proposed rule (88 FR 52420 through 52423)) in § 414.1335(a)(4). Specifically, in § 414.1335(a)(4)(i), we proposed that the data submission criteria pertaining to Medicare CQMs will be met by, a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

We solicited public comment on the proposals regarding the technical amendments that pertain to the data submission criteria for MIPS quality measures and the establishment of data submission criteria for Medicare CQMs. The following is a summary of the public comments received.

Comment: One commenter supported all proposed technical amendments.

Response: We appreciate the support from the commenter.

Comment: Several commenters supported the technical amendment pertaining to the data submission criteria for eCQMs requiring the utilization of CEHRT, which provided clarification regarding the requirement of using CEHRT for the data submission of eCQMs. A few commenters supported that a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity would need to utilize technology certified to the criteria at 45 CFR 170.315(c)(1) through (3) to report on eCQMs. The commenters indicated that while some third party intermediaries may not fully meet CEHRT criteria, it is essential that they adhere to the same standards as others when reporting eCQMs; such consistency would ensure uniform and reliable data submission across all third party intermediaries.

Response: We appreciate the support from commenters and agree with commenters regarding third party intermediaries adhering to the same standards to ensure the uniform and reliable submission of data.

Comment: One commenter encouraged CMS to further incentivize eCQM submissions by adding enough eCQMs to each MVP, which would allow for eCQMs alone to meet the reporting requirements under the quality performance category.

Response: It should be noted that we implement applicable eCQMs in MVPs when they are available. As more eCQMs are implemented in MIPS, we will assess and determine which eCQMs would be available for reporting in an MVP.

Comment: A few commenters indicated that EHR vendors with CEHRT do not automatically include the capability to easily report the most recent version of an eCQM for MIPS with minimal manual effort. Also, the commenters indicated that CEHRT requirements do not standardize the capture and reporting of individual eCQM data elements across vendor systems, which would require the tailoring of data extracts and uploads across systems and multiple sights (including Taxpayer Identification Numbers (TINs) participating in the Medicare Shared Savings Program as part of an ACO). Additionally, a few commenters indicated that CEHRT standards have not advanced enough to support quality measurement derived from multiple sources.

Response: We appreciate the feedback from commenters. We note that certification criteria referenced in the CEHRT definition for clinical quality measurement incorporate QRDA standards, which enable standardization of quality data for reporting and exchange. Also, we recognize that MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including Medicare Shared Savings Program ACOs, may use additional capabilities beyond those included in the certification criteria in 45 CFR 170.315(c)(1) through (3) to support aggregation of data for eCQMs across systems. We reiterate that the definition of CEHRT references the ''clinical quality measurement—filter'' certification criterion at 45 CFR 170.315(c)(4) as an optional criterion. Such criterion requires health IT to be able to filter eCQM results at both patient and aggregate levels. Moreover, a Health IT Module must be able to filter by a single data element (for example, provider type) or a combination of any of certain data elements.[492]

Comment: One commenter did not support the proposal to require the utilization of CEHRT for the data submission of eCQMs because such requirement would increase costs and complexity for third party intermediaries.

Response: We recognize that the proposal requiring the utilization of CEHRT for the data submission of eCQMs may require the investment of resources for third party intermediaries to support the submission of eCQMs. However, we previously noted that under the proposal, at a minimum, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity would need to utilize technology certified to the criteria at 45 CFR 170.315(c)(1) through (3) to report on eCQMs. We reiterated that certified Health IT Modules meeting these criteria are not required to be provided by the same health IT developer; a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity may use Health IT Modules to meet the certification requirements provided by more than one developer. For example, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could use certified health IT meeting the criteria in 45 CFR 170.315(c)(1) and (c)(2) provided as part of their EHR system while a third party intermediary that supports reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could supply a Health IT Module that meets the criterion in 45 CFR 170.315(c)(3) to generate a measure report and thus, enable a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the requirement to use CEHRT for eCQMs.

After consideration of public comments, we are finalizing, as proposed, the technical amendments that pertain to the data submission criteria for MIPS quality measures and the establishment of data submission criteria for Medicare CQMs.

(ii) Data Submission Criteria for the CAHPS for MIPS Survey Measure

The CAHPS for MIPS Survey measures patients' experience of care within a group, virtual group, subgroup, and APM Entity, including Shared Savings Program ACOs. The survey measures 10 dimensions of patient experience of care, known as summary survey measures, for which patients may be the best, if not only source of information. The CAHPS for MIPS Survey is optional for all groups, virtual groups, subgroups, and APM Entities of 2 or more eligible clinicians reporting via traditional MIPS or MIPS Value Pathways (MVPs) and is required for Shared Savings Program ACOs reporting under the APP.

(A) Require the Administration of the CAHPS for MIPS Survey in the Spanish Translation

We have created official translations of the CAHPS for MIPS Survey in 7 languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese, in addition to the required administration

[492] For more information regarding the ''clinical quality measurement-filter'' criterion, we refer readers to the ONC Certification Companion Guide available at *https://www.healthit.gov/test-method/clinical-quality-measures-cqms-filter.*

of English survey. However, use of these translations is generally voluntary, with the exception of the requirement to administer the Spanish language translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Organizations (groups, virtual groups, subgroups, and APM Entities) that elect CAHPS for MIPS Survey must contract with a CMS-approved survey vendor to administer the CAHPS for MIPS Survey and must request survey translations for the vendor to administer the CAHPS for MIPS Survey in an optional language. Generally, the use of the survey translations are an additional survey administration cost to the organizations.

Our analysis of historic CAHPS data indicated that the use of the survey translations has not been widespread and there is unmet need for access to surveys in the 7 available translations. The analysis of survey translation use by groups and Shared Savings Program ACOs fielding the CY 2021 performance period CAHPS for MIPS Survey indicated that 141 out of 559 organizations have 10 percent or more respondents reporting they speak a language other than English at home and out of these 141 organizations, 114 organizations have all of their survey responses in English. Analyzing data from the U.S. Census Bureau, specifically from the 2021 American Community Survey, we found that Spanish is spoken by 61 percent of those who speak a language other than English at home.[493]

To address unmet need, we proposed to require the administration of the CAHPS for MIPS Survey in the Spanish language translation; more specifically, we proposed to require organizations to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, would administer the Spanish language translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. Also, we recommended that organizations administer the survey in the other available translations (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese) based on the language preferences of their patients. The proposal and recommendation would make the survey more accessible to survey respondents who can only respond in Spanish or another available translation, better ensure that we are assessing the experience of patients who have limited English proficiency, and is part of our efforts to advance health equity. We refer readers to the CY 2024 PFS proposed rule (88 FR 52565) for further information regarding the proposal requiring the administration of the Spanish language translation of the survey.

We solicited public comment on the proposal to require the administration of CAHPS for MIPS Survey in the Spanish language translation, in particular from organizations that administer the CAHPS for MIPS Survey to understand if they consider contracting with vendors to administer the survey in one or more of the available survey translations based on the language preferences of patients. We were also interested in learning about the factors that more or less likely affect the administration of survey translations where there is need for one or more of the available translations.

Simultaneously, we also proposed the same proposal regarding the requirement to administer the Spanish language translation of the survey for the Medicare Shared Savings Program Accountable Care Organizations (Shared Savings Program ACOs) reporting the CAHPS for MIPS Survey measure under the APP as described in section III.G.2.g. of this final rule.

We received public comments regarding the proposal to require the administration of the CAHPS for MIPS Survey in the Spanish language translation. The following is a summary of the public comments received.

Comment: Most commenters supported CMS's efforts to improve health equity and language accessibility by requiring administration of the Spanish language translation of the survey. Many commenters suggested that requiring Spanish language survey administration could improve survey participation and response rates. A few commenters noted that survey results will better reflect the true perspectives of patients when surveys are provided in their preferred language. Some commenters also expressed support of CMS's recommendation to offer other language translations of the survey, while other commenters encouraged CMS to consider requiring use of additional translations in future rulemaking.

Response: We appreciate the commenters' support. We agree with commenters that requiring Spanish language survey administration will assist our efforts to advance health equity by assessing the experience of patients whose preferred language is Spanish and may result in increased survey participation and response rates. We are also appreciative of the support for our recommendation that organizations use the other available survey translations based on the needs of their patient populations and the suggestion to require additional language translations. We will consider this suggestion for future rulemaking; however, we intend to investigate the extent of additional burden, such as cost, to providing the survey translations before expanding the requirement to include translations other than Spanish.

Comment: One commenter supported the proposal but expressed concern about the additional cost burden to organizations fielding the survey; this commenter suggested shifting the increased costs to the survey vendors. Another commenter noted that they believed the additional costs associated with the Spanish language administration were outweighed by the benefits.

Response: We recognize the commenter's concern about the potential for additional cost burden of the Spanish language requirement to organizations fielding the CAHPS for MIPS survey. We do not have the legal authority to control vendor costs associated with the administration of the survey or to shift any increase in cost to the survey vendors as suggested. Further, we agree with the comment that any additional costs incurred by the Spanish language requirement is outweighed by the potential benefits such as promoting better response rates by enabling more patients to participate in the survey and ensuring that language does not hinder quality or experience of care. As mentioned earlier in this section, we intend to investigate the extent of additional costs to providing the survey translations before expanding the requirement to include translations other than Spanish.

Comment: One commenter mentioned the challenges with capturing the correct language from the patient during patient registration and requested more time to administer additional languages after the addition of Spanish during CY 2024. Another commenter expressed support for the intent of requiring use of a validated and reliable translated CAHPS for MIPS survey, but also expressed concern with physician burden to meet the requirement.

Response: We appreciate the commenters' concerns about physician burden to meet the requirement as well as the challenges with capturing the correct language preferences of patients

[493] U.S. Census Bureau, 2021 American Community Survey, S1603: Characteristics of People by Language Spoken at Home, 2021 American Community Survey 5-Year Estimate Subject Tables. Available at *https://data.census.gov/table?q=S1603&tid=ACSST5Y2021.S1603.*

during patient registration and the additional time needed to assess the need for the other available translations. First, assessing Spanish language preference will not result in additional burden to organizations or physicians administering the CAHPS for MIPS Survey as this will be determined by the vendor during survey administration with the survey respondents. We also want to clarify that since we are not requiring the administration of the other available translations, organizations will continue to have the flexibility on how best to determine the language preferences of their patients within their practices and the need for the administration of the other available survey translations.

After consideration of public comments, we are finalizing, as proposed, to require the administration of the CAHPS for MIPS Survey in the Spanish language translation.

(d) Data Completeness Criteria

(i) Data Completeness Criteria for Quality Measures, Excluding the Medicare CQMs

As described in the CY 2017 Quality Payment Program proposed rule (81 FR 28188 and 28189), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not individuals entitled to benefits under Part A or enrolled under Part B of Medicare. In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we also noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), CMS established the data completeness criteria threshold to reflect a threshold of at least 50 percent (81 FR 77125). We increased the data completeness criteria threshold from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and maintained a threshold of at least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, we increased the data completeness criteria threshold from at least 60 percent to at least 70 percent (84 FR 62952). We maintained data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). We continue to believe that it is important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS.

The incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049). We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632, 86 FR 65436, and 87 FR 70049). The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. A data completeness criteria threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632, 86 FR 65436, and 87 FR 70049).

We previously noted concerns raised by interested parties regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, 84 FR 62951, and 87 FR 70049). We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[494] it is feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform in MIPS.

As MIPS eligible clinicians, groups, and virtual groups have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 7 years (from CY 2017 performance period to CY 2023 performance period), such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entity to meet incremental increases in the data completeness criteria threshold. We have maintained a data completeness criteria threshold of at least 70 percent for four years from the CY 2020 performance period to the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent for a 2-year timeframe (CY 2024 and CY 2025 performance periods) with more than 12 months to prepare for an increased data completeness criteria threshold of at least 75 percent before such threshold becomes effective for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

As we assessed the timeframe for increasing the data completeness criteria threshold, we determined that maintaining the data completeness criteria threshold of at least 75 percent for a total of 3 years would provide sufficient time for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to transition to another increase in the data completeness criteria threshold. For the CY 2026 performance period/2028 MIPS payment year, we proposed to maintain the data completeness criteria threshold of at least 75 percent. This would provide MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities with sufficient time to prepare for an incrementally increase in the data completeness criteria threshold starting with the CY 2027 performance period/2029 MIPS payment year. Therefore, MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities could continue transitioning to an incrementally increased data completeness criteria threshold of at least 75 percent to at least 80 percent. In establishing data completeness criteria thresholds in advance of an applicable performance period, it is advantageous to delineate

[494] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

the expectations for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, so they can adequately prepare for a transition to higher data completeness criteria threshold, particularly the increase in data completeness criteria threshold to at least 80 percent. Thus, we proposed to increase the data completeness criteria threshold from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year.

The use of EHRs and eCQMs can reduce burden associated with meeting higher data completeness standards as the collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. We continued to encourage individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including small and rural practices, to explore EHR adoption and the reporting of eCQMs to reduce burden and technical challenges to ensure data accuracy as we seek to increase the data completeness criteria threshold. Individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities that continue to utilize other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or QCDRs, would need to have the logic code of their EHRs to be updated to account for the increased data completeness criteria threshold. Increasing the data completeness criteria threshold would not pose a substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, unless they are manually extracting and reporting quality data. However, increasing the data completeness criteria threshold provides for the more accurate assessment of performance.

For the aforementioned reasons, it is important to incrementally increase the data completeness criteria threshold. In the CY 2024 PFS proposed rule, we proposed to maintain the data completeness threshold for an additional year before incrementally increasing the data completeness criteria threshold. Specifically, in § 414.1340(a), we proposed the following data completeness criteria thresholds pertaining to QCDR measures, MIPS CQMs, and eCQMs:

- At paragraph (a)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's Denominator criteria, regardless of payer.
- At paragraph (a)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

Similarly, in § 414.1340(b), respectively, we proposed the following data completeness criteria thresholds pertaining to Medicare Part B claims measures:

- At paragraph (b)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.
- At paragraph (b)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

Also, for the data completeness criteria pertaining to the quality performance category, we proposed technical amendments to recognize that a virtual group, subgroup, and APM Entity must meet the data completeness criteria requirements established at § 414.1340(a), (b), and formerly paragraph (d), new paragraph (e) due to the proposal to establish the data completeness criteria for the new collection type, Medicare CQM, in § 414.1340(d) as described in the CY 2024 PFS proposed rule (88 FR 52567).

We solicited public comment on these proposals. The following is a summary of the public comments received.

Comment: A few commenters expressed their appreciation for the gradual and incremental increase in the data completeness criteria threshold, which would allow for a more accurate assessment of performance.

Response: We appreciate the support from commenters.

Comment: Some commenters supported the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, which would extend the data completeness threshold of at least 75 percent for another performance period.

Response: We appreciate the support from commenters.

Comment: Some commenters requested for the previously established data completeness criteria threshold of at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2028 MIPS payment years to be lowered to at 70 percent. A few commenters indicated that there are technical and interoperability challenges (that is, data collection variability across multiple EHRs, systems, and sights (including multiple TINs participating in the Medicare Shared Savings Program as part of an ACO); lack of agreed upon semantic and syntactic standards; data privacy concerns; and patient misidentification), which make it difficult to meet the data completeness criteria threshold. A few commenters indicated that a data completeness criteria threshold of more than 70 percent would make it difficult for small and rural practices with fewer resources and staff to meet the data completeness criteria threshold.

Response: As previously noted, we believe that MIPS eligible clinicians, groups, and virtual groups have gained experience participating in MIPS, particularly meeting the increased data completeness criteria thresholds over the last 7 years (from CY 2017 performance period to CY 2023 performance period), and such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entity to meet incremental increases in the data completeness criteria threshold. The data completeness criteria threshold of at least 70 percent was maintained for 4 years from the CY 2020 performance period to the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent.

We have implemented a slow, gradual, and incremental increase in the data completeness criteria threshold in order to provide sufficient time for the preparation of an increase. We continued to encourage individual MIPS

eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including small and rural practices, to explore EHR adoption and the reporting of eCQMs to reduce burden and technical challenges to ensure data accuracy as we seek to increase the data completeness criteria threshold.

Also, we recognize that there are technical challenges such as data collection variability across multiple EHRs, systems, and sights, particularly as such the technical challenges pertaining to Medicare Shared Savings Program ACOs with multiple TINs under an ACO. In order to assist with the mitigation of the technical challenges encountered by Medicare Shared Savings Program ACOs reporting eCQM and/or eCQM, we are finalizing, as proposed, the proposal that establishes the Medicare CQMs collection type; the Medicare CQMs will serve as a transition collection type under the APP and be available as determined by CMS. For the Medicare CQMs collection type, Medicare Shared Savings Program ACOs report quality data on a subset of Medicare beneficiaries (beneficiaries eligible for Medicare CQMs as defined at § 425.20) instead of the reporting of quality data on all-payers as required for eCQMs and MIPS CQMs. We refer readers to section III.G.2.b.of this final rule for the discussion regarding the implementation and operationalization of the Medicare CQMs collection type under the APP.

We are maintaining the previously finalized policy of increasing the data completeness criteria threshold of at least 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years and extending such data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/ 2028 MIPS payment year.

Comment: No commenters supported the increase of the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/ 2029 MIPS payment year. Many commenters indicated that increasing the data completeness criteria threshold to at least 80 percent would increase burden, and in particular, disproportionately increase burden for smaller and rural practices due to limited resources and staff. Some commenters expressed concerns that an increase in the data completeness criteria threshold to at least 80 percent would exacerbate the technical and interoperability challenges pertaining to data aggregation across multiple EHRs, systems (utilizing different registries, and EHR developers and vendors), and sites (including multiple TINs participating in the Medicare Shared Savings Program as an ACO), which would make it more difficult to meet the data completeness criteria threshold. A few commenters indicated that some practices are still recovering from the COVID–19 Public Health Emergency and as a result, increasing the data completeness criteria threshold would increase burden. One commenter recommended that CMS allow for the implementation of the data completeness criteria threshold of at least 75 percent to occur prior to increasing the data completeness criteria threshold to at least 80 percent, which would enable for the evaluation of the policy.

Response: While we believe it is important to increase the data completeness criteria threshold in order to assess a MIPS eligible clinician's performance more accurately on quality measures and prevent selection bias to the extent possible performance, we recognize the concerns raised by the commenters and believe it is inappropriate to finalize the policy as proposed. In this final rule, we are not establishing the data completeness criteria threshold for the CY 2027 performance period/2029 MIPS payment year.

Comment: One commenter requested for CMS to stabilize the data completeness criteria threshold, which would allow clinicians participating in MIPS to focus on improvement and successfully transition to reporting digital quality measures and meeting reporting requirements under MVPs.

Response: Advance notice of the gradual and incremental increase in the data completeness criteria threshold provides a sufficiently stable data completeness policy for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to focus on improvement. The pace at which the data completeness standard has increased provides ample time to prepare for an increase while also transitioning to the reporting of digital quality measures and participation in an MVP. The data completeness criteria threshold of at least 70 percent was maintained for 4 years from the CY 2020 performance period/2022 MIPS payment year to the CY 2023 performance period/2025 MIPS payment year. The data completeness criteria threshold is increasing to at least 75 percent and will be maintained at that level for 3 years from the CY 2024 performance period/2026 MIPS payment year to the CY 2026 performance period/2028 MIPS payment year. The data completeness criteria threshold is predictable and stable during a segment of time.

Comment: One commenter requested for CMS to consider the establishment of different data completeness criteria thresholds for certain measures such as patient-reported outcome measures. As an example, the commenter indicated that it would be difficult to meet a data completeness criteria threshold of at least 50 percent for a patient-reported outcome measure.

Response: We note that the CAHPS for MIPS Survey, which is a patient-reported outcome measure, has different data completeness criteria requirements from QCDR measures, eCQMs, MIPS CQMs, and Medicare Part B claims measures. For the CAHPS for MIPS survey measure, groups, virtual groups, subgroups, and APM Entities report data on a sample of Medicare Part B patients provided by CMS. We recognize that patient-reported outcome measures would require differing data completeness criteria threshold requirements from QCDR measures, eCQMs, MIPS CQMs, and Medicare Part B claims measures.

Comment: Some commenters requested for CMS to establish a different data completeness criteria threshold for Medicare Shared Savings Program ACOs reporting eCQMs, MIPS CQMs, and Medicare CQMs. Other commenters expressed concerns regarding the data completeness criteria requirement for Medicare CQMs as having a much higher expectation for data completeness than the CMS Web Interface and as a result, may not ease the transition to the collection of all-payer data for the reporting of eCQMs and MIPS CQMs.

Response: To provide consistency regarding the data completeness criteria threshold across collection types and prevent confusion regarding the expectations concerning the data completeness criteria threshold, we believe it is imperative to establish the same data completeness criteria threshold requirements for QCDR measures, eCQMs, MIPS CQMs, Medicare Part B claims measures, and Medicare CQMs.

We recognize that there are technical challenges for Medicare Shared Savings Program ACOs as they prepare to report eCQMs and MIPS CQMs under the APP. As a result of the aforementioned technical challenges, we are finalizing, as proposed, to establish the Medicare CQMs collection type; the Medicare CQMs will serve as a transition collection type under the APP and be available as determined by CMS. For the Medicare CQMs collection type, Medicare Shared Savings Program ACOs

report quality data on a subset of Medicare beneficiaries (beneficiaries eligible for Medicare CQMs as defined at § 425.20) instead of the reporting of quality data on all-payers as required for eCQMs and MIPS CQMs. We refer readers to section III.G.2.b.of this final rule for the discussion regarding the implementation and operationalization of the Medicare CQMs collection type under the APP.

After consideration of public comments, we are finalizing, as proposed, the proposals in § 414.1340(a), (b), (d), and (e) as follows:

- At paragraph (a)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

- At paragraph (b)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

- At paragraph (d)(1), for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

- Technical amendments at §§ 414.1340(a), (b), and formerly paragraph (d), new paragraph (e) due to the establishment of the data completeness criteria for the new collection type, Medicare CQM, in § 414.1340(d).

However, we are not finalizing the proposals at § 414.1340(a)(5), (b)(5), and (d)(2) to increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

(ii) Data Completeness Criteria for the Medicare CQMs

As we proposed to establish a new collection type, the Medicare CQMs specific to the APM Performance Pathway (APP) as described in the CY 2024 PFS proposed rule (88 FR 52420 through 52423), we also proposed to establish the data completeness criteria thresholds for the Medicare CQMs. Specifically, in § 414.1340(d), respectively, we proposed the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.
- At paragraph (d)(2), for the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 80 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.

We proposed to establish the aforementioned data completeness criteria thresholds for the Medicare CQMs collection type in advance of the applicable performance periods. We recognize that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP. We will assess the availability of the Medicare CQMs as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

As previously noted, we are finalizing, as proposed, the following proposal the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

However, we are not finalizing the proposal at § 414.1340(d)(2) to increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

(e) Selection of MIPS Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding to the list, as appropriate, new measures; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968); CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We proposed changes to the MIPS quality measure set, as outlined in Appendix 1 of the CY 2024 PFS proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2024 performance period, we proposed a measure set of 200 MIPS quality measures in the inventory.

The new MIPS quality measures that we proposed to include in MIPS for the CY 2024 performance period and future years can be found in Table Group A of Appendix 1 of the CY 2024 PFS proposed rule. For the CY 2024 performance period, we proposed 14 new MIPS quality measures, which includes one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures.

In addition to the establishment of new individual MIPS quality measures,

we developed and maintained specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. We proposed modifications to existing specialty sets and new specialty sets as described in Table Group B of Appendix 1 of the CY 2024 PFS proposed rule. Specialty sets may include new measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 3, 2023, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 8 of MIPS under the Quality Payment Program.[495] These recommendations were based on the MIPS quality measures finalized in the CY 2022 PFS final rule and the 2022 Measures Under Consideration List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with were proposed in the CY 2024 PFS proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of the CY 2024 PFS proposed rule, we referred readers to Table Group C of Appendix 1 of the CY 2024 PFS proposed rule for a list of quality measures and rationales for measure removal. We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959). For the CY 2024 performance period, we proposed to remove 12 MIPS quality measures and partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. We referred readers to Table Group DD of Appendix 1 of the CY 2024 PFS proposed rule for further information regarding the proposals to retain such measures for retention for use in relevant MVPs. Of the 12 MIPS quality measures proposed for removal, the following pertains to such measures: 2 MIPS quality measures are duplicative to a proposed new MIPS quality measure; 3 quality measures are duplicative of current measures; 5 MIPS quality measures that are under the topped-out lifecycle; one measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see,* for example, 83 FR 59763 through 59765). The proposal to remove the quality measures described in Table Group C of the CY 2024 PFS proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria.

Also, we proposed substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of the CY 2024 PFS proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). We proposed substantive changes to 59 MIPS quality measures, which includes 3 MIPS quality measures proposed to be retained for utilization under MVPs (we referred readers to Table Group DD of Appendix 1 of the CY 2024 PFS proposed rule for such measures that are proposed for retention for use in relevant MVPs). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive.

Lastly, we proposed substantive changes to the CMS Web Interface measures that are available as a collection type and submission type for the Medicare Shared Savings Program ACOs meeting reporting requirements under the APP. The substantive changes to the CMS Web Interface measures can be found in Table Group E of Appendix 1 of the CY 2024 PFS proposed rule.

We solicited public comment on the proposals to modify the quality performance category measure set, a measure set of 200 MIPS quality measures in the inventory for the CY 2024 performance period, which includes the following:

- Implementation of 14 new MIPS quality measures: one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures;
- Removal of 12 MIPS quality measures: 2 quality MIPS measure are duplicative to a proposed new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 5 MIPS quality measures are under the topped-out lifecycle; one MIPS quality measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden;
- Partial removal of 3 MIPS quality measures: 3 MIPS quality measures removed from traditional MIPS and retained for use in MVPs; and
- Substantive changes to 59 MIPS quality measures.

We refer readers to Table Groups A through E of Appendix 1 of this final rule for a summary of public comments received regarding the proposed modifications to the MIPS quality measure set for the CY 2024 performance period and the discussion regarding final decisions.

After consideration of public comments, and for the reasons stated in the aforementioned Table Groups A through E of Appendix 1 of this final rule and the CY 2024 PFS proposed rule (88 FR 52766 through 53132), we are finalizing, with modification, a measure set of 198 MIPS quality measures in the inventory for the CY 2024 performance period, which includes the following:

- Implementation of 11 new MIPS quality measures: 1 composite measure; and 6 high priority measures, of which 4 are also patient-reported outcome measures;
- Removal of 11 MIPS quality measures: 1 quality MIPS measure is duplicative to a new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 5 MIPS quality measures are under the topped-out lifecycle; 1 MIPS quality measure is extremely topped out; and 1 MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden;
- Partial removal of 3 MIPS quality measures: 3 MIPS quality measures removed from traditional MIPS and retained for use in MVPs; and
- Substantive changes to 59 MIPS quality measures.

[495] Message to the Quality Payment Program listserv on January 3, 2023, entitled: ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2024 Performance Year of the Merit-based Incentive Payment System (MIPS).''

(2) Cost Performance Category

Section 1848(q)(2)(A) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the cost performance category.

In the CY 2024 PFS proposed rule (88 FR 52568 through 52576), we proposed to add five new episode-based measures to the cost performance category using a 20-episode case minimum and to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. In addition, we proposed to add the five new episode-based measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

For a description of the statutory basis for and existing policies pertaining to the cost performance category, we referred readers to § 414.1350 and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), and CY 2023 PFS final rule (87 FR 70055 through 70057).

(a) Addition of Episode-Based Measures

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 25 cost measures in the cost performance category for the CY 2023 performance period/2025 MIPS payment year, comprising of 23 episode-based measures covering a range of conditions and procedures and two population-based measures. We worked with the measure development contractor to identify the proposed five new episode-based measures for development through empirical analyses and public comment. These measures cover clinical topics and MIPS eligible clinicians currently with limited or no applicable cost measures. As such, these measures will help fill gaps in the cost performance category's measure set. In addition, these measures will support the transition from traditional MIPS to MIPS Value Pathways (MVPs) by allowing new MVPs to be created and enhancing existing MVPs. Further, the addition of these measures will address interested parties' feedback about the need for more clinically refined episode-based measures in the cost performance category. They will also increase the cost coverage of care episode and patient conditions groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

All five of the new measures have been developed with extensive engagement from interested parties, including clinicians, persons with lived experience, and the public. For more information regarding episode-based measures and the measure development process, we refer readers to the overview in the CY 2024 PFS proposed rule (88 FR 52569 through 52571). In sections IV.A.4.f.(2)(a) and IV.A.4.f.(2)(b) of this final rule, we provide detail about the new measures that we proposed to include in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

(ii) New Episode-Based Measures Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of this final rule, we discuss the five new episode-based measures, which we proposed to add to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. As we discuss in this section, after consideration of public comments, we are finalizing our proposal to add the five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

In conjunction with our measure development contractor, we developed these measures with consideration of the common standards that are described in the CY 2022 PFS final rule (86 FR 65455 through 65459) to ensure consistency across episode-based measures being developed. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment. The five new episode-based measures we proposed meet all requirements described in CY 2022 PFS final rule, including these features. We provide more information on the specific requirements for each of the episode-based measures later in this section of the final rule.

Generally, for all episode-based measures, we exclude episodes where costs cannot be fairly compared to the costs for the whole cohort in the episode-based measure. These exclusions, like other features of each episode-based measure, are developed with extensive clinician and interested parties' engagement. We have specified exclusions for all five proposed episode-based measures. We discuss certain exclusions for the Psychoses and Related Conditions and the Emergency Medicine measure in further detail in this section of this final rule.

We also apply a risk adjustment model to all episode-based measures in the cost performance category. The model includes standard risk adjustors that are applied to all episode-based measures (for example, CMS Hierarchical Condition Category [HCC] variables, comorbidities, age brackets, disability status, ESRD status), and measure-specific risk adjustors (for example, patient transfers from another setting for the Emergency Medicine measure). We assess the risk adjustment model at the level of each stratification to ensure that only like patients are compared to each other. The risk adjustment model we use in development of the cost performance category's episode-based measures is described in detail in CY 2019 PFS final rule (83 FR 59767 through 59773). As mentioned previously in this section, all five proposed episode-based measures have been risk adjusted in accordance with this model.

More information on the episode-based measure development requirements, which were outlined so that external interested parties could develop measures in the future, are available in the Blueprint for the CMS Measures Management System (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*) and the Meaningful Measures Framework (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*).

The episode-based measures that we proposed for the CY 2024 performance period/2026 MIPS payment year and future performance periods are listed in the Table 51.

TABLE 51: Proposed Episode-Based Measures Beginning with CY 2024 Performance Period/2026 MIPS Payment Year

Measure Name	Episode Type
Depression	Chronic condition
Emergency Medicine	Care Setting
Heart Failure	Chronic condition
Low Back Pain	Chronic condition
Psychoses and Related Conditions	Acute inpatient medical condition

The three chronic condition episode-based measures assess outpatient treatment and ongoing management of the following chronic conditions: depression, heart failure, and low back pain. The measure construction for these three proposed measures follows the approach described in the CY 2022 PFS final rule (86 FR 65445 through 65461), which also includes detailed discussion of the attribution methodology and examples of how episodes are attributed.

The attribution methodology that identifies a clinician-patient care relationship is slightly different at the clinician group and individual MIPS eligible clinician levels, to reflect that care provided at the clinician group and individual MIPS eligible clinician levels, respectively. At a high level, these proposed chronic condition episode-based measures attribute episodes to the clinician group that renders services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group. Both claims must have a diagnosis code indicating the same chronic condition related to the specific episode-based measure. For example, for the Heart Failure measure, both claims of the trigger event must have a diagnosis indicating heart failure. The services that trigger an event for these chronic condition episode-based measures are identified first by Evaluation and Management (E/M) codes for outpatient services, and then by a second claim with either another E/M code for outpatient services or a condition-related Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code (CPT/HCPCS) related to the treatment or management of the chronic condition. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic condition. If we see evidence that the relationship is ongoing, represented by another E/M or condition-related procedure code that we refer to as the reaffirming claim, then this window can be extended.

For individual MIPS Eligible clinicians, we would attribute episodes to each individual MIPS eligible clinician within an attributed clinician group that renders at least 30 percent of trigger or reaffirming codes on Part B Physician/Supplier claim lines during the episode, such as office visits or diagnostic services. We also apply conditions to ensure the MIPS eligible clinicians to whom the episode is attributed are reasonably responsible for the management of the patient's chronic condition. Specifically, the MIPS eligible clinician must have provided condition-related care to this patient prior to or on the episode start date.

Additionally, we use the provider-level prescription billing patterns to ensure that we are capturing the MIPS eligible clinicians directly involved in providing ongoing chronic care management, rather than clinicians who might have only refilled a patient's prescription once, as a courtesy to the patient. Specifically, for some measures (that is, Diabetes, Asthma/COPD episode-based measure that were finalized for use in the MIPS cost performance category for the CY 2022 PFS final rule [86 FR 64996], and Heart Failure episode-based measure that is being finalized in this rule), the MIPS eligible clinician must also have prescribed at least two prescriptions claimed under Medicare Part D and/or Medicare Part B related to the management of the condition for two different patients during the measurement period, plus a one-year lookback period. These conditions, which we use to attribute a cost measure to MIPS eligible clinicians, also apply to the attribution methodology at the clinician group level. Specifically, the clinician group will always meet the first condition by construction (that is, there will always be an individual MIPS eligible clinician under the clinician group that has provided care to the patient prior to or on the episode start date). However, the clinician group must have at least one potentially attributable MIPS eligible clinician under it who meets the second condition.

The Psychoses and Related Conditions measure is an acute inpatient medical condition episode-based measure, which focuses on patients hospitalized for schizophrenia, delusional disorders, brief psychotic disorder, schizoaffective disorder, manic episode with psychotic symptoms, bipolar disorder with psychotic symptoms, major depressive disorder with psychotic symptoms, or unspecific psychosis. This acute inpatient medical condition was developed in accordance with the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59769 through 59771). We selected the Psychoses and Related Conditions measure for development because empirical analyses have identified psychoses-related hospitalizations are one of the most common inpatient stays, so it has a strong potential to be impactful on Medicare spending. This measure would also contribute to filling the current identified gap in the cost performance category's measurement of mental health care, as currently there are no episode-based or other cost measures assessing this clinical area.

The Psychoses and Related Conditions measure has been refined since the RFI in CY 2020 PFS proposed rule (84 FR 40760 through 40761) considering expert and other interested parties' input and to further address the Measures Application Partnership (MAP) Coordinating Committee's previously expressed concerns in the 2018–2019 measure development cycle about the ability of inpatient clinicians to affect post-discharge care. In response to this input and these concerns, we implemented three refinements to this measure. First, we reduced the length of the episode window from 90 to 45 days. This shortened episode window helps to ensure that MIPS eligible clinicians

can reasonably be held accountable for post-discharge care, while still capturing readmissions and ED visits shortly after the trigger event, which persons with lived experience had noted as being important outcomes to identify and measure because these outcomes could be avoided with better discharge planning and follow-up care. Second, we refined this measure's specifications to account for specific scenarios where MIPS eligible clinicians have limited ability to influence a patient's care. Specifically, this measure now excludes episodes with involuntary holds at admission and episodes that are transfers to State hospitals. Third, we refined this measure's specifications to risk adjust for facility type to account for differences in payment policies between Inpatient Prospective Payment System (IPPS) and Inpatient Psychiatric Facility (IPF) hospitals. While we continue to believe that the original measure had accounted for concerns about the ability of inpatient clinicians to influence costs after discharge as described in the CY 2020 PFS proposed rule (84 FR 40760 through 40761), we also believe that these changes further refine the measure to meaningfully assess costs related to the role of clinicians caring for patients during mental health hospitalizations.

The Emergency Medicine measure assesses the cost of care clinically related to the treatment of a patient during an ED visit. The intent of this measure is to comprehensively assess all types of care in an ED, so the construction of the measure reflects the goal of capturing this broad scope of care. As such, this measure is characterized as a ''care setting'' episode type.

A CPT/HCPCS code indicating that a clinician has furnished care in the ED setting triggers the Emergency Medicine measure. The clinician billing the trigger code is attributed the episode. A clinician group is attributed by aggregating all episodes attributed to clinicians that bill to the clinician group. The trigger code also opens a 14-day episode window, during which the attributed clinician is responsible for costs.

The Emergency Medicine measure stratifies episodes based on the type of care the patient received during their ED visit and by disposition status. First, episodes are divided into 28 mutually exclusive groups called ED visit types that characterize the focus of care a patient received during their visit. These represent more granular, exhaustive patient populations defined by clinical criteria including the three-digit diagnosis codes available on a patient's ED visit claims, as well as a Medicare Severity Diagnosis Related Group (MS–DRG) of a subsequent inpatient stay if present. Given the goal of the Emergency Medicine measure to capture the broader universe of care provided in the emergency setting, dividing this measure's episodes into ED visit types is a technique to ensure clinical comparability. Examples of a few of the most frequent ED visit types associated with this Emergency Medicine measure are respiratory, gastrointestinal or liver, and kidney and urinary conditions. The 28 ED visit types are further stratified by whether (1) the ED visit resulted in subsequent observation care or inpatient admission or (2) the patient was discharged without subsequent observation care or inpatient admission. For example, ED visits for a stroke that end in discharge are only compared with other ED visits for a stroke that also end in discharge.

The Emergency Medicine measure includes all Medicare Parts A and B services during the 14-day episode window, except for certain services determined not to be clinically relevant to the ED visit type. This reflects the intent of the measure and the broad clinician role in the ED setting. The ED visit type associated with the specific episode determines whether a service is clinically unrelated and therefore excluded from the episode. For example, if a patient visits the ED for ear, nose and throat (ENT) and eye disorders, any subsequent services for psychoses or behavioral and developmental disorders are excluded. However, if a patient visits the ED to receive care for an altered mental state, these subsequent services for psychoses or behavioral and developmental disorders are not excluded.

The Emergency Medicine measure risk adjusts costs just like all other episode-based measures. This measure uses the standard risk adjustment model described previously in this section. Also, as discussed, we assessed the risk adjustment model at the level of each stratification. This means that for the Emergency Medicine measure, the risk adjustment is applied to each combination of ED visit type and disposition status. For example, the risk adjustment model would assess separately a kidney and urinary episode that resulted in an inpatient stay, a kidney and urinary episode that resulted in a discharge, a fracture episode that resulted in an inpatient stay, and a fracture episode that resulted in a discharge.

Similar to other episode-based measures in use in the cost performance category and the episode-based measures being finalized in this rule, we exclude episodes in cases where costs cannot be fairly compared to the costs for the whole cohort in the Emergency Medicine measure. For example, episodes are excluded for patients transferred to another ED facility from the triggering ED facility.

The specifications for all five proposed episode-based measures, which we are finalizing in this rule, are available at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/quality-payment-program-cost-measure-information*. The specifications documents for each measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides detailed methodology describing each step to construct the measure, including: identifying patients receiving care, defining an episode-based measure, attributing episodes to MIPS eligible clinicians and clinician groups, assigning costs, defining exclusions, risk adjusting, and calculating measure score. Second, the measure codes list file contains the codes used in the measure specifications, including the episode triggers, attribution, stratification, assigned items and services, exclusions, and risk adjustors.

More information about the five episode-based measures is available in the measure justification forms, which provide a comprehensive characterization of the measures, their justification, and testing results of these measures' specifications. These documents are available through the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/quality-payment-program-cost-measure-information*.

We solicited public comment on our proposal to add these five episode-based measures, which are listed in Table 51. We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the adoption of new episode-based measures. Commenters stated that cost measures are critical to understanding the value of care, that they should be centered on specific conditions or periods of care, and that they should reflect the group practice model of care where multiple practitioners utilize a team-based approach to treating patients. One commenter supported the development

of more cost measures that measure chronic conditions in primary care settings.

Response: We appreciate the commenters' support of the new episode-based measures and we agree with their comments. We will continue to assess potential areas for development of cost measures related to chronic conditions in the future.

Comment: Commenters supported the inclusion of Emergency Medicine and Low Back Pain measures, as they capture specialties that have not had an applicable cost measure yet. For example, one commenter stated that physical therapists have limited options to participate in either track of the Quality Payment Program due to few physical therapy-inclusive measures and to have applicable measures available in MIPS is the first step to improving participation by physical therapists and providing financial incentives to them. One commenter expressed that Low Back Pain was also a first step in increasing occupational therapy engagement within MIPS. Another commenter stated that maintaining multiple cost measures applicable to emergency medicine physicians will result in a more robust and adequate assessment of emergency medicine services in future years.

Response: We thank the commenters for their support. We agree that the Emergency Medicine and Low Back Pain measures present an opportunity to provide cost measures to MIPS eligible clinicians who have previously not had an applicable measure.

Comment: A few commenters expressed support for the Depression and Psychoses and Related Conditions episode-based measures, as their inclusion indicates that CMS values the care provided for behavioral health.

Response: We thank the commenters for their support. We agree that the inclusion of the Depression and Psychoses and Related Conditions episode-based measures aligns with CMS's prioritization of behavioral health and our Behavioral Health Strategy (*https://www.cms.gov/cms-behavioral-health-strategy*).

Comment: A few commenters supported the measure development process and engagement with specialty organizations. One commenter appreciated CMS' efforts to engage specialty organizations when developing appropriate attribution for anesthesiologists in cost measures. This commenter stated that its specialty organization's members have participated in several cost measure development panels and hope to continue these collaborative efforts with CMS to work toward a cost measure that fairly and consistently provides attribution to anesthesiologists.

Response: We will continue to work with specialty societies in future years to develop episode-based measures for clinicians who currently do not have an applicable measure in MIPS.

Comment: Some commenters urged CMS to ensure that measures appropriately adjust for clinical and social risk factors to avoid inadvertently creating disincentives for providing care.

Response: We strive to ensure that episode-based measures adjust for clinical risk factors. During measure development, clinician experts discuss and advise on specific risk factors. As discussed previously in this section, the risk adjustment model includes standard risk adjustors as well as risk adjustors for factors specific to the condition or procedure, as identified by clinician feedback and empiric analyses. The standard risk adjustors include the following: comorbidities captured by 86 Hierarchical Condition Category (HCC) codes, which map with thousands of ICD–10–CM diagnosis codes; the number of HCC codes, which reflects the number of conditions risk adjusted for a patient; interaction variables, which account for instances where comorbidities are impacted by another variable (for example, the interaction between HCC 47 for immunity disorders and cancer); patient age category; patient disability status; patient end-stage renal disease status; the number of clinician specialties and types of clinician specialties from which the patient has received care; and recent use of institutional long-term care.

During measure development, we also consider adjusting for social risk factors. Many measures risk adjust for dual eligibility for Medicare and Medicaid as a proxy for social risk factors when testing suggests that it is appropriate. This includes three of the five proposed episode-based measures we are finalizing: Depression, Emergency Medicine, and Heart Failure. Additionally, the episode-based measure construction helps to safeguard against clinicians withholding necessary healthcare services because stinting on necessary care will lead to worse outcomes and higher cost scores by including the costs of complications and acute exacerbations.

Comment: Some commenters suggested that CMS provide timely and actionable feedback on the five proposed measures. Some commenters recommended that CMS does not incorporate additional episode-based measures, suggesting that CMS wait to incorporate the measures into the MIPS cost performance category scoring while clinicians become familiar with the proposed episode-based measures or while clinicians become familiar with understanding their performance on episode-based measures already implemented for previous performance periods.

Response: We are continuing to work towards providing meaningful and timely information on cost measures generally and we recognize the importance of providing this information for measures implemented in MIPS. We believe that clinicians have many opportunities to become familiar with the episode-based measures and their specifications in advance of any potential implementation. Opportunities include joining measure development meetings as listen-only participants and reviewing publicly posted meeting summaries, participating in national field testing, reviewing the publicly available information and discussions on the measures during pre-rulemaking (for example, MAP discussions), as well as reviewing the information outlined in the proposed rule. Generally, the cost performance category constitutes 30 percent of MIPS eligible clinicians' final score as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act and finalized under §§ 414.1380(c)(1)(ii) and 414.1350(d)(5). Unless an exception applies to an individual MIPS eligible clinician, group, virtual group, or subgroup under § 414.1380(b)(2) or § 414.1380(c)(2), we calculate and report all the cost measures for which we have determined a benchmark for MIPS eligible clinicians, groups, virtual groups, and subgroups who are attributed and met the case minimum for those measures implemented for use in the MIPS cost performance category.

Comment: Some commenters expressed concerns about the methodology for assessing MIPS eligible clinicians' performance on episode-based measures. One commenter stated that the measure developer's multi-step approach to attributing measure performance, and the use of algorithms for identifying costs relevant to an episode, add unnecessary complexity. Another commenter recommended that the attribution methodology for cost measures be changed so that the same costs are not attributed to multiple physicians. One commenter requested that CMS consider measures for chronic conditions that do not have an inpatient trigger so that costs for chronic conditions can be included even if an inpatient stay does not occur. One commenter expressed concerns that the

measures could unfairly affect urologists.

Response: We disagree with the commenters' feedback about our methodology for assessing MIPS eligible clinicians' performance on episode-based measures. The attribution methodology for the episode-based measures was developed with extensive stakeholder feedback, as required by section 1848(r) of the Act. The measure developer gathered clinician and person and family feedback through a Technical Expert Panel (TEP), Clinical Subcommittees, Clinician Expert Workgroups, and public comment periods. Our attribution methodology identifies a clinician-patient care relationship and is unique to the type of care that is being assessed by the measure. The measure developer thoroughly tested this approach, and the analyses suggest that it works to accurately capture clinicians who have influence over the care of patients with a specific condition or procedure. Additionally, considering input from Clinician Expert Workgroups, we determine the triggering methodology for chronic condition episode-based measures based on what is appropriate for the type of condition. We will consider whether the current attribution methodology continues to be an appropriate approach for future measures. Finally, we clarify that a chronic condition measure does not rely on an inpatient trigger to initiate a clinician-patient relationship. A clinician must bill two services specific to the care of the condition. One must be a clinician visit (for example, diagnostic visit, office or other outpatient visit, or annual wellness visit), and the other can be either another visit or a service for the treatment of the condition (for example, lung imaging test for Asthma/COPD). Specifically, the trigger claim is for a ''primary care'' E/M visit with a relevant chronic condition diagnosis, and the confirming claim is for either another ''primary care'' E/M visit with a relevant chronic condition diagnosis or a condition-related CPT/HCPCS code with a relevant chronic condition diagnosis.

Additionally, we do not see evidence that urologists are negatively impacted by the current set of episode-based measures we are finalizing for use.

Comment: A few commenters expressed concerns with the development and implementation process for cost measures used in the cost performance category. One commenter recommended that CMS not prioritize developing cost measures that cover a large number of clinicians or portion of Medicare Parts A/B spending based on a statutory goal. Commenters recommended that CMS should focus on developing cost measures that align with quality measures (for example, outcome measures) and that CMS address areas of improvement for the clinical population participating in MIPS. Another commenter recommended that cost measures go beyond assessing whether there is waste in the system, and that CMS develop cost measures that seek to promote clinically appropriate utilization of health care services, including for those clinicians who serve a significant portion of the frail and elderly population. One commenter urged CMS to pursue consensus-based entity (CBE) endorsement of all cost measures.

Response: When selecting measures for development, we base our decision on a variety of considerations. While one consideration is the potential scope of Medicare Parts A/B spending that is captured by the measures, as statutorily mandated by section 1848(r)(2)(D)(i) of the Act, we also consider potential for improvement and performance gaps to ensure that the measure will be a meaningful assessment of clinician performance. We also consider potential scope of Medicare beneficiaries that are captured by the measures. The goal of episode-based measures is not to categorically reduce resource use, but to encourage efficient and meaningful resource use. Considering areas where there is potential for improvement in clinicians' efficient use of resources (for example, overuse of diagnostic testing) can help to encourage appropriate use of health care services. During measure development, Clinician Expert Workgroups consider ways to align cost and quality goals, such as aligning with existing quality measures (for example, selecting an aligned episode window length or aligning overall measure scope). Additionally, the cost measures are risk adjusted for patient age and certain measures include risk adjustment variables that indicate patients' frailty to ensure that the measures do not disincentivize care for these populations. Finally, we plan to pursue CBE endorsement for the five new cost measures that we are finalizing in this rule in the future.

Comment: Commenters raised concerns about the Heart Failure measure, stating that the complexity and heterogeneity of the patient population could lead to unintended consequences that impact care. Commenters made several recommendations to address this heterogeneity, such as adjusting certain trigger codes (for example, telehealth codes) and limiting the heart failure diagnosis to a more specific subset of ICD–10 codes to avoid capturing patients with other conditions. One commenter mentioned exclusion of patients with underlying health issues and that assessing heart failure with preserved ejection fraction (HFpEF) patient outcomes can be difficult because of a lack of information available on claims. A commenter also recommended the use of modeling as a proxy to distinguish between different ejection fraction (EF) classes for heart failure patients. Commenters expressed concerns about attribution of a heart failure episode to a single clinician as opposed to a clinician group, due to the breadth of care settings and the inclusion of multiple TINs within the same setting or care team. A commenter also expressed concerns that any clinicians that are part of a patient's care team (that is, cardiologists, primary care clinicians, clinician assistants, advanced practice nurses, and other specialties) could be attributed the full costs of the measure equally. Commenters added that based on field test reports, they anticipate that highly specialized subspecialties, specifically electrophysiologists, are attributed. They stated that while these specialists manage certain aspects of the patient's care, they are often not the primary clinician responsible for overall management. They encouraged CMS and Acumen to consider unintended consequences of specialists and subspecialists being identified as high-cost providers.

Additionally, commenters emphasized the importance of alignment of cost measures with appropriate quality measures. The commenters cautioned against any unintended consequences of the measure, most notably if the measure could potentially inhibit guideline-directed care or encourage clinicians to switch to less effective care to lower costs.

Response: While the Heart Failure measure assigns services identified as related to cardiac conditions, the initial trigger for an episode has to indicate explicitly that the patient has Heart Failure. The Clinician Expert Workgroup for the Heart Failure measure supported the inclusion of several ICD–10 diagnosis codes, rather than limiting to just ICD–10 CM codes for Heart Failure under the I50 classification. The measure developer and the Clinician Expert Workgroup also carefully evaluated the CPT/HCPCS trigger codes. The Heart Failure trigger methodology intends to identify care relationships but does not limit those care relationships to a new diagnosis of

heart failure. Additionally, codes indicating services delivered via telehealth, such as telephone assessment and management, are used across all chronic condition episode-based measures, like this Heart Failure measure, as triggering, confirming, and reaffirming codes. The goal of the triggering and attribution methodology for the Heart Failure measure was to be inclusive of all clinically relevant settings where care for heart failure may be provided.

In developing the Heart Failure measure, we addressed the heterogeneity and complexity of the heart failure patient population. The Clinician Expert Workgroup discussed whether to risk-adjust or sub-group patients with diastolic heart failure. However, empirical data demonstrated that it would be challenging to categorize patients into these sub-populations, and that there would be no difference in risk-adjusted episode cost for these sub-populations. The measure developer did exclude high-output heart failure and other conditions with rarer, more complex prognoses. The Heart Failure measure is also risk-adjusted for End-Stage Renal Disease (ESRD), patient eligibility for both Medicare and Medicaid, right heart failure (RHF) clinical syndrome, cardiomyopathy, coronary artery disease (CAD), idiopathic heart failure, rheumatic and other valve disease, all-cause recent inpatient admission, substance abuse/cardiomyopathy, and obstructive sleep apnea. Testing showed that the Heart Failure measure is valid and reliable and the differences, if any, among the other types of heart failure mentioned are unlikely to be impact the measure score.

We had several reasons to not use modeling as a proxy to distinguish between different EF classes. The measure developer did consider qualified registries and/or electronic health record (EHR) data. However, there are concerns with using qualified registries and EHR data in administrative claims-based measures, including sufficient availability of data across the applicable patient and clinician cohorts captured by the measure. Given the lack of detailed information on EF in claims data, and an extensive conversation on shared treatment options and poor prognosis for both systolic and diastolic heart failure, the Clinician Expert Workgroup ultimately recommended pursuing a heart failure definition that was less reliant on EF information.

In regards to the commenter's concern about measure attribution of primary care clinicians or care team members in addition to cardiology specialists, the purpose of the Heart Failure measure is to assess the ongoing care provided to patients with heart failure and these clinicians contribute to that care. We believe that it is appropriate to attribute primary care clinicians or specialists if they provide relevant chronic condition care management to encourage care coordination. Persons and family with lived experiences provided input that a range of clinician types comprised their care team. In particular, they reported that cardiologists, primary care clinicians, device nurses, cardiac rehabilitation specialists, nutritionists, mental health clinicians, at-home physical therapists, pulmonologists, and electrophysiologists were part of their care team. Given the wide range of clinicians providing care to these patients, they also noted the importance of medication reconciliation for coordination across their care team. As a result, a clinician can be attributed if we see evidence of a relationship between a patient and clinician where they are providing care related to the management or treatment of heart failure. . Additionally, cost measures are not intended to assign partial costs to certain types of clinician. If a clinician is attributed the cost measure, then they are assigned the costs of any services that they provide as outlined in the Heart Failure codes list available at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/quality-payment-program-cost-measure-information*. The Clinician Expert Workgroup has identified these services as services that the attributed clinician could have influence on their provision, frequency, or intensity. They are intentionally included in the measure to gather a full picture of the care that a clinician provides a patient with the Heart Failure condition.

However, the Heart Failure measure is risk-adjusted for the specialty group providing care to account for higher costs of care provided by certain clinician types like electrophysiologists. This was designed to mitigate the cost differences in expected cost based on attributed specialty. We aim not to penalize clinicians who provide high quality care that is higher cost.

We aim to prioritize the alignment of cost measures with quality measures in MIPS. We consider cost and quality alignment throughout the measure development process and we include cost measures in MIPS in conjunction with quality measures to assess value of care.

In developing cost measures, we strive to ensure that the measure does not inhibit guideline-directed care. Testing has not indicated that there are any concerns about unintended consequences, particularly those raised by the commenter, and we will continue to monitor the measure for any instances.

Comment: A few commenters expressed concerns about the Low Back Pain episode-based measure. They recommended removing neurosurgeons and orthopedic surgeons from the list of eligible specialties for attribution to the measure to evaluate non-operative, chronic care. One commenter recommended that CMS develop a different episode-based measure for low back pain for care provided by orthopedic surgeons specifically. The commenters also urged CMS to incorporate clinical quality data from qualified registries into the measure.

Response: We disagree with commenters' recommendation to remove neurosurgeons and orthopedic surgeons from potential attribution for the Low Back Pain measure. The intent of the Low Back Pain measure is to assess the treatment and management of Low Back Pain and the triggering logic was designed to capture the range of clinicians that have a role in treating and managing this condition. The Clinician Expert Workgroup thoroughly considered the role of the surgeon in the Low Back Pain measure after reviewing the public's feedback on this topic gathered during field testing. The Workgroup discussed this feedback in conjunction with testing from the measure developer to explore the relationship between low back pain care management and spinal surgery. They ultimately recommended that the role of the surgeon was appropriate to include in the measure, and also recommended that the measure take additional steps to minimize the risk of identifying relationships that are only pre-operative or consultative. The measure developer and CMS agreed that it is clinically appropriate to include surgeons in the measure. To help address these concerns, if a spinal surgery occurs 90 days before a trigger code through 60 days after a trigger code, the relationship between the clinician group and patient will not be initiated. More information regarding these discussions are available in the Low Back Pain Post Field Test Meeting Summary available on the QPP Cost Measures Information page at *https://www.cms.gov/files/zip/summary-wave-4-post-field-test-refinement-webinar-pftr-workgroup-meetings.zip*.

Additionally, the Low Back Pain measure further safeguards against these concerns by stratifying episodes into subgroups to ensure that the measure

fairly compares clinicians with a similar patient case-mix. For the Low Back Pain measure, we include subgroup surgical episodes with and without history of low back pain and non-surgical episodes with and without history of low back pain. The measure is also risk-adjusted for history of spine surgery. The intention of these measure specifications is to make sure that clinically similar patients and episodes of care are being compared to each other.

Finally, we do not include data from qualified clinical data registries in this measure, but we will continue to monitor whether the measure includes the appropriate data elements for inclusion in the future.

Comment: Some commenters expressed concerns about the Depression episode-based measure. Commenters stated concerns that a low percentage of clinical psychologists would be attributed to the cost measure, continuing to leave them out of the scope of MIPS cost measures and potentially indicating that the current measure methodology does not align with how clinical psychologists work within healthcare. Commenters also raised concerns that interruptions to treatment due to physical hospitalizations or circumstances related to social determinants of health are not taken into consideration and would result in attributing costs related to circumstances outside the control of a provider to their care. Finally, they expressed concern that the Depression measure does not account for the large variation in costs for different forms of treatment for depression (for example, electroconvulsive therapy (ECT) and Transcranial Magnetic Stimulation (TMS), medications, psychotherapy), and the potentially unintended consequences of attributing very high-cost interventions like ECT to psychologists who are predominantly delivering significantly less costly treatments such as psychotherapy. The commenters stated that these concerns could be applicable to the Psychoses and Related Conditions measure as well.

Another commenter requested clarification about whether perinatal and postpartum depression is included in the Depression episode-based measure and if the measure would be attributed to obstetricians or gynecologists as a result.

Response: We disagree with the concerns the commenters have raised. While it may be the case that few clinical psychologists may meet the case minimum as an individual clinician participant, most clinicians participate in MIPS via clinician groups. Therefore, the participation rate of clinical psychologists is likely higher because they participate by contributing to the total number of episodes of their clinician groups. This is supported by empiric analysis conducted by the measure developer on the specialties attributed the Depression measure.

The attribution methodology for the Depression measure was developed with input from a TEP, a Clinician Expert Workgroup, and patients, families, and caregivers. Individuals with lived experience with receiving care for depression identified the most frequently attributed specialties as having been part of their respective care teams. Additionally, the measure includes a risk adjustor for dual status eligibility for Medicare and Medicaid. The process for determining whether it is appropriate to adjust for dual status involves rigorous statistical testing for each measure, and testing indicated that it is appropriate for the Depression measure. We risk adjust for dual status because it is both available and reliable in claims data at the individual beneficiary level. We will continue to monitor the potential for using Z codes for social determinants of health variables in the future. The measure includes other risk adjustors to account for the different types of care that a patient received. These include risk adjustors for two or more hospitalizations related to depression in the prior year, TMS within the last year, ECT within the last year, and prior observation stays that may indicate treatment-resistant depression (TRD).

We also clarify that it is possible that an obstetrician or gynecologist is attributed the Depression episode-based measure if they render the relevant trigger and confirming claims for an episode and meet the attribution methodology checks. The trigger methodology includes codes for premenstrual depression and adjustment disorder with depression, but it does not include codes for post-partum depression. Additionally, it is unlikely that obstetricians or gynecologists would be frequently attributed this measure due to the typical age of the Medicare population that is assessed by this measure. For more information about these codes, please see the measure specifications available on the QPP Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/quality-payment-program-cost-measure-information*.

Comment: Some commenters expressed concerns about the Psychoses and Related Conditions measure, and certain commenters did not support the implementation of the Psychoses and Related Conditions measure. One commenter stated that the use of this measure in MIPS could have a negative impact on the provision of mental health services to the most vulnerable patients, and may create a disincentive for psychiatrists to participate in Medicare. A couple commenters stated that it is inappropriate to hold inpatient psychiatrists responsible for outpatient care for persons with psychotic disorders because patients do not have adequate support when leaving the hospital and the inpatient psychiatrist rarely serves as the provider for follow-up outpatient care. One commenter expressed concerns about the geographic variation in the availability of care. Finally, one commenter stated that measure selection should not be based on potential savings to Medicare without an understanding of whether savings can be derived by reducing avoidable services while maintaining or improving the quality of care.

Response: We disagree that the Psychoses and Related Conditions measure will have a negative impact on the provision of mental health services. Many psychiatrists participating in MIPS are already being assessed on inpatient care through the Medicare Spending Per Beneficiary (MSPB) Clinician measure, and the Psychoses and Related Conditions measure would allow MIPS eligible clinicians to have their costs of care evaluated on a more specific scope of care. The measure's construction also guards against clinicians withholding necessary healthcare services by including the costs of adverse events, so attempts to lower costs by stinting on care increases the risk of costly events like Emergency Department visits, hospitalizations, or other complications. Testing conducted on this measure does support the commenter's concerns about unintended consequences in providing care. The predicative ratios suggest that the measure calculates risk appropriately across different levels of patient complexity. Testing also shows that geographic location and a patient's dual eligibility status for Medicare and Medicaid has little impact, supporting that the measure would not exacerbate access to care challenges. However, we will continue to monitor the measure closely for any unintended consequences.

Additionally, we believe that it is appropriate to include outpatient care in the Psychoses and Related Conditions measure. The measure aligns with the post-discharge care included in other episode-based measures focused on

inpatient care, MIPS claim-based readmission measures, and facility-level quality metrics like those used in the Hospital Inpatient Quality Reporting Program and Inpatient Psychiatric Facility (IPF) Quality Reporting Program. We have also taken steps to ensure that the MIPS eligible clinician has influence over the services they are attributed, as we considered this feedback extensively when revising the measure, as previously discussed in this section and in the proposed rule. We exclude from calculation of this measure specific scenarios where clinicians have less ability to influence care, such as involuntary holds and State hospital transfers, we use a 45-day episode window (shortened from 90 days), and the measure risk adjusts for facility type to account for differences in payment policies between hospitals paid under Inpatient Prospective Payment System (IPPS) and IPFs. Additionally, fragmented care, such as a lack of support for patient discharged from an inpatient setting, points to the need for this measure as it encourages care coordination. Person and family input consistently highlighted the need for better care coordination, discharge planning, and collaboration across clinicians on diagnosing and treating patients. Some also noted that better care coordination and discharge planning could avoid readmissions. As a result, we believe that the person and family engagement (PFE) perspective suggests including these services could be impactful in reducing more costly adverse outcomes.

While an important consideration in developing the Psychoses and Related Conditions measure was that psychoses is one of the most common inpatient stays, we also considered opportunities to improve care (for example, discharge planning, medication management, care coordination) identified through literature and feedback from interested parties. We believe that improving care and reducing resource use (for example, readmissions) will ultimately help improve capacity of the healthcare system, and improve access overall. MIPS includes cost measures alongside quality measures so that MIPS eligible clinicians can be assessed on the value of their care. The goal of assessing value is furthered through MVPs, which connect measures and activities across MIPS. The inclusion of this measure helps to support the transition to MVPs and reflects feedback from clinicians that they prefer the use episode-based measures.

After consideration of public comments, we are finalizing our proposal as proposed to add the five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

(b) Reliability and Case Minimum

In this section of the final rule, we discuss the case minima to use for the five proposed episode-based measures and provide clarification on the interpretation of our regulation at § 414.1350(c) regarding the case minima for episode-based measures. As we discuss in this section of the final rule, after consideration of public comments, we are finalizing our proposals to adopt a case minimum of 20 episodes for each of the five proposed new episode-based measures, as well as codify the 20-episode case minimum for care setting episode-based measures under § 414.1350(c)(7) and revisions to § 414.1350(c)(4) through (6), as proposed.

Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing meaningful differences between clinicians' performance. However, we continued to caution against using reliability as the sole metric to evaluate a measure because of the tradeoffs between accuracy and reliability, and the role of service assignment in reducing noise. These and other considerations are detailed in the CY 2022 PFS final rule (86 FR 65453 through 65455). We also noted that increasing case minima necessarily reduces the number of clinicians who meet the case minimum for a given measure. Because these are clinically refined measures, we aim to have as many MIPS eligible clinicians as possible to be able to have their costs evaluated by them. Therefore, we considered that a mean reliability of 0.4 represents moderate reliability because it accounts for these considerations and is a sufficient threshold to ensure that the measure is performing as intended when assessed in conjunction with other testing.

We previously established at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures in the CY 2019 PFS final rule (83 FR 59773 through 59774). We also established at § 414.1350(c)(6) a case minimum of 20 episodes for chronic condition episode-based measures in the CY 2022 final rule (86 FR 65453 through 65455). We have not adopted any care setting episode-based measures in the cost performance category, and therefore we have not established any case minima for this type of episode-based measures. In the CY 2024 PFS proposed rule (88 FR 52573 through 52574), we considered a case minimum of 20 for each of the five proposed episode-based measures and then examined the reliability of the measures against this case minimum.

We examined the reliability of the five proposed episode-based measures, and Table 52 presents the percentage of tax identification numbers (TINs) and TIN/National Provider Identifiers (NPIs) that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our case minimum of 20 for each of the episode-based measures. At a 20-episode case minimum, the mean reliability for the Depression, Heart Failure, Low Back Pain, and Psychoses and Related Conditions measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. Similarly, at a 20-episode case minimum, the mean reliability for the Emergency Medicine measure exceeds 0.4 for both groups and individual clinicians, and all groups and individual clinicians meet the 0.4 reliability threshold.

TABLE 52: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold and TIN and TIN/NPI Mean Reliability

Measure name (case minimum)	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Depression	99.62%	0.87	98.61%	0.80
Emergency Medicine	100.00%	0.91	100.00%	0.78
Heart Failure	91.81%	0.68	86.79%	0.60
Low Back Pain	96.27%	0.75	95.66%	0.73
Psychoses and Related Conditions	100.00%	0.83	100.00%	0.86

We believe that calculating these five proposed episode-based measures with these case minimums will accurately and reliably assess the performance of clinicians and clinician group practices. Therefore, we proposed to adopt a case minimum of 20 episodes for each of the five proposed new episode-based measures. Given that we have not previously established any case minimums for the care setting episode-based measures, we also proposed to codify the 20-episode case minimum for care setting episode-based measures under § 414.1350(c)(7).

Additionally, as we reviewed our existing regulatory language under § 414.1350(c), we recognized the need to clarify the intended interpretation of the language because we acknowledged that the current framing is open to reasonable interpretation. Specifically, we clarify that the regulatory language at § 414.1350(c)(4) through (6) establishes the case minima for episode-based measures of each episode type (that is, procedural, acute inpatient medical condition, and chronic condition, respectively) such that the case minimum specified therein applies to all episode-based measures of that episode type, regardless of when the measure is adopted for inclusion in the cost performance category, unless otherwise specified for individual measure(s). For example, under § 414.1350(c)(6), the chronic condition episode-based measures that were specified beginning with the CY 2022 performance period/2024 MIPS payment year when this regulatory provision was codified (that is, the Diabetes and the Asthma/COPD measure) and any chronic condition episode-based measure specified after the CY 2022 performance period/2024 MIPS payment year will have a case minimum of 20 episodes, unless we specify otherwise for an individual measure.

In the CY 2024 PFS proposed rule (88 FR 52573 through 52574), we proposed to update the regulatory language under § 414.1350(c)(4) through (6) to more clearly reflect this clarified interpretation. In addition, we proposed that this interpretation will also apply to § 414.1350(c)(7) for care setting episode-based measures, as discussed in this section of this final rule.

We believe that it is appropriate to use the case minimum based on the measure type for current and future measures in MIPS, as each measure episode type uses a consistent framework across measures so the case minimum should be also consistent, where possible. Additionally, consistent case minimum simplifies the level of information a MIPS eligible clinician or clinician group must monitor for the episode-based measures as the number of measures used in the cost performance category continues to grow. We noted that for any future measure under consideration to be implemented in the cost performance category, case minima would still be evaluated against reliability testing, and could be different from the standard case minimum established for the respective measure type under § 414.1350(c), as needed.

We invited comment on our proposals in section IV.A.4.f.(2)(b) of the proposed rule, including our proposal to adopt the case minima for the five episode-based measures proposed for the cost performance category and our interpretation of the existing regulatory language on the case minima for episode-based measures.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed their belief that episode-based measures in use in MIPS should have a high reliability and that CMS should increase all case minima to ensure a measure can meet or exceed this threshold at both the individual NPI and TIN level. One commenter stated that minimum reliability should be at least 0.7 and another stated it should be at least 0.8. A commenter also requested that CMS release more detailed reliability results, noting concerns that less than 100 percent of groups and individuals meet CMS's reliability threshold of 0.4 for certain measures.

Response: We refer stakeholders to the CY 2022 PFS final rule (86 FR 65453 through 65455), where we discussed the 0.4 reliability threshold in detail. As noted in section IV.A.4.f.(2)(b), we will continue to monitor the scientific evidence on reliability to consider whether the 0.4 threshold should be increased. In finding a balance between reliability and cost measures that have the potential to be impactful, we also consider stakeholder feedback about the need for clinicians to be assessed under episode-based measures. Since these measures are designed to be specific to a particular type of care, many clinicians would be attributed fewer of these episodes than of episodes for global or population-based cost measures. We do not have concerns about the reliability of these five proposed episode-based measures because their mean reliability is between 0.6 and 0.9, which well above the 0.4 threshold and falls within moderate to high reliability. Using a moderate reliability threshold ensures the reliability of the measures while also guarding against the unintended consequences of excluding clinicians from episode-based measures. More information about the measures' reliability testing, such as the percentage above a 0.7 reliability at the TIN and TIN–NPI reporting level, is included in the Measure Justification Forms that are available on the QPP Cost Measures Information page at

https://www.cms.gov/files/zip/macra-wave-4-measure-justification-forms.zip.

After consideration of public comments, we are finalizing our proposal to adopt a case minimum of 20 episodes for each of the five proposed new episode-based measures, codify the 20-episode case minimum for care setting episode-based measures under § 414.1350(c)(7), and amend § 414.1350(c)(4) through (6) to clarify our policy, as proposed.

(c) Removal of Simple Pneumonia With Hospitalization Measure From the MIPS Cost Performance Category Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of the final rule, we proposed to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. As we discuss in this section, after consideration of public comments, we are finalizing our proposal to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category as proposed.

The Simple Pneumonia with Hospitalization episode-based measure was implemented for use in the MIPS cost performance category starting with CY 2019 performance period/2021 MIPS payment year (83 FR 59767 through 59773). Due to the impact of the COVID–19 pandemic, in accordance with § 414.1380(c)(2)(i)(A)(2), we assigned a weight of zero percent to the cost performance category for the CY 2020 performance period/2022 MIPS payment year and CY 2021 performance period/2023 MIPS payment year, and redistributed the prescribed weight to another performance category or categories, as established at § 414.1380(c)(2)(ii)(D) and (E), respectively. For the CY 2022 performance period/2024 MIPS payment year, the measure was excluded from scoring in accordance with § 414.1380(b)(2)(v)(A) due to International Classification of Diseases, Tenth Revision (ICD–10) coding updates related to COVID–19 that impacted the underlying population originally intended to be captured by this measure. More information is available in the CY 2024 PFS proposed rule (88 FR 52574 through 52575).

Empirical testing demonstrated that these coding changes have resulted in a marked decrease in the number of Simple Pneumonia with Hospitalization episodes. The measure does not use MS–DRGs 177–179 in its trigger logic and, therefore, the measure is unable to capture many pneumonia episodes, per the original measure intent. This significant decrease in the number of pneumonia episodes captured by this measure has resulted in many MIPS eligible clinicians no longer meeting the 20-episode case minimum for attribution of the measure.

Given that these underlying coding issues affect the measure's ability to capture the intended population and that their uneven impact on MIPS eligible clinicians is expected to continue, we proposed to remove the Simple Pneumonia with Hospitalization measure from the cost performance category beginning with CY 2024 performance period/2026 MIPS payment year. We do not believe that it is appropriate to continue to use the measure as currently specified without any changes to address the coding changes that formed our basis to suppress this measure in the CY 2022 performance period/2024 MIPS payment year. More information is available in the CY 2024 PFS proposed rule (88 FR 52574 through 52575).

We invited comments on this proposal.

Comment: Some commenters expressed support for the removal of the Simple Pneumonia with Hospitalization episode-based measure.

Response: We appreciate the commenters' support of the removal of the Simple Pneumonia with Hospitalization episode-based measure and we agree with their comments.

After considering the public comments, we are finalizing our proposal to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year, as proposed.

(d) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

We proposed revisions to the operational list of care episode and patient condition groups and codes to reflect our proposals to add new episode-based measures and remove the Simple Pneumonia with Hospitalization measure beginning with the CY 2024 performance period/2026 MIPS payment year. As we discuss in this section, after consideration of public comments, we are finalizing our proposal as proposed.

In accordance with section 1848(r)(2)(H) of the Act, we proposed to revise the operational list beginning with the CY 2024 performance period/2026 MIPS payment year to include five new care episode and patient condition groups, based on input from clinician specialty societies and other interested parties, as outlined in section IV.A.4.f.(2)(a)(ii) of the proposed rule. We proposed including Emergency Medicine and Psychoses and Related Conditions as care episode groups and Heart Failure, Low Back Pain, and Depression as patient condition groups. These care episode and patient condition groups serve as the basis for the five new episode-based measures that we proposed in section IV.A.4.f.(2)(a)(iii) of the proposed rule for the cost performance category. The codes that define these five-care episode and patient condition groups align with the trigger codes of the proposed episode-based measures in section IV.A.4.f.(2)(a)(iii) of the proposed rule. As described in section IV.A.4.f.(2)(a)(ii), these specifications are developed with extensive input from interested parties. As discussed in section IV.A.4.f.(2)(a) of the final rule, we will add these five episode-based measures to the cost performance category.

Additionally, we proposed to revise the operational list to remove the Simple Pneumonia with Hospitalization care episode group. As discussed in section IV.A.4.f.(2)(c) of the final rule, we will remove this episode-based measure from the cost performance category, so the codes that define this care episode group will no longer need to remain in the operational list.

More information on the statutory requirements for care episode and patient condition groups and proposed changes to the operational list is available in the CY 2024 PFS proposed rule (88 FR 52575 through 52576). Our revisions to the operational list are available on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/quality-payment-program-cost-measure-information*.

We invited comments on this proposal. We did not receive public comments on this provision, and we are finalizing it as proposed.

(e) Summary of Previously Established and Finalized Measures for the Cost Performance Category Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

The previously established and finalized measures for the cost performance category for the CY 2024 performance period/2026 MIPS payment year and future periods are summarized in Table 53.

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TABLE 53: Summary Table of Cost Measures for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Performance Periods

Measure Topic	Measure Type	Measure Status
Total Per Capita Cost	Population-Based	Currently in use for 2024 Performance Period and Beyond
Medicare Spending Per Beneficiary Clinician	Population-Based	Currently in use for 2024 Performance Period and Beyond
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Knee Arthroplasty	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Screening/Surveillance Colonoscopy	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based	Currently in use for 2024 Performance Period and Beyond
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based	Removed from use for 2024 Performance Period and Beyond
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition episode-based	Currently in use for 2024 Performance Period and Beyond
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Elective Primary Hip Arthroplasty	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Femoral or Inguinal Hernia Repair	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Hemodialysis Access Creation	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition episode-based	Currently in use for 2024 Performance Period and Beyond
Lower Gastrointestinal Hemorrhage *(at group level only)*	Acute inpatient medical condition episode-based	Currently in use for 2024 Performance Period and Beyond
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Lumpectomy, Partial Mastectomy, Simple Mastectomy	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Melanoma Resection	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Colon and Rectal Resection	Procedural episode-based	Currently in use for 2024 Performance Period and Beyond
Sepsis	Acute inpatient medical condition episode-based	Currently in use for 2024 Performance Period and Beyond
Asthma/Chronic Obstructive Pulmonary Disease (COPD)	Chronic condition episode-based	Currently in use for 2024 Performance Period and Beyond
Diabetes	Chronic condition episode-based	Currently in use for 2024 Performance Period and Beyond
Depression	Chronic condition episode-based	Finalized for 2024 Performance Period and Beyond
Emergency Medicine	Care Setting episode-based	Finalized for 2024 Performance Period and Beyond
Heart Failure	Chronic condition episode-based	Finalized for 2024 Performance Period and Beyond
Low Back Pain	Chronic condition episode-based	Finalized for 2024 Performance Period and Beyond
Psychoses and Related Conditions	Acute inpatient medical condition episode-based	Finalized for 2024 Performance Period and Beyond

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(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), and the CY 2023 PFS final rule (87 FR 70057 through 70061). We also refer readers to 42 CFR 414.1305 for the definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

While we did not propose any changes to the traditional MIPS improvement activities policies for the CY 2024 performance period/2026 MIPS payment year, we proposed changes to the improvement activities inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

We refer readers to the CY 2024 PFS proposed rule (88 FR 52576 through 52577) for details about the annual Call for Improvement Activities.

(ii) Changes to the Improvement Activities Inventory

We refer readers to the CY 2024 PFS proposed rule (88 FR 52577 through 52578) for details about changes to the improvement activities Inventory.

We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvement Activities&py=2022#measures* for a complete list of the current improvement activities.

We proposed to add five new improvement activities, modify an existing improvement activity, and remove three previously adopted improvement activities for the CY 2024 performance period/2026 MIPS payment year and future years. We refer readers to Appendix 2 of the CY 2024 PFS proposed rule (88 FR 53132) for more details.

Two of the five proposed new improvement activities are in the Population Management subcategory. One new activity, IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services'' will allow MIPS eligible clinicians to receive credit for establishing policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources through taking action with the goals of increasing capacity to expand HIV prevention screening, improving HIV prevention education and awareness, and reducing disparities in pre-exposure prophylaxis (PrEP) uptake. Another activity, IA_PM_XX, titled ''Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines'' will allow MIPS eligible clinicians to receive credit for incorporating cervical cancer clinical decision support (CDS) within the electronic health record (EHR) system. This activity leverages the convenience and efficiency of more sophisticated decision support tooling to assist clinicians in applying complex data-driven guidelines to provide optimal care and better engagement with their patient population, including historically underserved populations. This activity proposal was submitted by the CDC.

Two of the five proposed new activities are in the Behavioral and Mental Health (BMH) subcategory, reflecting this important Federal priority. IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women'' will allow MIPS eligible clinicians to receive credit for screening for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans. The second new activity proposed in the BMH subcategory, IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults'' will allow MIPS eligible clinicians to receive credit for the completion of age-appropriate screening for mental health and substance use in older adults, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans.

Of the five proposed new improvement activities, four activities directly align with Priority 5 of CMS' Framework for Health Equity, Increase All Forms of Accessibility to Health Care Services and Coverage. Efforts undertaken that align with Priority 5 aim to create a fair and just opportunity for all people to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and/or other factors that affect access to care and health outcomes. These four new improvement activities are the following: IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services''; IA_PM_XX, titled ''Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults.''

The fifth new improvement activity is focused on MVP: IA_MVP, titled ''Practice-wide quality improvement in the MIPS Value Pathways Program (MVP).'' With the advent of MVPs, MIPS eligible clinicians can report measures that are more relevant to their specialized practice, including through subgroup reporting. The IA_MVP activity will require a clinician to complete a formal model for quality improvement action that is linked to a minimum of three of the measures within the specific MVP. We believe this activity will expand and formalize quality improvement (QI) activities across practices, ultimately leading to improvements in quality of care and fostering a culture of participation among staff. In addition, this activity will incentivize voluntary MVP adoption. It is important to note that, a clinician who reports an MVP can attest to the MVP improvement activity. However, a clinician in traditional MIPS is ineligible to report the MVP improvement activity. Also, registration for an MVP is not sufficient for reporting the MVP improvement activity. Reporting the chosen MVP and attesting to having completed the necessary elements of the MVP

improvement activity are both required. We referred readers to the proposed rule (88 FR 52557) for more information on MVPs.

We proposed to modify one existing activity's description, titled ''Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs,'' and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. Additionally, we proposed to remove three previously finalized improvement activities to ensure that the improvement activities Inventory best reflects current clinical practice.

We refer readers to Appendix 2 of the CY 2024 PFS proposed rule (88 FR 53132) for details on the proposed revisions to the improvement activities inventory, comments received and our responses.

(iii) Improvement Activity Reporting Policies

We did not propose changes to the improvement activity group reporting policies. We refer readers to the CY 24 PFS proposed rule (88 FR 52578) for details related to improvement activities reporting policies.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to our regulation at § 414.1375, the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), and the CY 2023 PFS final rule (87 FR 70060 through 70087).

(b) Promoting Interoperability Performance Category Performance Period

In the CY 2021 PFS final rule (85 FR 84886), we established that for the CY 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We codified the policy at § 414.1320(g)(1) of our regulations, and subsequently re-designated that section as § 414.1320(h)(1) in the CY 2022 PFS final rule (86 FR 65671).

In the CY 2024 proposed rule (88 FR 52578 through 52579), we proposed that, beginning with the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of any continuous 180-day period within the calendar year, up to and including the full calendar year (for CY 2024, January 1, 2024, through December 31, 2024). As discussed in V.B.11.a in this final rule, this policy would minimally increase the information collection burden on data submitters. We also proposed to revise the regulation text at § 414.1320 to reflect this change. As discussed herein, after consideration of public comments, we are finalizing our proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year, and to revise the regulation text at § 414.1320 to reflect this change as proposed.

We believe that having additional data available from a longer performance period is beneficial to further improve the Promoting Interoperability performance category, and an integral step towards promoting health information exchange. Reporting on additional data during a longer performance period will provide MIPS eligible clinicians the opportunity to continuously monitor their performance, identify gaps in their reporting, and identify areas that may require their investigation and corrective action. We believe that requiring MIPS eligible clinicians to report additional data during a longer performance period will encourage MIPS eligible clinicians to produce more comprehensive and reliable data demonstrating that they are meaningful users of CEHRT.

Our long-term goal for the Promoting Interoperability performance category is to ensure the meaningful use of CEHRT and information exchange throughout the year, for all data, all clinicians, and all patients. Currently, when MIPS eligible clinicians select a 90-day performance period, this data is often not representative of their overall use of CEHRT throughout the entire calendar year. Instead, it reflects their best performing 90-days during the calendar year. For MIPS eligible clinicians to have a more accurate understanding of their overall performance, we want to move towards reporting on a full years' performance, which can be achieved by incrementally increasing the number of days in the performance period.

We continue to focus on patient safety, and the Promoting Interoperability performance category continues to focus on the safety and safe use of patient data by demonstrating the meaningful use of CEHRT. If a MIPS eligible clinician were to only focus on their best 90-day performance period, they may not focus on improving their overall performance by meaningfully using CEHRT throughout the year, and ultimately, observe, correct, and mitigate any potential patient safety concerns that may arise due to gaps in interoperability throughout the calendar year. If a MIPS eligible clinician does not meaningfully use CEHRT throughout the entire calendar year, there is a possibility for gaps in the transfer of key patient data necessary for supporting a diagnosis, continued treatment, or overall care planning.

Therefore, in the CY 2024 PFS proposed rule, we proposed to modify § 414.1320(h) for the Promoting Interoperability performance category performance period to remove the reference to subsequent years after the CY 2024 MIPS payment year, and instead specify that the policy applies only through the CY 2025 MIPS payment year. We further proposed to add a new paragraph at § 414.1320(i)(1) to reflect a performance period of a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year for the Promoting Interoperability performance category, beginning with the CY 2026 MIPS payment year (88 FR 52578 through 52579).

We invited public comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support our proposal to lengthen the performance period to a minimum of 180 days. One commenter stated that they did not believe the proposal was an effective or appropriate policy lever that would move the needle on health information exchange.

Response: We respectfully disagree. As required by section 1848(o)(2)(A) of the Act, one of our goals for the MIPS Promoting Interoperability performance category is for MIPS eligible clinicians to demonstrate their meaningful use of CEHRT, and that they maintain the interoperability of their CEHRT by ensuring it is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care. We believe it is important for MIPS eligible clinicians to demonstrate their meaningful use of CEHRT continuously throughout the year, rather than only during a self-selected best performance period. We believe our proposal, to require a longer period during which MIPS eligible clinicians must meet the requirements of the Promoting Interoperability performance category including ensuring their CEHRT is interoperable, will move health information exchange forward.

Comment: Some commenters supported our proposal to extend the length of the minimum performance period to 180 days. One commenter requested that CMS consider offering an ''exception'' or additional flexibilities for MIPS eligible clinicians that may be switching their EHR vendor during their selected performance period, because EHR implementation often extends well beyond a 180-day timeframe. These commenters further recommended that CMS offer MIPS eligible clinicians the flexibility to report on two separate, but still continuous, 90-day periods within the performance year.

Response: We appreciate the feedback provided in support of our proposal and asking for additional flexibilities. We do understand that MIPS eligible clinicians have planned and unplanned system downtime for their CEHRT, which may include scheduled software updates, or even a change in vendor. We do not specify which 180-day performance period a MIPS eligible clinician must select within a calendar year, only that the 180 days are a single, continuous period. Additionally, we understand that updates or changes to CEHRT may occur during any 180-day period, regardless of the performance period chosen. We suggest that MIPS eligible clinicians work with their chosen vendor to minimize downtime during the 180-day performance period selected. We also note that, while downtime may occur during the performance period, this should not directly impact scoring for the Promoting Interoperability performance category, so long as the minimum reporting requirements for the objectives and measures are met during the performance period as well. As discussed in the Stage 1 final rule (75 FR 44329) and the Stage 3 final rule (80 FR 62779 through 62780), we understand that planned and unplanned downtime will occur; so long as the minimum threshold for each measure is met using CEHRT, specifically numerator/denominator measures, this is acceptable.

As a reminder, for any MIPS eligible clinician that faces a significant hardship, we recommend that the MIPS eligible clinician files a hardship exception application to potentially avoid penalty for reasons outside of their control. Even though there may be specific requirements or limitations associated with a basis to request and receive an exception under § 414.1380(c)(2)(i)(C), we encourage MIPS eligible clinicians to apply for this exception as needed. For additional information on hardship exceptions, please see *https://qpp.cms.gov/mips/exception-applications?py=2023#promotingInteroperabilityHardshipException-2023*.

Comment: Several commenters did not support our proposal to extend the length of the minimum performance period from 90 to 180 days and expressed concern over the increase in relation to administrative burden. One commenter stated that the capacity of EHR vendors is finite, and with multiple clinician types simultaneously drawing from the same pool of vendors, this increases the burden of work for these vendors, and reduces the amount of time the vendor can spend with each client. Compliance among clinicians and health care staff was also a concern, with one commenter expressing that training at the beginning of the year means that practices will not be able to adjust any technical or other problems that occur during the 180-day period, as there is little room for error. One commenter stated that additional support staff will need to be hired to capture information that is not directly collected by EHRs.

Response: We believe that MIPS eligible clinicians utilizing CEHRT are using it throughout the entire calendar year. Therefore, we respectfully disagree that our proposal to extend the performance period from 90 to 180 days would create significant burden. We believe the extension will have few implications in implementing, updating, and testing CEHRT to maintain compliance throughout the performance period. We suggest MIPS eligible clinicians consider early planning with health IT vendors on the timing of system updates and downtimes to allow for maximum flexibility in choosing the 180-day performance period. We do understand that when technical issues arise, MIPS eligible clinicians will work with their vendor to remediate these issues. Unforeseen circumstances happen, and it is possible that they may happen at any time, regardless of the 180-days chosen. As discussed previously, so long as the minimum threshold for each measure is met using CEHRT, specifically numerator/denominator measures, this is acceptable.

Another reminder that for any MIPS eligible clinician that faces a significant hardship, we recommend that the MIPS eligible clinician file a hardship exception application to potentially avoid penalty for reasons outside of their control. Even though there may be specific requirements or limitations associated with a basis to request and receive an exception under § 414.1380(c)(2)(i)(C),we encourage MIPS eligible clinicians to apply for this exception as needed. For additional information on hardship exceptions, please see *https://qpp.cms.gov/mips/exception-applications?py=2023 num;promotingInteroperabilityHardshipException-2023*.

We understand the burdens MIPS eligible clinicians face with maintaining adequate staffing; however, we disagree with the commenter's concerns regarding the need to hire additional staff solely to collect information to report on objectives and measures during a longer 180-day performance period. Regardless of the length of the performance period, we anticipate minimal additional administrative burden. Several of the objectives and measures for the Promoting Interoperability performance category require MIPS eligible clinicians to use the CEHRT itself to collect and submit the required data. For those objective and measures that require collection and reporting of information regarding the use of CEHRT (such as attestations) that do not rely on data collected by the CEHRT itself (such as the Security Risk Analysis measure or the SAFER Guides measure), we do not believe collection and reporting will be affected by the increased performance period. The completion and reporting of these objectives and measures is the same whether the performance period is 90 days or 180 days.

Comment: Two commenters who opposed our proposal stated that the challenges created from the COVID–19 public health emergency (PHE) will present complications in meeting reporting requirements during the proposed 180-day performance period.

One commenter expressed that different types of clinical practices face different and unique challenges following the PHE. The commenters stated that choosing any continuous 90-day performance period currently allows individual MIPS eligible clinicians to best fit their needs while focusing on patient care in an unpredictable environment. Another commenter stated that the PHE has created financial, workforce, and operational challenges that have implications for the resources needed to meet new Promoting Interoperability performance category requirements.

Response: We believe that the COVID–19 PHE has created opportunities for us to identify areas where MIPS eligible clinicians can put their focus into performance improvement, specifically within the performance period. Considering the COVID–19 PHE, we tried to keep our modifications to the Promoting Interoperability performance category in CY 2024 to a minimum, only proposing substantive changes to the SAFER Guide measure and the lengthening of the performance period. While we empathize with MIPS eligible clinicians that the COVID–19 PHE has brought a unique set of challenges that many continue to face, we also recognize that the COVID–19 PHE heightened the need to strengthen the interoperability of health IT, and to ensure meaningful use of CEHRT throughout the year. During the COVID–19 PHE, telehealth became more widely available, makeshift clinics were created to care for patients, and clinical partnerships allowed for more clinical coverage. The ability and inability to send and receive health information during the COVID–19 PHE showed all clinicians the importance of having fully functional and interoperable systems to best care for their patients and ensure records integral to the patient's care were sent and received.

After consideration of public comments, we are finalizing our proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year and are revising the regulation text at § 414.1320 to reflect this change, as proposed.

(c) Certified Electronic Health Record Technology Requirements

Section 1848(q)(2)(B)(iv) of the Act requires that, for the Promoting Interoperability performance category, the MIPS eligible clinician must meet the requirements established for the specified performance period under section 1848(o)(2) of the Act for determining whether the MIPS eligible clinician is a meaningful electronic health record (EHR) user. Under section 1848(o)(2)(A) of the Act, a MIPS eligible clinician must be using CEHRT for a specified performance period in order to be treated as a meaningful EHR user. Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

Accordingly, the MIPS Promoting Interoperability performance category regulation at § 414.1375(b)(1) requires a MIPS eligible clinician to use CEHRT as defined at § 414.1305 for the performance period. Since the CY 2019 performance period/2021 MIPS payment year, this has consisted of EHR technology (which could include multiple technologies) certified under ONC's Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition of CEHRT at § 414.1305.

As discussed in the CY 2024 PFS proposed rule (88 FR 52546 through 52548), in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23758), which appeared in the April 18, 2023 **Federal Register**, ONC proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC proposed to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines (88 FR 23750). As further outlined in section III.R. of this final rule, we finalized our proposal to modify the definition of CEHRT for purposes of the Quality Payment Program at § 414.1305 to incorporate any changes made by ONC to its definition of Base EHR and its certification criteria for health IT.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

i. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

We previously adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing (e-Prescribing) objective for the Promoting Interoperability performance category. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888) and the CY 2022 PFS final rule (86 FR 65466 through 65467), we finalized that the Query of PDMP measure would remain optional and eligible for 10 bonus points for the CY 2021 and CY 2022 performance periods/2023 and 2024 MIPS payment year.

In the CY 2023 PFS final rule, we finalized our proposal to require the Query of PDMP measure beginning with the CY 2023 performance period/2025 MIPS payment year, and that the measure will be worth 10 points (87 FR 70061 through 70067). In addition, along with other key specifications described in the CY 2023 PFS final rule, we removed the phrase ''except where prohibited in accordance with applicable law'' from the measure description, and established two exclusions beginning with the CY 2023 performance period/2025 MIPS payment year: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period (87 FR 70061 through 70067). Finally, in the CY 2023 PFS final rule, we finalized a third exclusion for the Query of PDMP measure, but this exclusion was only available for the CY 2023 performance period/2025 MIPS payment year. (87 FR 70067)

The second exclusion is the same exclusion that we adopted for e-Prescribing measure in the CY 2018 PFS final rule (82 FR 53679). It has come to our attention that the second exclusion is problematic because it does not address situations where the MIPS eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the

performance period, but does write more than 100 permissible prescriptions during the performance period. Therefore, we proposed to modify the second exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion. (88 FR 52579)

We invited public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for the proposal to modify the second exclusion for the Query of PDMP measure. They stated that the modification is consistent with the intent of this measure and provides necessary clarity surrounding reporting requirements.

Response: We believe the modification better reflects our intent. It addresses situations where the MIPS eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the performance period.

After consideration of public comments, we are finalizing our proposal to modify the second exclusion for the Query of PDMP measure as proposed so that it reads as follows: ''Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period'' beginning with the CY 2024 performance period/2026 MIPS payment year, as proposed.

ii. Technical Update to the Electronic Prescribing Measure

The ONC 21st Century Cures Act final rule (85 FR 25660 through 25661) retired the ''drug-formulary and preferred drug list checks'' certification criterion at 45 CFR 170.315(a)(10), which was associated with measures under the Electronic Prescribing objective for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). ONC retired this criterion after January 1, 2022, as provided in 45 CFR 170.550(m)(1) (85 FR 26661).

In the CY 2021 PFS final rule, we finalized that the ''drug-formulary and preferred drug list checks'' criterion will no longer be associated with measures under the Electronic Prescribing objective and will no longer be required to meet the CEHRT definition for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, beginning with CY 2021 EHR reporting and performance periods (85 FR 84815 through 84825).

In the CY 2023 PFS final rule, we inadvertently omitted a revision to TABLE 92: Objectives and Measures for the Medicare Promoting Interoperability Performance Category for the CY 2023 performance period/2025 MIPS payment year to reflect this change (87 FR 70075). In an effort to more clearly capture the previously established policy finalized in the CY 2021 PFS final rule with respect to the e-Prescribing measure, we proposed in the CY 2024 PFS proposed rule to revise the measure description as shown in Table 54 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read ''Number of prescriptions in the denominator generated and transmitted electronically using CEHRT'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.'' (88 FR 52579 through 52580)

We invited public comments on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter expressed support for our proposal to make technical corrections to the e-Prescribing measure.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposal to revise the e-Prescribing measure description as shown in Table 54 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT,'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically using CEHRT'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.''

iii. Changes to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

A. Background

In the CY 2022 PFS final rule (86 FR 65475 through 65477), we adopted the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure under the Protect Patient Health Information Objective in the Promoting Interoperability performance category beginning with the CY 2022 performance period/2024 MIPS payment year. ONC developed several SAFER Guides, including the High Priority Practices SAFER Guide, to help organizations at all levels conduct self-assessments which optimize the safety and use of EHRs. Under the SAFER Guides measure, MIPS eligible clinicians are currently required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. Beginning with the CY 2022 performance period/2024 MIPS payment year, we required MIPS eligible clinicians to complete this attestation for this measure, though MIPS eligible clinicians were not scored based on their answer to the attestation, or whether they fully implemented all components of the self-assessment. An attestation of ''yes'' or ''no'' is currently acceptable, and a MIPS eligible clinician can attest ''no'' without penalty. For additional information, please refer to our discussion of the SAFER Guides measure in the CY 2022 PFS final rule (86 FR 65475 through 65477).

B. Modification of the SAFER Guides Measure

The SAFER Guides measure is intended to encourage MIPS eligible clinicians to use the High Priority Practices SAFER Guide, annually, to assess their progress and status on important facets of patient safety, including CEHRT implementation and effectiveness, identifying vulnerabilities, and developing a ''culture of safety'' within their organization. For instance, the High Priority Practices SAFER Guide asks users to review and ensure that entries of allergies, problem lists, and diagnostic test results utilize standardized coding elements in their CEHRT (such as uniformly and consistently coding results as ''normal'' or ''high''). By ensuring their CEHRT consistently documents and codes health information, MIPS eligible clinicians confirm their CEHRT supports clear communication of a patient's health status, mitigating the risk of oversight, gaps, or potential safety risks introduced by the CEHRT, in the interoperable exchange of health information. By continuing to implement the High Priority Practices SAFER Guide's recommended practices, MIPS eligible clinicians may be better positioned to operate CEHRT

responsibly in care delivery, and to make improvements to the safe use of CEHRT as necessary over time.

Given our interest in promoting the safety and the safe use of CEHRT, in the CY 2024 PFS proposed rule (88 FR 52580 through 52581), we proposed to amend the SAFER Guides measure to require MIPS eligible clinicians to conduct this self-assessment annually, and attest a ''yes'' response, accounting for completion of the self-assessment for the High Priority Practices SAFER Guide. The self-assessment should be completed as a team among clinicians, staff members, and their vendors together, allowing MIPS eligible clinicians to see a snapshot of the status of the CEHRT used by their organization in terms of safety, and to identify areas needing improvement. Therefore, we proposed to modify the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year such that only a ''yes'' response on the attestation will constitute completion of this measure, and a ''no'' response will result in a score of zero for the whole Promoting Interoperability performance category, indicating that the MIPS eligible clinician failed the requirements of the Promoting Interoperability performance category and is not a meaningful user of CEHRT. To reflect this proposed amendment to the SAFER Guides measure, we also proposed to modify our reporting requirements at § 414.1375(b)(2)(ii)(C) to include ''For the 2024 MIPS payment year through the 2025 MIPS payment year'', and to add § 414.1375 (b)(2)(ii)(D), to say ''Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.''

We believe this modification is feasible for MIPS eligible clinicians to implement, as they have had two years to grow familiar with the use of the SAFER Guides under this measure by attesting either ''yes'' or ''no'' to conducting the self-assessment. We also noted the availability of resources to assist MIPS eligible clinicians with completing the self-assessment as required by the SAFER Guides measure. One example of such a resource is the SAFER Guides authors' paper titled ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' available without charge to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984* (88 FR 52580).

Therefore, we proposed to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period and subsequent years, to require MIPS eligible clinicians to conduct, and therefore attest ''yes,'' an annual self-assessment of their CEHRT using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs. We further proposed that, although the SAFER Guides measure would continue to be required with no associated points, an attestation of ''no'' would result in the MIPS eligible clinician not meeting the measure's requirements and therefore they would not be a meaningful user of CEHRT, which would result in a score of zero for the Promoting Interoperability performance category. We also proposed to modify our reporting requirements at § 414.1375(b)(2)(ii)(C), and to add § 414.1375(b)(2)(ii)(D). Specifically, at § 414.1375(b)(2)(ii)(C), we proposed to end our current requirements for the SAFER Guides measure with the 2025 MIPS payment year. Then, at § 414.1375(b)(2)(ii)(D), we proposed to require, beginning with the 2026 MIPS payment year, that a MIPS eligible clinician submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs. As discussed herein, after consideration of public comments, we are finalizing our proposal to modify the SAFER Guides measure and amend our regulation at § 414.1375(b)(2)(ii), as proposed.

As a reminder, under the SAFER Guides measure, we do not currently require, and did not propose to require MIPS eligible clinicians to attest to whether they have implemented any best practices ''fully in all areas'' as described in the High Priority SAFER Guide, nor will a MIPS eligible clinician be scored on how many of the practices they have fully implemented. We refer readers to Table 54 in this final rule for a description of the measure, and to the CY 2022 PFS final rule for additional background information (86 FR 65475 through 65477).

Upon review of our current regulation governing reporting of the current SAFER Guides measure at § 414.1375(b)(2)(ii)(C), we identified areas where our regulation is unclear regarding the requirements for reporting the SAFER Guides measure. Therefore, we also proposed to amend the regulatory text at § 414.1375(b)(2)(ii)(C) to specify clearly that a MIPS eligible clinician must submit an attestation, with either a ''yes'' or ''no'' response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs. As previously discussed, the regulatory provision will only be applicable for the 2024 MIPS payment year through the 2025 MIPS payment year. (88 FR 52580 through 52581)

We invited public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed their overall support for the proposal. One commenter stated that in requiring a ''yes'' attestation of the SAFER Guides measure, we are promoting safe patient care.

Response: We agree that requiring an annual self-assessment of the High Priority Practices SAFER Guide is an important component of promoting safe patient care.

Comment: Several commenters supported the overall goals and utility of the High Priority Practices SAFER Guide measure, stating that protecting patient health information remains a top priority for clinicians, vendors, patients, and policy makers alike. However, commenters asked that CMS delay implementation of this proposed requirement from the CY 2024 performance period/2026 MIPS payment year to a later date. One commenter suggested that we consider delaying this requirement until the CY 2025 performance period/2027 MIPS payment year, allowing for MIPS eligible clinicians to continue to submit a ''yes'' or ''no'' response without penalty for the CY 2024 performance period/2026 MIPS payment year. Another commenter suggested that CMS wait another three years before requiring a ''yes'' attestation for this measure, implementing this modification to the SAFER Guides measure beginning with the CY 2027 performance period/2029 MIPS payment year. This commenter stated that such delay would allow ONC additional time to review the guides' content to ensure it remains current. A couple commenters asked that we delay requiring a ''yes'' attestation on the SAFER Guides measure until CMS has publicly reported the number of MIPS eligible clinicians who responded ''yes'' and ''no,'' allowing for the public to gauge overall performance.

Response: We note that MIPS eligible clinicians will have had 2 years to complete the self-assessments without penalty (the CY 2022 and CY 2023

performance periods) before requiring a ''yes'' attestation beginning with the CY 2024 performance period/2026 MIPS payment year as we proposed. Therefore, while we understand that commenters have asked for additional time, we believe that the 2 years of preparation that we provided is adequate. We also understand that commenters have requested that CMS and ONC work together on reviewing the SAFER Guides, and that ONC update the content as appropriate. CMS will continue to share the feedback we receive with ONC, so they may update the content as deemed appropriate. In addition, as the SAFER Guides measure was required with both ''yes'' and ''no'' attestation fulfilling the requirement, we do not believe that publicly reporting this data reflects performance or ability, as much as it reflects which MIPS eligible clinician chose to complete the self-assessment or not. As a reminder, for all MIPS performance categories, we will continue to publicly post data on MIPS eligible clinicians' performance on measures and activities as the data becomes available.

Comment: Several commenters supported utilizing the High Priority Practices SAFER Guide in clinical practice but suggested that CMS and ONC seek stakeholder feedback regarding updates to consider including in the SAFER Guides. These commenters expressed concern that the SAFER Guides have not had a comprehensive review since their release, several references are outdated, and current practices are not reflected, such as the use of telehealth which grew and changed substantially during and after the COVID–19 PHE. Additionally, commenters asked that CMS communicate suggestions for ONC to consider for the SAFER Guides, such as data privacy protections, social determinants of health, and present-day safety practices.

Response: As mentioned, ONC continues to review of the SAFER Guides' content, and questions included in the self-assessment. At this time, we believe that the baseline self-assessment questions are relevant to MIPS eligible clinicians, but we will share commenters' suggestions on including telehealth, patient privacy, and social determinants of health with ONC for future consideration. As a reminder, we encourage MIPS eligible clinicians to utilize the annual MIPS Promoting Interoperability performance category call for measures to submit feedback for future policy consideration before we release our next proposed rule.

Comment: Several commenters supported requiring MIPS eligible clinicians to complete an annual self-assessment using the High Priority Practices SAFER Guide, but they asked that CMS and ONC make publicly available the additional resources and materials mentioned in rulemaking (86 FR 65476). Commenters asked for educational materials, examples of how to complete the guides, and sources of information available to aid in the self-assessment.

Response: We thank commenters for their support and suggestions. We are sharing one resource that is now publicly available for MIPS eligible clinicians as one additional tool to assist with completing their self-assessments. The ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' is now publicly available without charge to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984.* We may also take into consideration making additional resources available to the public.

Comment: Some commenters did not support the proposed modification to the SAFER Guides measure, stating that requiring MIPS eligible clinicians to attest to having completed the self-assessment places additional administrative burden on already taxed clinicians. Commenters also raised concern that administrative tasks are taking away from clinical time, while many are still recovering from staffing shortages after the COVID–19 PHE.

Response: While we fully appreciate that MIPS eligible clinicians are still working through the complexities that arose during the COVID–19 PHE, we also recognize that the COVID–19 PHE has had a direct effect on health IT, patient data, and system infrastructures. We disagree that the administrative burden associated with this proposed modification to this measure outweighs the protection of health IT, as well as the safety and safe use of CEHRT. As mentioned previously, while we understand the initial self-assessment may require the most effort, subsequent self-assessments should largely remain the same, unless there have been changes in vendors, or significant system upgrades (see section V.B.11.a. of this final rule and 86 FR 65476). Also, to reiterate, we are only requiring the completion and attestation of the self-assessment. We do not require that all items in the questionnaire are implemented fully, nor that the worksheets be completed in full. We also remind commenters that we understand not all recommended practices are applicable to every organization. In these instances, it is acceptable to check ''not implemented'' for that practice (86 FR 65475). Our minimum requirements to satisfy the SAFER Guides measure are to complete the self-assessment for self-awareness, and to attest to having completed the checklist. Lastly, we encourage MIPS eligible clinicians to complete the self-assessment in a team approach, utilizing administrative staff, clinicians, and their vendors, to lessen clinician burden.

Comment: Several commenters supported the High Priority SAFER Guide self-assessment, but they did not agree that we should take an ''all or nothing'' approach to determining whether a MIPS eligible clinician passes or fails the SAFER Guides measure. Commenters suggested a performance-based scoring approach instead to create incentives for MIPS eligible clinicians to continuously make improvements.

Response: We understand that an ''all or nothing'' approach is not a typical performance-based approach and appreciate the feedback. While we do have performance-based objectives and measures in the Promoting Interoperability performance category, we also have several unscored requirements as well. It is difficult to score the SAFER Guides measure, as it is constructed to only require an attestation of completion (did you complete the self-assessment, ''yes'' or ''no''). Without scoring based on the level of implementation of each of the practices, an all or nothing approach is more appropriate.

After consideration of public comments, we are finalizing our proposal to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year, to require MIPS eligible clinicians to conduct, and therefore, attest ''yes,'' to having completed an annual self-assessment of their CEHRT using the High Priority Practices SAFER Guide. We are finalizing our proposal to codify this modification at § 414.1375(b)(2)(ii)(D). Additionally, we are finalizing our proposal to amend the regulatory text at § 414.1375(b)(2)(ii)(C) to clearly specify that a MIPS eligible clinician must submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs; this regulatory provision will only be applicable for the 2024 MIPS payment year through the 2025 MIPS payment year.

(e) Requirements for the Promoting Interoperability Performance Category for the CY 2024 Performance Period/2026 MIPS Payment Year

i. Objectives and Measures for the CY 2024 Performance Period/2026 MIPS Payment Year

For ease of reference, Table 54 lists the objectives and measures for the Promoting Interoperability performance category required for the CY 2024 performance period/2026 MIPS payment year as revised to reflect the policies we are finalizing in this final rule.

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TABLE 54: Objectives and Measures for the Promoting Interoperability Performance Category for the CY 2024 Performance Period/2026 MIPS Payment Year

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.*	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.*	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.*
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
summary of care information from other health care providers into their EHR using the functions of CEHRT	summary of care record.			
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: ● Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. ● Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
information.	patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable

Objective	Measure	Numerator	Denominator	Exclusion
	agency to electronically submit case reporting of reportable conditions.			disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
	technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides*	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

* Signifies a policy finalized in this final rule.

ii. Scoring Methodology for the CY 2024 Performance Period/2026 MIPS Payment Year

Table 55 reflects the scoring methodology for the Promoting Interoperability performance category for the CY 2024 performance period/ 2026 MIPS payment year.

TABLE 55: Scoring Methodology for the CY 2024 Performance Period/2026 MIPS Payment Year

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored. In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iii. Exclusion Redistribution

Many required measures have exclusions associated with them as shown in Table 54. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 55 do not include the points that will be redistributed if a MIPS eligible clinician claims an exclusion. For ease of reference, Table 56 shows how points will be redistributed among the objectives and measures for the CY 2024 performance period/2026 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE 56: Exclusion Redistribution for CY 2024 Performance Period

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iv. 2015 Edition Health IT Certification Criteria

For ease of reference, Table 57 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2024 performance period/2026 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. We refer readers to section III.R. of this final rule for our discussion of and amendments to the definition of CEHRT at § 414.1305.

TABLE 57: Promoting Interoperability Performance Category Objectives and Measures and ONC Health IT Certification Criteria

Objective	Measure	Certification Criteria (CY 2024 Performance Period/2026 MIPS payment adjustment year)
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

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(f) Clinical Social Workers

In the CY 2022 PFS final rule (86 FR 65387 through 65389), we added clinical social workers to the definition of a MIPS eligible clinician under § 414.1305, beginning with the CY 2022 performance period/2024 MIPS payment year. Prior to the CY 2022 performance period, this clinician type was not eligible to participate in the Medicare Promoting Interoperability

Program to earn incentive payments for the meaningful use of CEHRT, or to receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers were also not eligible for Medicaid EHR incentive payments.

In the CY 2022 PFS final rule (86 FR 65489), we stated that clinical social workers therefore may lack experience with the adoption or use of CEHRT, and that we believed there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to them. In the CY 2022 PFS final rule (86 FR 65489) and the CY 2023 PFS final rule (87 FR 70087), we established that we will apply to clinical social workers the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and other types of MIPS eligible clinicians who are non-physician practitioners for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year. Specifically, because we believed there may not be sufficient Promoting Interoperability performance category measures available and applicable to clinical social workers, pursuant to section 1848(q)(5)(F) of the Act, we assigned a weight of zero to the Promoting Interoperability performance category for clinical social workers. However, if a clinical social worker submits any data for any of the measures specified for the Promoting Interoperability performance category, then this category will not be reweighted to zero, and we will score the clinical social worker on this category as part of their final composite performance score in accordance with § 414.1380(c)(1). This reweighting policy for clinical social workers is codified at § 414.1380(c)(2)(i)(A)(*4)(iii).*

Because CY 2022 was the first year that clinical social workers were included in our definition of MIPS eligible clinicians, we do not yet have any performance period data that we could use to evaluate whether the Promoting Interoperability performance category measures are applicable to this type of MIPS eligible clinician. In the CY 2023 PFS final rule (87 FR 70087), when we reweighted the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year, we noted we would evaluate whether this reweighting policy should be continued for future years when we have performance period data available. Given that we do not have data from the CY 2022 performance period available to analyze, we proposed (88 FR 52590) to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year, and to make the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4)(iii*).

We invited public comments on this proposal, but did not receive public comments on this provision, and we are finalizing as proposed.

(5) APM Improvement Activities Performance Category Score

(a) Background

Section 1848(q)(5)(C) of the Act establishes scoring rules for the MIPS improvement activities performance category. Section 1848(q)(5)(C)(ii) of the Act specifically provides that a MIPS eligible clinician who is in an Alternative Payment Model (APM), as defined in section 1833(z)(3)(C) of the Act, with respect to a performance period shall earn a minimum score of one half of the highest potential score for the improvement activities performance category. In accordance with section 1848(q)(5)(C)(ii) of the Act, we codified at § 414.1380(b)(3)(i) that individual MIPS eligible clinicians participating in APMs (as defined in section 1833(z)(3)(C) of the Act) for a performance period will earn at least 50 percent for the improvement activities performance category (81 FR 30132). Further, we also stated that MIPS eligible clinicians participating in an APM for a performance period may receive an improvement activity score higher than 50 percent (81 FR 30132). Subsequently, in the CY 2021 PFS final rule, we finalized the APM Performance Pathway (APP) under MIPS (85 FR 84859 through 84866).

The APP is an optional MIPS reporting and scoring pathway available to MIPS eligible clinicians and groups who are also participants in MIPS APMs. The APP is designed to reduce reporting burden and encourage participation in APMs (85 FR 50285). Performance in the APP is weighted across 3 areas—quality, improvement activities, and Promoting Interoperability (§ 414.1380(d)). Like traditional MIPS, the APP allows APM participants to receive credit for improvement activities. With respect to the APP, eligible clinicians, groups, and APM Entities currently receive full credit for the improvement activities performance category with no additional data submission requirements because we have identified all MIPS APMs as having met the improvement activity threshold score requirement to receive a score of 100 percent for that performance category (85 FR 84865, 85031).

(b) Proposal

We stated in the CY 2024 PFS proposed rule that it had come to our attention that in the preamble to the MIPS Performance Category Scoring in the APM Performance Pathway of the CY 2021 PFS final rule (85 FR 84865) the terminology ''automatically'' was used in reference to the baseline score provided by section 1848(q)(5)(C)(ii) of the Act (85 FR 84865). This has led to an interpretation by some that the baseline score represents ''credit'' that is ''automatically applied'' in all circumstances.[496] This is not how we intended this provision to function, and we wish to clarify that our rules do not automatically grant such ''credit''.[497] Further, we are concerned that absent revisions, application of our current regulation, which initiates MIPS composite scoring when at least two performance categories are reported in traditional MIPS, may produce unintended or unexpected scoring outcomes for MIPS eligible clinicians and groups.

To prevent such scoring scenarios, we proposed to amend § 414.1380 by revising paragraph (b)(3)(i) to require that, in order to receive the baseline score of 50 percent for the improvement activities performance category, a MIPS eligible clinician or group with APM participation must have submitted data for two performance categories or attest to having completed an improvement activity. We also proposed to amend § 414.1380 by adding paragraph (c)(2)(iv) to provide that we will not apply a baseline score of 50 percent for the improvement activities performance category if we have also approved a request for performance category reweighting or hardship exception affecting the improvement activities performance category, including MIPS EUC Exception applications under

[496] For example, in the ''2022 Data Submission FAQs,'' available at *https://qpp.cms.gov/resources/resource-library*, we stated that MIPS eligible clinicians participating in APMs are eligible to receive ''automatic credit'' in the improvement activities performance category.

[497] Similarly, in the CY 2021 PFS final rule, we finalized a proposal to modify § 414.1380(b)(3)(ii) to make clear that the baseline score provided by section 1848(q)(5)(C)(i) of the Act for the improvement activities performance category is not automatically granted for clinicians participating in patient-centered medical homes and comparable specialty practices (83 FR 59868).

§ 414.1380(c)(2)(i)(A)(*6*) or (C)(*2*), and automatic EUC events per § 414.1380(c)(2)(i)(A)(*8*) or (C)(*3*).

These proposals relate to reporting and scoring in traditional MIPS. We believe that these proposals are necessary in part because § 414.1380(c)(2)(i)(A)(*6*) requires us to score any data submitted by a MIPS eligible clinician with an approved application-based hardship exception or who was identified as a clinician in a CMS-designated area affected by an EUC event as identified by CMS under §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), regardless of whether that submission was for the purpose of MIPS final scoring. Based upon our current policies, a submission of data for the quality or Promoting Interoperability performance categories makes the improvement activities performance category eligible for scoring. For MIPS eligible clinicians participating in APMs, this means the improvement activities performance category score would be 50 percent, potentially resulting in a lower composite score than may otherwise be possible, unless additional improvement activities are attested to. We believe that result is contrary to the purpose of hardship exceptions, such as the MIPS EUC Exception application provided by § 414.1380(c)(2)(i)(A)(*6*), which are designed to reweight the improvement activities performance category to zero percent.

We also believe this proposal will further our vision that ''the bedrock of the Quality Payment Program is high-quality, patient-centered care followed by useful feedback, in a continuous cycle of improvement'' (81 FR 77010). Generally speaking, through MIPS, we collect feedback based upon data and measures submitted for the quality, Promoting Interoperability, improvement activities, and cost performance categories. We need scores from at least two of those four performance categories for us to calculate a clinician's final score. There is no data submission requirement for the cost performance category—we use the Medicare claims data submitted by that clinician to calculate their cost-measure performance. Similarly, a MIPS eligible clinician is not required to submit detailed data for the improvement activities performance category; instead, a MIPS eligible clinician simply attests to having completed an activity or activities to report the performance category. Therefore, we believe that it is most appropriate for a MIPS eligible clinician to submit measurable data on the quality and Promoting Interoperability performance categories for the purpose of final scoring in order to be credited with the baseline score for the improvement activities performance category.[498]

We believe these proposals are timely in light of the proposal at section III.F.h.2. of the CY 2024 PFS proposed rule to require that Medicare Shared Savings Program (SSP) Accountable Care Organization (ACO) clinicians report the Promoting Interoperability performance category at the TIN level, as opposed to the APM Entity (that is, the, ACO) or individual level. Reporting the quality performance category through the APP is already required for MIPS eligible clinicians participating in a Medicare SSP ACO. If our existing policies are not amended, an SSP ACO clinician's submission of data to the Promoting Interoperability category will prompt the baseline score in the improvement activities performance category in every circumstance regardless of whether the clinician's group requested or otherwise qualified for reweighting of the performance categories, leaving these Medicare ACO clinicians reporting improvement activities outside the APP at risk of unintended or unexpected MIPS scoring outcomes. This proposal will allow us to conform to the general scoring expectation that, in the event the participant's request to reweight three or four performance categories to zero percent due to a hardship, per §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), the participant will receive a final score equal to the performance threshold, resulting in a neutral payment adjustment, even if data are incidentally submitted for other performance categories.

In summary, we proposed to amend § 414.1380 by revising paragraph (b)(3)(i) and adding paragraph (c)(2)(iv) to limit the application of baseline scores provided under section 1848(q)(5)(C)(ii) of the Act for the purpose of MIPS final scoring. We sought comment on these proposals.

The following is a summary of the comments we received on these proposals and our responses.

Comment: We received one comment in support of our proposed changes.

Response: We thank the commenter for their support.

Comment: A commenter expressed concern that our proposal will increase reporting burden for MIPS eligible clinicians in APMs reporting through the APP. The commenter stated that the objective of the proposal could easily be accomplished without additional reporting by scoring MIPS eligible clinicians reporting through the APP that have requested a hardship exemption when such clinicians report a MIPS performance category score other than the improvement activities performance category and the final score is higher than performance threshold that would otherwise be achieved through the hardship exception. This commenter further indicated that they believe that our proposal is a departure from current CMS guidance.

Response: We appreciate the commenter's concern about administrative burden as we are mindful of the burden placed on clinicians and groups who are APM participants and report MIPS performance categories. We recognize that we could have been more clear about our intent and what is required of MIPS eligible clinicians to meet MIPS reporting requirements outside the APP. Here, additional information from the MIPS eligible clinician or group is necessary to ensure that a MIPS eligible clinician or group does, in fact, intend to trigger the scoring consequences that will result from their reporting.

As we discussed in the proposed rule (88 FR 52590 and 52591), the submission of quality or Promoting Interoperability data would trigger a minimum improvement activities performance category score of 50 percent for all APM participants, resulting in the calculation of a MIPS final score, even in situations where the improvement activities performance category otherwise would have been reweighted to zero. This is not a common scenario; nonetheless, it is significant for those MIPS eligible clinicians and groups that it affects as it can be the difference between a clinician or group receiving a neutral payment adjustment and a negative payment adjustment due to existing CMS scoring rules. When a MIPS eligible clinician is scored on two MIPS performance categories, CMS will calculate a final score for the MIPS eligible clinician (§ 414.1380(c)), subjecting the clinician to a MIPS payment adjustment (§ 414.1405(a) and (b)). For this reason, any marginal increase in the reporting burden is justified by the protection it offers MIPS eligible clinicians from inadvertently receiving an unexpected MIPS final score and payment adjustment.

[498] There is no data submission requirement for the quality and cost performance categories for a MIPS eligible clinician assessed under the facility-based measurement scoring methodology described in § 414.1380(e). Therefore, we would require that such clinicians report data on the Promoting Interoperability performance category (or attest to having completed an improvement activity) to prompt the baseline score for the improvement activities performance category.

We appreciate the commenter's suggested alternative policy as it highlights some of the confusion that our past statements may have caused. Not all APM participants are scored under the APP, which is an optional reporting pathway for eligible clinicians and groups who are participants in MIPS APMs.

Our proposal was intended to resolve an issue that affects APM participants who are not scored under the APP. Section 1848(q)(5)(C) of the Act provides that a MIPS eligible clinician participating in an APM, with respect to a performance period, shall earn a minimum score of one half of the highest potential score for the improvement activities performance category. Separate and distinct from this statutory credit, CMS scoring rules provide for a MIPS eligible clinician who elects to be scored under the APP to be assigned an improvement activities performance category score ''based on the activities required by the MIPS APM'' (42 CFR 414.1367(c)(3)).[499] A MIPS eligible clinician who does not elect to be scored under the APP will not automatically receive full credit for the improvement activities performance category but would instead receive the minimum statutory credit of 50 percent unless the clinician attests to additional improvement activities. While affirmatively electing to be scored under the APP demonstrates a MIPS eligible clinician's clear intention to trigger scoring in the improvement activities performance category, passive eligibility for the 50 percent statutory credit outside the APP provides no similar indication of intent.

For this reason, we proposed to limit the circumstances in which we would provide the statutory credit to a MIPS eligible clinician participating in a APM to circumstances in which the clinician's actions clearly indicate an intention to receive a MIPS final score: when the clinician has attested to one or more additional improvement activities or when the clinician has submitted data for the quality and Promoting Interoperability performance categories. To make this intent easier to understand, we are revising § 414.1380(b)(3)(i) to state that a MIPS eligible clinician participating in an APM receives an improvement activities performance category score of at least 50 percent if the MIPS eligible clinician reports a completed improvement activity or submits data for the quality and Promoting Interoperability performance categories. This revision more clearly reflects the policy we described in the CY 2024 PFS proposed rule (88 FR 52590).

We acknowledge that our proposal could be viewed as different from our past guidance. Indeed, the purpose of the proposal is to correct confusion caused by our past statements while clarifying our intent with respect to those statements. We note that in the proposed rule we acknowledged that we may have caused confusion through past guidance and cited prior rulemaking where we better indicated how our actual intent has evolved based on our experience operating the program (88 FR 52590 and 52591).

After consideration of the comments, we are finalizing this proposal with modification.

g. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards with respect to applicable measures and activities specified for the four performance categories for a performance period and use such methodology to provide for a composite performance score for each such clinician for each performance period.

For the CY 2024 performance period/ 2026 MIPS payment year, we intend to continue to build on the scoring methodology we have finalized for prior years. This scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. In the CY 2024 proposed rule, we proposed to update our scoring policies consistent with this framework. Specifically, we proposed to—

- Provide a technical update to § 414.1380(a)(1)(i) and (b)(1)(v)(A),
- Amend our criteria for assessing ICD–10 coding impacts under our scoring flexibilities policy; and
- Update our policies regarding Improvement scoring for the cost performance category.

We did not propose changes to scoring policies for the Promoting Interoperability or improvement activities performance categories.

(b) Technical updates

In the CY 2022 PFS final rule, we finalized proposals to remove measure bonus points for reporting additional high priority measures and using end to end electronic reporting beginning in the CY 2022 performance period/2024 MIPS payment year (86 FR 65504 through 65507). We updated corresponding regulation at § 414.1380(b)(1)(v)(B)(1)(iii) regarding the end- to- end measure bonus points, but not § 414.1380(a)(1)(i) regarding performance standards or § 414.1380(b)(1)(v)(A) regarding the high priority bonus points. Accordingly, we proposed to revise § 414.1380(a)(1)(i) to provide that, measure bonus points for submitting high priority measures and using end-to-end reporting are available for performance periods and payment years prior to the CY 2023 performance period/2025 MIPS payment year. We also proposed to revise § 414.1380(b)(1)(v)(A) to state that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points for submitting high priority measures.

We referred readers to our regulation at § 414.1380 for our current policies on scoring. We requested comments on these technical update proposals.

We did not receive public comments on the technical update proposals. We are finalizing this proposal as proposed.

(c) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We referred readers to § 414.1380(b)(1) for our current policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, and 87 FR 70088 through 70091). In the CY 2023 PFS final rule, we finalized policies to score administrative claims measures in the quality performance category using benchmarks calculate from data submitted during the associated performance period and clarified the topped-out measure lifecycle (87 FR 70088 through 70091).

[499] As noted under the proposed rule (88 FR 52590), to date, CMS has determined each MIPS APM to require the performance of improvement activities worth 100 percent of the improvement activity performance score (85 FR 84865, 85031).

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We referred readers to CY 2018, CY 2019, Quality Payment Program final rules and the CY 2021, and CY 2022 PFS final rules (82 FR 53714 through 53716, 83 FR 59845 through 59847, 85 FR 84898 through 84901, and 86 FR 65491 and 65492 respectively) and § 414.1380(b)(1)(vii)(A) for our previously established scoring flexibilities policy.

We refer readers to the CY 2024 PFS proposed rule (88 FR 52592) for a detailed description of the development of the scoring flexibilities policy.

In the CY 2024 PFS proposed rule, we proposed two modifications to the criteria by which we assess the impacts of ICD–10 coding changes (88 FR 52592). Firstly, we proposed to eliminate the 10 percent ICD–10 coding change factor established in the CY 2018 Quality Payment Program rule (82 FR 53714). The quality and cost performance categories rely on measures that use detailed specifications that include ICD–10 code sets. We annually issue new ICD–10 coding updates, which are effective from October 1 through September 30. As part of this update, codes are added and removed from the ICD–10 code sets. When we adopted this standard in the CY 2018 Quality Payment Program final rule (82 FR 53714), we were concerned that ICD–10 coding changes in the final quarter of the performance period may render a measure no longer comparable to its historical benchmark. However, we have found that a 10 percent change to ICD–10 codes does not necessarily reflect a meaningful impact to clinicians' ability to report and be fairly scored on a quality measure. In the CY 2018 Quality Payment Program proposed rule, we discussed an approach where we would consider any change in ICD–10 coding to impact performance on a measure and thus only rely on the first 9 months of the 12-month performance period for such measures; however, we stated that such an approach was too broad (overly inclusive of changes) and would truncate measurement for too many measures where performance may not be significantly affected (82 FR 30098). We maintain this perspective but have concluded that a 10 percent change in codes is similarly over inclusive as it leads to the suppression of measures that can still be scored using all 12 months of the performance period. In place of the 10 percent threshold, we proposed to assess the overall impact on a measure resulting from changes to ICD–10 codes. Rather than consider a flat 10 percent change as a factor for when ICD–10 coding changes affect a measure, we will instead assess how the coding changes affect the measure numerator, denominator, exclusions, and exceptions in ways that could lead to misleading or harmful results. We will assess whether resultant changes to the numerator, denominator, exceptions, exclusions, or other measure elements change the scope or intent of the measure.

Changes in measure scope or intent will be considered significant changes that affect the applicability of the historical benchmark. ICD–10 codes include information related to clinical diagnoses and eligible patient population. For example, ICD–10 codes in the denominator correspond to the total eligible patient population considered for a measure. If as a result of a clinical guideline change a code is changed from an exclusion to a code to be considered in the total patient population indicated in the denominator for a measure, this will meaningfully change the scope of the measure and could lead to misleading results in measurement. Additionally, instances in which coding changes change the designation of whether performance was met or not (numerator) could similarly lead to misleading results. These changes would be considered significant and therefore trigger our scoring flexibilities policy.

Second, we proposed to assess the impacts of coding changes and our associated course of action (suppression, truncation, or standard 12-month reporting) by measure collection type. Our scoring policy states that we calculate benchmarks by collection type (§ 414.1380(b)(1)(ii). As benchmarks are assessed by collection type, we must consider by collection type whether the changes or errors will result in patient harm or misleading results. We refer readers to the 2024 PFS proposed (88 FR 52592) rule for relevant discussion.

Each collection type has different technical limitations. For example, measure specifications for the MIPS CQMs and Medicare Part B claims collection types can be updated in the performance period immediately following the publication each October of changes to ICD–10 codes. If an ICD–10 coding change occurs in October of 2024, CMS can immediately update the specifications for the measure's MIPS CQMs and Medicare Part B claims collection types for the next performance period, and the ICD–10 changes would not result in any misleading results for the measure for those collection types.

This differs from eCQM measure specifications, which are posted in the May the year before the measure specifications take effect and are valid for the 12-month reporting period. For the CY 2024 performance period/2026 MIPS payment year, eCQM measures specifications will be posted in May of 2023 and are valid for the applicable 12-month performance period in CY 2024. In the example given above, the measure's eCQM collection type would not be updated again until May 2025 for the CY 2026 performance period/2028 MIPS payment year, and clinicians would be left reporting pursuant to outdated specifications for the final quarter of the CY 2024 performance period. This could result in misleading results for the measure's eCQM collection type. As a result, it would be appropriate for CMS to assess the impact of changes to measures and implement the appropriate scoring flexibility by collection type. Lastly, we proposed that measure specifications for eCQMs include the capability to be truncated to a 9-month performance period. Current measure specifications for eCQMs provide exclusively for a 12-month reporting period. If a measure is significantly impacted by ICD–10 coding changes, it therefore cannot be reported for a truncated performance period of 9-month. In order to implement the scoring flexibilities policy as intended and protect our ability to score measures where 9 consecutive months of data is available, we proposed to begin requiring measure specifications to include logic for a 9-month performance period in addition to the currently existing 12-month performance period.

These updates will help us to better provide scoring flexibilities to clinicians by being sensitive to the particular impacts to and capabilities of the particular quality measures collection types. We sought comment on our proposal to update the criteria by which be apply scoring flexibilities in response to ICD–10 coding changes.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal for CMS to eliminate the criterion of a 10 percent change in the ICD–10 coding specifications and instead assess the significance of changes. One commenter encouraged CMS to work with interested parties in each instance to assess the appropriateness of measuring on 9 months of data for quality

measures with a 12-month performance period. Another commenter stated that suppressing a measure at the end of the year could undermine the work of the care team to achieve high performance and that if the measure intent remains the same and the coding impact is minimal, providers should be able to continue to report the measure. One commenter stated that evaluating measure changes on a case-by-case basis could prevent suppression of measures with favorable performance scores. One commenter agreed with assessing the impact of ICD–10 coding changes separately for each collection type.

Response: We agree with interested parties that assessing the measures for appropriateness could help to ensure quality measurement, working to recognize and support the hard work clinicians are doing to improve clinical quality. Eliminating the 10 percent change in ICD–10 coding specifications and consideration by collection type and on a case-by-case basis, will help us to better support quality measurement and clinicians in this way.

Comment: One commenter opposed elimination of the 10 percent ICD–10 coding change factor, stating that although coding education on annual changes is important, education does not overcome the impact of the transition to updated ICD–10 codes. Another commenter expressed concerns about the burden imposed on practices by coding changes and suppression/truncation of measures during the performance year. The commenter stated that because benchmark and logic changes are released late in the year, their EHR vendor does not implement updates until well into the new year, resulting in workflow changes and administrative burden.

Response: Eliminating the 10 percent threshold, will allow us to better find alternatives to suppression or truncation to support clinicians and their workflows. We will continue to consider alternatives that will preserve scoring and support clinicians, to the extent feasible.

Comment: A few commenters opposed the proposal to require eCQM measure stewards to develop specifications to support a truncated 9-month reporting period. One commenter stated that EHR developers should not be required to support two sets of specifications for each measure when CMS or the measure developer makes changes during the reporting period. One commenter stated that it may not be feasible to develop specifications for a 9-month reporting period for measures that depend on actions from more than one patient encounter. A few commenters raised concerns about the burden associated with requiring both 9-month and 12-month specifications for eCQMs, stating that this would increase burden for EHR developers and undermine their ability to support eCQMs. A few commenters offered alternatives to requiring measure stewards to develop specifications for a 9-month reporting period. One commenter suggested that CMS could change the date of ICD–10 to the end of the calendar year to align with the quality measure performance period. Another commenter recommended that eCQMs be specified for only a 9-month reporting period running from January to September.

Response: We thank commenters for expressing their concerns regarding the proposed requirement for eCQM measures to account for the reporting of a 9-month performance period. While supporting a truncated 9-month reporting period would help our mission to preserve quality measurement and scoring in MIPS, we recognize the concerns described by commenters in implementing these changes. We will possibly consider the implementation of alternative options through future rulemaking.

After consideration of public comments, we are finalizing this proposal with modifications. We are finalizing our proposal to the implementation of the scoring flexibilities policy at § 414.1380(b)(1)(vii)(A) to eliminate the 10 percent ICD–10 coding change factor established in the CY 2018 Quality Payment Program rule (82 FR 53714) and to assess the impacts of coding changes and our associated course of action (suppression, truncation, or standard 12-month reporting) by measure collection type. We are not finalizing our proposal to require eCQM measure specifications to include logic for a truncated 9-month performance period.

(d) Cost Performance Category Score

(i) Improvement Scoring Methodology

(A) Background

We refer readers to the CY 2024 PFS proposed rule (88 FR 52593) for details on the history of the cost improvement scoring methodology.

Briefly, in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), we established policies related to measuring improvement for the cost performance category at the measure level. We codified these policies at 42 CFR 414.1380(b)(2)(iii) and (iv) (82 FR 53748 through 53752, 53957). After the publication of the CY 2018 Quality Payment Program final rule, the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123, February 9, 2018) was enacted. Section 51003(a)(1)(B) of the BBA 18 added a new clause at section 1848(q)(5)(D)(iii) of the Act which provided that the cost performance category score shall not take in to account the improvement of the MIPS eligible clinician for CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year. On this basis, we set the maximum cost improvement score for the CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year at zero percentage points, in the CY 2019 PFS final rule (83 FR 35956, 36080 through 36082), which we codified at § 414.1380(a)(1)(ii) and (b)(2)(iv)(E). Further, due to the COVID–19 Public Health Emergency (PHE) ((85 FR 19277 through 19278; See ''Extension to Data Submission Deadline'' on Quality Payment Program website at *https://qpp.cms.gov/*) and under our authority at § 414.1380(c)(2)(i)(A)(8), we reweighted the cost performance category's score to zero percent of the final score for the CY 2020 performance period/2022 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year. In the CY 2024 PFS proposed rule (88 FR 52593), we this reweighting began with stated the CY 2019 performance period/2022 MIPS payment year, but we want to clarify that we were referring to the CY 2020 performance period/2022 MIPS payment year.

On these bases, to date, we have not applied a cost improvement score to MIPS eligible clinicians' final scores in accordance with the policies we established in the CY 2018 Quality Payment Program final rule and our regulations at § 414.1380(b)(2)(iii) and (iv).

(B) Description of Previously Finalized Cost Improvement Scoring Methodology

We refer readers to the CY 2024 PFS proposed rule (88 FR 52593 and 52594) for details on previously finalized cost improvement scoring methodology that we established in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752). In summary, we established the following policies:

- Determine the cost improvement score at the individual measure level (82 FR 53749 through 53750);
- Calculate the cost improvement score, generally by comparing the number of cost measures with

significant improvement in performance and the number of cost measures with significant declines in performance for a MIPS eligible clinician or group between two consecutive performance periods (82 FR 53750 through 53752);

- Determine whether there was significant improvement or decline in performance for individual cost measures between the two performance periods by applying a common standard statistical test to measure significance, the t-test, as used in the Shared Savings Program (82 FR 53750 through 53752); and
- Establish that the cost improvement score cannot be lower than zero percentage points (82 FR 53750 through 53752).

(C) Mathematical Feasibility Issue for Cost Improvement Scoring Methodology

In reviewing our cost improvement scoring methodology, we discovered that calculating cost improvement scoring based on comparing only cost measures with a statistically significant change, determined by using a t-test, is not congruent with the underlying data. We refer readers to the CY 2024 PFS proposed rule (88 FR 52594) for details on the mathematical feasibility issues of calculating cost improvement scoring with a statistical significance requirement. Generally, we failed to identify that the currently established cost improvement scoring method is not mathematically feasible, because we have not implemented cost improvement scoring since we finalized this methodology in the CY 2018 Quality Payment Program final rule as discussed previously. We identified the mathematical infeasibility of the current cost improvement methodology in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year. To address this mathematical feasibility issue, we proposed to remove the statistical significance requirement for the cost improvement scoring methodology (88 FR 52594 and 52595).

(D) Operational Feasibility Issues for Cost Improvement Scoring Methodology

In addition, in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year, we identified three issues with our current policy at § 414.1380(b)(2)(iv)(A) because we determine each MIPS eligible clinician's cost improvement score at the individual cost measure level, and not the category level, for the cost performance category. We refer readers to the CY 2024 PFS proposed rule (88 FR 52594 and 52595) for detailed descriptions of these issues. In summary, these issues are:.

- *Measure level improvement scoring implementation issue:* As of CY 2023 performance/2025 MIPS payment year, there are 25 cost measures, two of which are population based measures and the remaining 23 are episode-based measures. We expect to add additional episode-based measures to the cost performance category as MIPS matures. The growing number of cost measures bring into question if using the current methodology for cost improvement scoring introduces complexities to its implementation, which in turn brings into question operational feasibility. Maintaining measure level improvement scoring, for a performance category that will continue to see growth in the number of measures, would be resource intensive, complex to implement, and error prone (88 FR 52594).
- *Performance category improvement scoring consistency:* As set forth at § 414.1380(b)(1)(vi)(C), we calculate each MIPS eligible clinician's improvement score for the quality performance category in MIPS at the performance category level. Upon further evaluation, we found that using two different methods of improvement scoring for the quality and cost performance categories would increase the implementation cost and operational complexity described above—as well as confuse MIPS eligible clinicians and call into question why we use two different methodologies. As such, we concluded that using category level assessment for cost improvement scoring would establish consistency across MIPS and allow effective communication with MIPS eligible clinicians, while reducing implementation cost and operational complexity (88 FR 52594).
- *Fairness of improvement scoring:* The episode-based cost measures are specific to certain clinical conditions and/or care settings. Some MIPS eligible clinicians might not have the sufficient volume threshold for any or all the episode-based cost measures for two consecutive performance periods, which would make year over year improvement scoring at the measure level less viable. Measure level improvement scoring might negatively impact these clinicians' overall cost performance category score because of the inclusion of measures outside of their scope of practice. A category level assessment provides an equitable cost improvement scoring for MIPS eligible clinicians with different scopes of practice because it would only reflect measures that are applicable to them (88 FR 52594 and 52595).

To address these three issues, we proposed to revise our policy so that we will determine the cost improvement score at the category level, instead of the cost measure level, for the cost performance category.

(E) Modifications for Cost Improvement Scoring Methodology Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2024 PFS proposed rule (88 FR 52595 and 52596), we proposed two modifications to our current cost improvement scoring methodology beginning with the CY 2023 performance period/2025 MIPS payment year because of the mathematical and operational feasibility issues we discovered.

First, we proposed to determine each MIPS eligible clinician's cost improvement score at the category level, instead of the current measure level, beginning with the CY 2023 performance period/2025 MIPS payment year. We proposed this modification based on the operational feasibility considerations previously discussed. We also proposed that, if this proposal is finalized, § 414.1380(b)(2)(iv)(A) and (C) will be amended to reflect that the cost improvement score will be determined at the category level for the cost performance category. In addition, we proposed that, if this proposal is finalized, § 414.1380(b)(2)(iv)(B) will be amended to reflect that we will determine whether sufficient data are available to measure improvement to calculate the cost improvement score based on whether a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods.

Second, we proposed to modify the cost improvement scoring methodology to remove the requirement that we compare measures with a ''statistically significant change (improvement or decline) in performance'' as determined based on application of a t-test beginning with the CY 2023 performance period/2025 MIPS payment year. As previously discussed, determining cost improvement scoring based on statistical significance, using a t-test, is not congruent with our underlying data and is mathematically infeasible.

As such, we proposed to remove the statistical significance requirement and update the calculation on how we quantify cost improvement scoring

accordingly. Specifically, at § 414.1380(b)(2)(iv)(C), we proposed to determine the cost improvement score at the category level by subtracting the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year) from the cost performance category score from the current performance period (for example, CY 2023 performance period/2025 MIPS payment year), and then by dividing the difference by the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year), and by dividing by 100.

In our current and established policy set forth at § 414.1380(b)(2)(iii), the overall cost performance category score for the current year with the improvement assessment is based on the following calculation: Cost Performance Category Score = Current Year Performance Score + Improvement Score. We did not propose any changes to this established policy.

We proposed that these two modifications to our cost improvement scoring policy would be effective beginning with the CY 2023 performance period/2025 MIPS payment year. As discussed in the CY 2024 PFS proposed rule (88 FR 52593), section 1848(q)(5)(D)(i) of the Act requires that we account for a MIPS eligible clinician's improvement in the cost performance category if we have sufficient data available to measure improvement. Because we have not implemented cost improvement scoring to date, we did not have sufficient data available to measure year-over-year improvement scoring for the cost performance category until the CY 2023 performance period/2025 MIPS payment year. However, we do have such sufficient data available beginning with the CY 2023 performance period/2025 MIPS payment year. Further, section 1848(q)(5)(D)(iii) of the Act, requiring that we delay our implementation of cost improvement scoring through the CY 2021 performance period/2023 MIPS payment year, no longer applies. Therefore, we proposed to implement cost improvement scoring, with these two proposed modifications, beginning with the CY 2023 performance period/2025 MIPS payment year.

On this basis, we proposed to amend § 414.1380(b)(2)(iv)(E) to state that the maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment years is zero percentage points and that the maximum cost improvement score beginning with the CY 2025 MIPS payment year is 1 percentage point. In addition, we proposed to amend § 414.1380(a)(1)(ii) to state that improvement scoring is available in the cost performance category starting with the 2025 MIPS payment year, instead of the 2024 MIPS payment year. The remainder of the language currently at § 414.1380(a)(1)(ii) will remain the same.

We solicited public comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed changes to modify the cost improvement scoring methodology stating they appreciate CMS's thoughtful approach in continuing to refine the methodology.

Response: We thank and appreciate the commenters for their support of our proposed modifications to the cost improvement scoring methodology.

Comment: A few commenters suggested for CMS to use a phase-in approach for increasing the maximum cost improvement percentage point to allow for better year-to year comparisons in the cost performance category scores, given the COVID–19 PHE and lack of cost data from the last few years.

Response: As discussed previously, section 1848(q)(5)(D)(i) of the Act requires that we account for a MIPS eligible clinician's improvement in the cost performance category if we have sufficient data available to measure improvement. We did not implement cost improvement scoring to date because we did not have 2 consecutive years of cost performance category data to measure year-over-year improvement scoring. We do have such data beginning with CY 2023 performance period/2025 MIPS payment year. On this basis, we proposed to implement cost improvement scoring beginning with the CY 2023 performance period/2025 MIPS payment year. Further, we are taking a phased-in approach by also proposing that the maximum cost improvement score beginning with the 2025 MIPS payment year is only 1 percentage point. We may consider amending the maximum percentage point amount for the cost improvement score as the program matures.

Comment: A few commenters stated that there is a need for CMS to prioritize clinician education, to help providers understand how the cost improvement score impacts their overall MIPS performance. For example, the commenters asked for clarification regarding how cost improvement score is a bonus for the cost performance category score rather than of a separate benchmark.

Response: We agree with commenters regarding the need to prioritize clinician education on how the cost improvement score impacts their cost performance category and their overall MIPS performance. To this end, we are looking into possible educational resources for cost improvement scoring, in the future.

Comment: A commenter shared their concerns regarding our for proposal to increase the maximum cost improvement score to 1 percentage point beginning with CY 2023 performance period/2025 MIPS payment year, which is an increase from 0 percentage points for previous years. The commenter stated they are concerned that this modification is being proposed mid-performance cycle. They stated that practices work to implement updates to their data collection and refinement activities for a given performance year based on proposals made and finalized in previous MIPS rulemaking cycles. Further, the commenter stated that, if this proposal is implemented mid-cycle, they will likely not be able to modify their collection and refinement practices with enough time to mitigate this change in cost performance category scoring. As such, they recommended delaying this proposed update to the cost performance category scoring to give clinicians the ability to prepare for the changes.

Response: We believe a few clarifications are needed. First, clinicians do not report cost performance category measures to CMS. Instead, we use administrative claims data, which clinicians already submit for billing purposes, to calculate scores on the cost performance category's measures and we take into consideration all applicable cost measures for each given performance year. Second, our current policy at § 414.1380(a)(1)(ii), established prior to the CY 2024 PFS proposed rule, states that, starting with the 2024 MIPS payment year, improvement scoring is available in the cost performance category. As discussed previously, we are statutorily required to take into account the improvement of a MIPS eligible clinician in the cost performance category and potentially provide a bonus to the cost performance category score through this mechanism. MIPS eligible clinicians are generally incentivized under MIPS to always improve their performance.

The change in the cost improvement scoring methodology being finalized in

this rule for the CY 2023 performance period/2025 MIPS payment year should not necessarily change MIPS eligible clinicians' behavior since they should have been aware of the potential benefit of improving their performance on the cost performance category's measures.

Since we calculate performance on cost measures based on administrative claims data submitted for billing purposes in the regular course of business, MIPS eligible clinicians do not need to make any data collection changes in order to be scored for the cost performance category and are scored on all applicable cost measures for a given performance period. Second, cost improvement scoring is a bonus that can be applied to the cost performance category score. The proposed 1 percentage point is the maximum cost improvement score available that we will apply to the cost performance category.

Comment: A commenter shared concerns with the CMS proposal to determine the cost improvement score at the category level instead of the measure level. They shared an example where a clinician was scored on one measure and performed well. However, they were unexpectedly attributed a measure outside of their specialty and scored poorly, bringing their cost performance category score down significantly.

Response: We thank and appreciate the commentor for bringing to our attention issues with clinicians being attributed measures outside of their specialty and thus impacting their overall cost performance category score.

We understand that inclusion of out-of-scope cost measures would cause concerns for evaluating improvement at the category level. We score MIPS eligible clinicians on cost measures that are applicable to the care they provided during the performance period for the cost performance category. We continually review our attribution methodology for the cost performance category to make sure we attribute cost measures appropriately to MIPS eligible clinicians. We note that each cost measure has a minimum case volume threshold (§ 414.1350(c)) that the MIPS eligible clinician must exceed for CMS to assess performance and calculate a score on that measure (§ 414.1380(b)(2)(ii), (iv)); therefore, a MIPS eligible clinician would need to provide a service that triggered that cost measure more than a few times before CMS would attribute that cost measure to them. Further, we note that, if a MIPS eligible clinician has a concern that CMS has attributed a cost measure to them incorrectly, they may request targeted review under § 414.1385.

In the CY 2024 PFS proposed rule (88 FR 52594 and 52595), we described in detail the three reasons that informed our decision to change cost improvement scoring from measure to category level. These reasons are summarized previously in this section of the final rule. For instance, we explained that some MIPS eligible clinicians might not have the sufficient volume threshold for any or all the episode-based measures for two consecutive performance periods. This would make year over year improvement scoring at the measure level less viable. As such, we explained that measure level improvement scoring might negatively impact these clinicians' overall cost performance category scoring because of the inclusion of episode-based measures outside of their scope of practice (88 FR 52594 and 52595).

Comment: A few commenters suggested CMS further modify the cost improvement methodology as it continues to be confusing for clinicians. One commenter suggested a more straightforward approach would be to multiply the change between current and previous year performance scores by the maximum cost improvement score (for example, 1 percentage point as proposed). Another commenter noted that there may be unintended errors in the newly proposed formula for the cost improvement score, specifically in the final step of the calculation (dividing the calculated score by 100).

Response: Upon reviewing the final step of the cost improvement score calculation, (that is, dividing by 100), we agree that there was an unintended error in our proposal and the suggested approach to multiply the change between current and previous year performance scores by the maximum cost improvement score (for example, 1 percentage point as proposed) addresses this error.

After consideration of public comments, we are finalizing our policies for the cost improvement scoring methodology with some modifications.

First, we are finalizing that we will determine each MIPS eligible clinician's cost improvement score at the category level, instead of the current measure level, beginning with the CY 2023 performance period/2025 MIPS payment year. As such, we are finalizing as proposed amendments to § 414.1380(b)(2)(iv)(A) and (C) to reflect that the cost improvement score will be determined at the category level for the cost performance category. In addition, we are finalizing as proposed amendments to § 414.1380(b)(2)(iv)(B) to reflect that we will determine whether sufficient data are available to measure improvement to calculate the cost improvement score based on whether a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods.

Second, we are finalizing our proposal to modify the cost improvement scoring methodology to remove the requirement that we compare measures with a ''statistically significant change (improvement or decline) in performance'' as determined based on application of a t-test beginning with the CY 2023 performance period/2025 MIPS payment year. Accordingly, we are finalizing our proposal to remove the statistical significance requirement and update the calculation on how we quantify cost improvement scoring.

However, based on feedback from commenters, we are finalizing our proposal with modification to amend our formula for calculating the cost improvement score at the category level. Specifically, at § 414.1380(b)(2)(iv)(C), we are finalizing that we will determine the cost improvement score at the category level by subtracting the cost performance category score from the previous performance period from the cost performance category score from the current performance period, then by dividing the difference by the cost performance category score from the previous performance period, and by multiplying the result with the maximum available cost improvement score (for example, 1 percentage point beginning in CY 2023 performance year/2025 MIPS payment year). With this approach, the finalized cost improvement scoring methodology is consistent with improvement scoring for the quality performance category and previously finalized cost improvement scoring calculation at § 414.1380(b)(2)(iv)(C) (82 FR 53748 through 53752), where the final step was also to multiply the resulting fraction with the maximum available cost improvement score.

We are also finalizing our proposal to amend § 414.1380(b)(2)(iv)(E) to state that the maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment years is zero percentage points and that the maximum cost improvement score beginning with the CY 2025 MIPS payment year is 1 percentage point. In addition, we are finalizing our proposal to amend § 414.1380(a)(1)(ii) to state

that improvement scoring is available in the cost performance category starting with the 2025 MIPS payment year, instead of the 2024 MIPS payment year. The remainder of the language currently at § 414.1380(a)(1)(ii) will remain the same.

f. MIPS Payment Adjustments

(1) Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), and CY 2023 PFS final rule (87 FR 70096 through 70102).

In the CY 2023 PFS final rule (87 FR 70096 through 70102), we established the performance threshold for the CY 2023 performance period/2025 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. In addition, we included information about our timing for providing MIPS performance feedback to MIPS eligible clinicians for the CY performance period in accordance with section 1848(q)(12) of the Act.

(2) Establishing the Performance Threshold

(a) Statutory Background and Authority

As discussed above, in order to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with Section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. These special rules are no longer applicable for establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year. We refer readers to the CY 2024 PFS proposed rule (88 FR 52596) for further information on these previously applicable requirements as they explain our prior computations of the performance threshold.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years. We also established in our regulation at § 414.1405(g) that, for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period.

For the CY 2022 through CY 2023 performance periods/2024 through 2025 MIPS payment years, we selected a single performance period when selecting a prior period to compute the mean of the final scores and establish the performance threshold. However, as discussed under paragraph (b) of this section, we proposed to modify and refine our policy for selecting a ''prior period'' to establish the performance threshold under paragraph (b) of this section.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), and CY 2023 PFS final rule (87 FR 70096 through 70100).

We codified the performance thresholds for each of the first 7 years of MIPS at § 414.1405(b)(4) through (9). These performance thresholds are shown in Table 58.

TABLE 58: Performance Thresholds for the CY 2017 through CY 2023 Performance Periods/2019 through 2025 MIPS Payment Years

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 Points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points

(b) Modification to Our Policy for Establishing the Performance Threshold

In previous years, we selected a single performance period when selecting a prior period. In the proposed rule, we reassessed our previous interpretation of ''prior period'' as described at section 1848(q)(6)(D)(i) of the Act. We refer readers to the CY 2024 PFS proposed rule for more detailed information on how we interpreted ''prior period'' within the statutory language (88 FR 52597). Because section 1848(q)(6)(D)(i) of the Act does not specifically refer to ''a performance period'' or ''year'' to establish the performance threshold, we noted that the term ''prior period'' could refer to a time span other than a single year or performance period as long as that ''prior period'' is specified by the Secretary.

Given our interpretation that ''prior period'' does not require CMS to select a single performance year as the period, we proposed to add § 414.1405(g)(2) to specify that, beginning with the CY 2024 performance period/2026 MIPS payment year, a ''prior period'' for purposes of establishing a performance threshold as identified in § 414.1405(b) is a time span of 3 performance periods. Subsequently, we also proposed to redesignate language at § 414.1405(g) which states that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section, as § 414.1405(g)(1) (88 FR 52597 and 52598).

Using three performance periods as the prior period would prevent the performance threshold from being dependent on a single potentially anomalous performance period, or on two performance periods, whose mean or median final score may be an outlier compared to other performance periods. The mean or median of final scores over 36 months is less likely to be impacted by unusual fluctuations in performance specific to a shorter time frame, is more likely to reflect clinician performance, and therefore, more appropriate to set the performance threshold. Additionally, as more data become available, we will consider whether a longer time span than three performance periods may be appropriate to mitigate outliers and better reflect clinician performance trends.

We requested comments on our proposal to use three performance periods as the ''prior period'' we use to establish the performance threshold and codify the policy at § 414.1405(g)(2).

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal that, for purposes of establishing a performance threshold, a ''prior period'' would be 3 performance periods beginning with the CY 2024 performance period/2026 MIPS payment year. Some commenters stated that this proposal has promise to improve stability in MIPS in future years.

Response: We thank the commenters for their support.

Comment: A number of commenters suggested that we treat the CY 2024 performance period/2026 MIPS payment year as a ''recovery'' period given the public health emergency (PHE) for COVID–19. On this basis, commenters suggested we delay implementation of the proposal to define ''prior period'' as 3 years. Several commenters suggested not using a 3-year prior period until we are able to use more recent data that is not impacted by the PHE for COVID–19.

Response: We agree that MIPS eligible clinicians, health systems, and physician groups may still be recovering from the PHE for COVID–19, which expired on May 11, 2023,[500] and this recovery may continue into CY 2024. After consideration of this feedback, we are not finalizing our proposal in defining a ''prior period'' as a time span of 3 performance periods for purposes of establishing a performance threshold. While we continue to believe that using 3 years of data better accounts for outliers as opposed to using a single year, we agree with commenters that it is in our best interest to delay finalizing this proposal until we have more recent data that is not impacted by the PHE for COVID–19. We will continue to examine the issue and will propose any changes in future rulemaking. In response to public comment, we also note that we do not intend to rely on data from the CY 2020 through 2021 performance periods/CY 2022 through CY 2023 MIPS payment years due to the PHE for COVID–19, as discussed in section IV.A.4.h.(2)(c)of this final rule.

Comment: A few commenters did not support our proposal to define ''prior period'' for purposes of establishing a performance threshold as a time span of 3 performance periods. More specifically, a few commenters noted their belief that we misinterpreted the statute's language when it references ''prior period'' and do not believe that the statute allows us to combine performance data from multiple years to establish the performance threshold. Rather, the commenters stated that we should continue to use a single performance period for the purposes of establishing the performance threshold.

Response: We disagree that we misinterpreted the statute's language when it references ''prior period.'' As previously stated, the use of ''prior period'' in section 1848(q)(6)(D)(i) of the Act differs from other provisions in the statute which specifically refer to ''a year'' or ''performance period.'' Certain statutory provisions governing MIPS clearly distinguish the terms ''performance period'' and ''year'' from ''prior period'' used in section 1848(q)(6)(D)(i) of the Act. If the ''prior period'' we use to determine the mean or median of all MIPS eligible clinicians' final scores to establish the performance threshold under section 1848(q)(6)(D)(i) of the Act was intended to be limited to a single year or performance period, we believe the statute would have been more specific and used ''performance period'' or ''year'' rather than using the unique term ''prior period.'' However, as discussed herein, after consideration of the feedback we received, we will continue to use a single performance period for the purposes of establishing the performance threshold for the CY 2024 performance period/CY 2026 MIPS payment year. We note that we will continue to examine the issue and will propose any changes in future rulemaking.

After consideration of public comments, we are not finalizing our proposal to add to § 414.1405(g)(2) such that it will specify that, beginning with the CY 2024 performance period, we will define a ''prior period'' for purposes of establishing a performance threshold as identified in § 414.1405(b) as a time span of 3 performance periods. We are also not finalizing our proposal to redesignate language at § 414.1405(g) which states that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section, as § 414.1405(g)(1).

(c) Performance Threshold for the CY 2024 Performance Period/2026 MIPS Payment Year

While we chose to use the mean in our methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024

[500] *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023.*

through 2026 MIPS payment years, we did not specify which prior period's mean final score we would use for the CY 2024 performance period/2026 MIPS payment year's performance threshold. From our review of the data available at the time, we identified the mean final scores for each of the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years individually, as well as the mean of the final scores for CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years combined, as shown in Table 59. We included means of final scores for MIPS eligible clinicians spanning over three performance periods within Table 59 in addition to a single year performance period. These six values represent the mean final scores for all MIPS eligible clinicians from prior periods that are available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold.

We did not consider the means of the final scores for certain prior periods for the purpose of establishing the performance threshold because of issues with the underlying data. First, we did not consider the CY 2020 through 2021 performance periods/2022 through 2023 MIPS payment years because we extensively applied our extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which we believe resulted in skewing the final scores from those years such that they are not an appropriate indicator for future clinician performance. We announced on April 6, 2020, the application of extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 through 19278). However, given the timing of the COVID–19 PHE and this announcement, the data from that CY 2019 performance period was likely minimally impacted because many MIPS eligible clinicians had already submitted the data. Second, the final scores for the CY 2022 performance period/2024 MIPS payment year were not finalized in time for the proposed rule and, therefore, the mean final score for the CY 2022 performance period/2024 MIPS payment year was not included for consideration as a potential performance threshold value for the CY 2024 performance period/2026 MIPS payment year.

TABLE 59: Possible Values for the CY 2024 Performance Period/2026 MIPS Payment Year Performance Threshold

2017 Performance Period	2018 Performance Period	2019 Performance Period	2020 Performance Period	2021 Performance Period	2017-2019 MIPS Performance Periods
74.65 Points	87.00 Points	85.63 Points	89.47 Points	89.22 Points	82.06 Points

As shown in Table 59, the mean final scores available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold cover a range of values from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). We proposed to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points, rounded down from 82.06 points) as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year for several reasons. We refer readers to the CY 2024 PFS proposed rule for our discussion of this proposal (88 FR 52598 through 52599).

For the last 2 performance periods/MIPS payment years, we established at § 414.1405(b)(9) the performance threshold as 75 points based on the CY 2017 performance period/2019 MIPS payment year. We did not increase the performance threshold between the CY 2023 performance period/2025 MIPS payment year and the prior year (CY 2022 performance period/2024 MIPS payment year) due to reasons noted in the CY 2023 PFS final rule (87 FR 70096 through 70100) and discussed in the CY 2024 PFS proposed rule (88 FR 52599). Generally, these reasons were related to expiration of transition policies and the COVID–19 PHE.

We proposed, pursuant to the methodology we established previously at § 414.1405(g), that the performance threshold for the CY 2024 performance period/2026 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years, which is 82 points (rounded from 82.06 points). We proposed corresponding changes to § 414.1405(b)(9) to reflect this proposal (88 FR 52599).

Alternatively, in an effort to use more recent data, we considered using the single CY 2019 performance period/2021 MIPS payment year, with a mean of 86 (rounded from 85.63) to establish the performance threshold for the CY 2024 performance period/2027 MIPS payment year. However, in an effort to use more robust data from a longer period of time, we proposed using the CY 2017 through 2019 performance period/2019 through 2021 MIPS payment year as the prior period, with its mean of 82 points, to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year. We also believe the performance threshold of 82 instead of 86 would be more appropriate for clinician practices that are still recovering from the impacts of the COVID–19 PHE.

In the Regulatory Impact Analysis (RIA) in section VI.E.22.d.(4) of the final rule, we estimate that approximately 22 percent of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2024 performance period/2026 MIPS payment year if the performance threshold is established at 75 points. Under the original proposal of establishing the performance threshold at 82 points, we estimated that approximately 46 percent of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2024 performance period/2026 MIPS payment year (88 FR 52599). We refer readers to the alternatives considered under the RIA where we present the impact of using data from alternative years to determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year.

We requested comments on this proposal, as well as whether we should use means of final scores from alternative years to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year, which we considered and discussed in the RIA in section VII.F.4 of the proposed rule. We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points), as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2016 MIPS payment year.

Response: We thank the commenters for their support.

Comment: Many commenters urged us to not finalize the proposal to use the CY 2017 through the CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points), as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year. Specifically, some commenters stated that many health systems and physician practices continue to face financial and resource constraints and clinicians are continuing to recover from the PHE for COVID–19.

Commenters further opposed using data from the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years as the prior period for the CY 2024 performance period/2026 MIPS payment year due to concern that those years, and their data and final scores, reflect prior transition policies. A few commenters voiced concerns that, because there are now new cost measures within the program in addition to the cost performance category weight increasing, MIPS eligible clinicians need more time getting acclimated with those measures. Many commenters suggested we continue to keep the performance threshold at 75 points and treat the CY 2024 performance period/CY 2026 MIPS payment year as a transition year given that we applied our automatic extreme and uncontrollable circumstances (EUC) policy for the COVID–19 PHE for the CY 2019 through 2021 performance periods/CY 2021 through 2023 MIPS payment years.

Response: We aim to balance concerns regarding the impact of the PHE for COVID–19 on MIPS eligible clinicians with policies that motivate clinicians to participate in MIPS and strive for continuous improvement on the measures and activities. When we proposed establishing the performance threshold at 82 points for the CY 2024 performance period/2026 MIPS payment year, we considered what was appropriate for clinician practices that are still recovering from the impacts of the COVID–19 PHE (88 FR 52599). However, after consideration of public comments, we believe that establishing the performance threshold at 75 points, using data from the CY 2017 performance period/2019 MIPS payment year, for the CY 2024 performance period/2026 MIPS payment year better achieves this goal. This means that the performance threshold will remain at the same level as was established for CY 2022 through CY 2023 performance periods/2024 through 2025 MIPS payment years.

We recognize that clinician recovery from the PHE coincides with several changes to the Quality Payment Program, including the removal of transition policies such as quality bonus points, which had been established for scoring the quality performance category for the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years (86 FR 65491 through 65507). We also acknowledge that for the CY 2019 through 2021 performance periods/2021 through 2023 MIPS payment years, we applied certain extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which resulted in some clinicians not gaining experience with reporting on MIPS measures and activities due to the reweighting of some performance categories. The application of the automatic extreme and uncontrollable policies also resulted in many clinicians not submitting data for certain performance categories in order to receive reweighting of some performance categories leading to potentially inflated scores that would not be representative of our current scoring policies. (87 FR 70097). Given the expiration of those transition policies, as well as the possibility that the performance categories will be reweighted for fewer MIPS eligible clinicians for the CY 2023 performance period/2025 MIPS payment year, we expect the mean final score for CY 2023 performance period/2025 MIPS payment year to be lower than the mean final scores from the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years.

We note that, on a similar basis, we established the performance threshold at 75 points for the CY 2023 performance period/2025 MIPS payment year, without any change from the prior performance period (87 FR 70096 through 70100). Maintaining the performance threshold at 75 points, without any change, for the CY 2024 performance period/2026 MIPS payment year is consistent with our prior policy and addresses concerns raised by commenters, as previously discussed.

After receiving overwhelming public comment in favor of continuing the existing performance threshold of 75 points, we believe the rationale we used in selecting the performance threshold for the CY 2023 performance period/2025 MIPS payment year should be further applied to the CY 2024 performance period/2026 MIPS payment year. We believe this approach addresses commenters' concerns about the COVID–19 PHE, the impact of removing transition policies and bonuses, and changes to the cost performance category weight and measure inventory. This approach also allows for at least one complete year of performance (the CY 2024 performance period) after the COVID–19 PHE expired on May 11, 2023, from which we may later gather data regarding final scores to inform future performance thresholds. Further, this policy aligns with the policy we are finalizing in section IV.A.4.h.(2)(b) of this final rule, where we are not finalizing the proposal that a ''prior period'' is a time span of 3 performance periods.

We continue to believe that once MIPS eligible clinicians have been given at least one complete year of performance after expiration of the COVID–19 PHE, as clinicians gain more experience with MIPS, and as more recent data are available, we should incorporate more recent data in determining the performance threshold. Accordingly, we will continue to consider updating the performance threshold with more recent data in future years.

Comment: A few commenters opposed using the CY 2017 through 2019 performance periods/CY 2019 through 2021 MIPS payment years but agreed that CMS should not use data from the CY 2020 through 2021 performance periods/2022 through 2023 MIPS payment years. One commenter suggested that we use data from CY 2022 through CY 2024 performance periods/CY 2024 through CY 2026 MIPS payment years for the purposes of establishing the performance threshold in future years.

Response: We agree with commenters that we should not use data from the CY 2020 through 2021 performance

periods/2022 through 2023 MIPS payment years, as discussed previously, and note our continued intention to not use these data. We also note that as more recent data becomes available (for example, CY 2024 performance period/CY 2026 MIPS payment year) we will continue to consider updating the performance threshold with more recent data in future years.

Comment: A few commenters expressed concerns that setting the performance threshold at 82 will inadvertently harm small and rural practices, creating further challenges for them to successfully participate within the MIPS program.

Response: We have several policies within MIPS that continue to support small and rural practices, including scoring and reweighting policies, and opportunities to apply for hardships. However, as previously discussed, we are finalizing a policy to establish the performance threshold for the CY 2024 performance period/2026 MIPS payment year at 75 points. As we consider the performance threshold and its related policies in future years, we will continue to consider the impact on small and rural practices.

Comment: A few commenters expressed concerns that there were not enough quality measures within MIPS for certain specialties (for example, psychologists and non-patient facing clinicians) to successfully achieve the performance threshold of 82 points. One commenter suggested we delay increasing the performance threshold until we adopt new quality measures for additional specialties within MIPS. Additionally, a few commenters stated their concerns that certain specialties only have topped out measures to report. For example, the quality measures available for physical therapists are process-based measures capped at seven points which make it difficult for them to meet the increased performance threshold even if they perform very well on those measures.

Response: We understand that some MIPS eligible clinicians may not have six measures to select in the quality performance category which are relevant to their practice or may be topped out measures. To address this, we established an eligible measure applicability policy within the quality performance category, to reduce the denominator of required measures for the collection type used by a clinician if the clinician has fewer than six applicable measures to report in that collection type. This allows clinicians to be scored on the quality measures that are relevant to their scope of practice. For more information on the eligible measure applicability policy please see the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77290 through 77291, 82 FR 53730 through 53732). To address the commenters' concerns on the specialty measures available, we solicit commenter recommendations for new specialty measure sets and revisions to existing specialty measure sets on an annual basis. We encourage interested parties to provide recommendations during the specialty measure set solicitation process (for more information please see the QPP resource library at *http://www.qpp.cms.gov*). We also encourage clinicians that do lack sufficient quality measures relevant to their scope of practice to work with their specialty societies to provide recommendations during the specialty measure set solicitation process and to consider reporting a relevant MVP when one becomes available. As previously discussed, we also note that, in response to commenters' concerns with the impact of PHE for COVID–19 still continuing, we are establishing the performance threshold at 75 points for the CY 2024 performance period/2026 MIPS payment year, which may be more achievable for specialists with limited measures relevant to their practice.

Comment: A few commenters suggested that we break down the data analysis by specialty and establish multiple performance thresholds for certain clinician types (for example, specialties or MIPS eligible clinicians within their first or second year, etc.).

Response: Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold, with respect to which ''the composite score of MIPS eligible professionals shall be compared for purposes of determining [MIPS] adjustment factors,'' such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. We would like to emphasize that section 1848(q)(6)(D)(i) of the Act requires us to compute ''a performance threshold,'' meaning one performance threshold. Similarly, section 1848(q)(6)(A)(i) of the Act requires that we then compare each MIPS eligible clinician's final score to ''the performance threshold established'' under section 1848(q)(6)(D)(i) of the Act for such year, requiring comparison of final scores against a singular threshold. We are unable to establish multiple performance thresholds as requested.

Comment: One commenter stated that clinicians with limited resources tend to score lower within MIPS and therefore have their payments reduced leading to having fewer resources to continue treating patients. Rather, the commenter stated their belief that MIPS is more about rewarding the ''well-resourced'' groups with significant bonuses at the expense of other groups that may not have the opportunity to score well.

Response: We strive to ensure that performing well within MIPS is an achievable goal across all MIPS eligible clinician types, and we have established various policies in place to allow that as possible. Further, we remind the commenter who is concerned about the magnitude or distribution of the positive payments adjustments that MIPS is a budget neutral by statute. Generally stated, it is designed to balance the positive payment adjustments of clinicians that achieve final scores above the performance threshold against the negative payment adjustments of clinicians that achieve final scores below the performance threshold. Therefore, a larger proportion of clinicians receiving a negative payment adjustment generally would result in larger positive payment adjustments for those above the performance threshold. Additionally, as discussed herein, after consideration of commenters' feedback, we are finalizing the performance threshold at 75 points, which we believe is an achievable performance threshold across all MIPS eligible clinicians. We encourage the commenter to look at our estimates of how our finalized policies will affect the payment adjustments in our regulatory impact analysis in section VI.E.22.d.(4). of this final rule.

Comment: A few commenters stated concerns about the proposed performance threshold due to the absence of an inflationary update and continued cuts to the conversion factor within the PFS.

Response: We note that, to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a payment year, we must compare the MIPS eligible clinician's final score for the given performance period/payment year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. We are unable to consider issues such as the inflation rate or the conversion factor that is discussed in the broader PFS rule. Rather, as is statutorily required, we continue to consider performance thresholds that are the mean or median of the final

scores from a ''prior period'' specified by the Secretary for all MIPS eligible clinicians.

As previously discussed, after consideration of public comments, we are not finalizing our proposal to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points, rounded from 82.06 points) as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year. We are no longer required by section 1848(q)(6)(D)(iv) of the Act [501] to methodically increase the performance threshold each year to ''ensure a gradual and incremental transition'' to the expected performance threshold. Instead, we are establishing that the performance threshold for the CY 2024 performance period/2026 MIPS payment year is 75 points, using the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. We are codifying this performance threshold of 75 points for the 2026 MIPS payment year, based on the 2019 MIPS payment year, at § 414.1405(b)(9)(iii).

We note that since we anticipate clinicians' scores to increase as they gain more experience in MIPS, the performance threshold may increase in future years based on the selected mean or median. We also strive to foster continuous improvement within MIPS.

[501] Section 1848(q)(6)(D)(iv) of the Act is a special rule applicable to establishing the performance threshold for the third, fourth, and fifth years of MIPS. As we are entering the eighth year of MIPS, the requirements of section 1848(q)(6)(D)(iv) of the Act no longer apply.

(3) Example of Adjustment Factors

Figure 1 provides an illustrative example of how various final scores will be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2024 performance period/2026 MIPS payment year. In Figure 1, the performance threshold is set at 75 points, as we finalized in section IV.A.4.h.(2)(c) of this final rule.

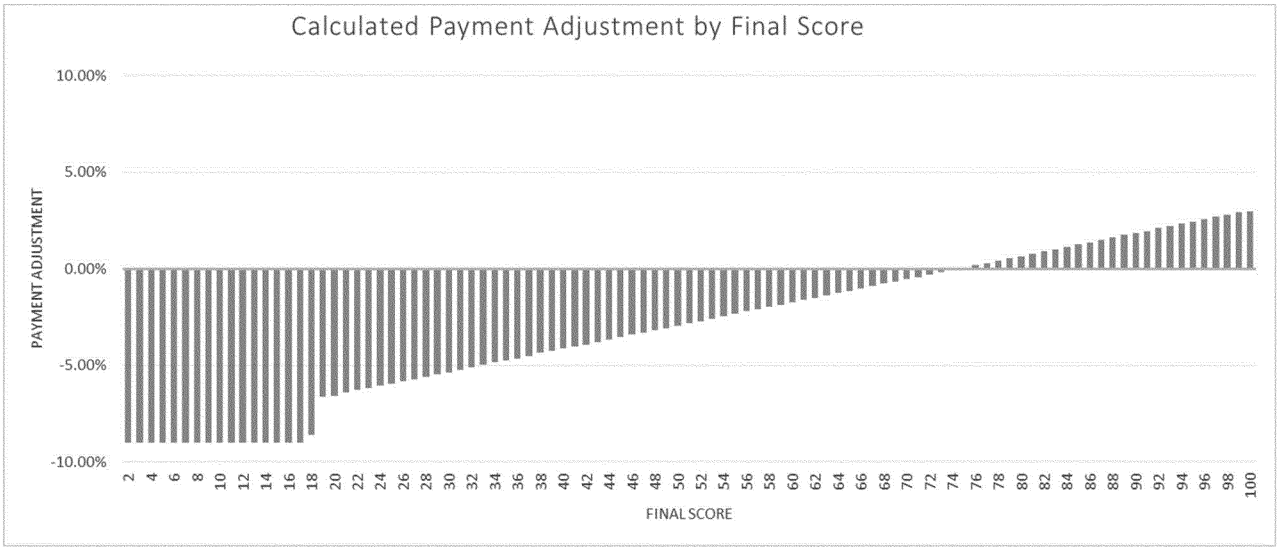
For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2024 performance period/2026 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment.

However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the performance threshold of 75 points for the CY 2024 performance period/2026 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (the performance threshold for the CY 2024 performance period/2026 MIPS payment year) will receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 1 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2024 performance period/2026 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 60 illustrates the changes in payment adjustment based on the final policies from the CY 2023 PFS final rule (87 FR 70096 through 70103) for the CY 2023 performance period/2025 MIPS payment year and the finalized policies for the CY 2024 performance period/ 2026 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 60: Illustration of Point System and Associated Adjustments Comparison between the CY 2023 Performance Period/2025 MIPS Payment Year and the CY 2024 Performance Period/2026 MIPS Payment Year

2023 Performance Period		2024 Performance Period	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 86.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

g. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; and for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022. Feedback for the CY 2022 performance period/2024 MIPS payment year was made available on August 10, 2023. We direct readers to *qpp.cms.gov* for more information.

K. Targeted Review

a. Background

Section 1848(q)(13)(A) of the Act requires that the Secretary establish a process under which a MIPS eligible clinician may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to the MIPS eligible clinician. In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we finalized a targeted review process and related requirements under MIPS wherein a MIPS eligible clinician or group may request a review of the calculation of the MIPS payment adjustment factor and, as applicable, the calculation of the additional MIPS payment adjustment factor applicable to such MIPS eligible clinician or group for a year. Currently, MIPS eligible clinicians, groups, and Alternative Payment Model (APM) entities may request and receive targeted review of our calculation of their MIPS payment adjustment factor(s) under our established process and related requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77546), we codified the MIPS targeted review process and related requirements at § 414.1385(a).

In the CY 2020 PFS final rule (84 FR 63045 through 63049), we revised the MIPS targeted review process and related requirements to address persons eligible to request targeted review, timeline for submission of targeted review requests, denial of targeted review requests, our requests for additional information, notification of targeted review decisions, and scoring recalculations. We codified these revisions to the targeted review process and related requirements at § 414.1385(a) (84 FR 63197 through 63198).

Currently, as specified at § 414.1385(a)(2), we provide that all requests for targeted review must be submitted within a 60-day period, beginning on the day that we make available the MIPS payment adjustment factors for the MIPS payment year applicable to each MIPS eligible clinician. In addition, § 414.1385(a)(2) provides that we may extend the targeted review request submission period. However, this current submission period for MIPS targeted review presents significant challenges to CMS as we seek to implement application of a differentially higher PFS conversion factor for eligible clinicians who are Qualifying APM Participants (QPs) for a year beginning with the CY 2024 QP Performance period/2026 payment year, as required by section 1848(d)(1)(A) of the Act.

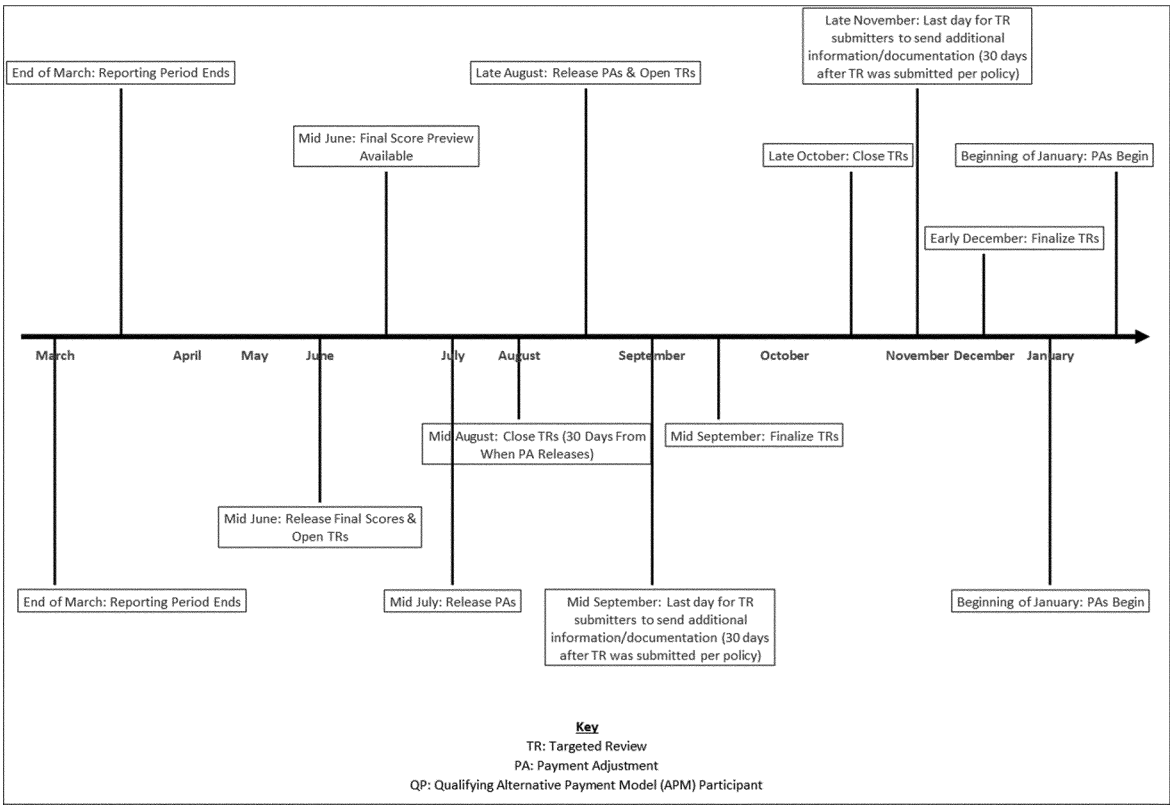
Specifically, to ensure application of the alternative conversion factor for eligible clinicians who are QPs, we must submit the final list of QPs to our Medicare Administrative Contractors no later than October 1st of the preceding year. However, under our current targeted review timeline for MIPS, this information would not be available until the first week of December. This is because the targeted review request submission period begins upon notification of the MIPS payment adjustment factors, which takes place sometime in August, and ends 60 days later, sometime in November. While QPs are excluded from MIPS reporting and any MIPS payment adjustment, we have received and addressed several requests for targeted review based on a clinician disputing whether they should be designated as a QP or a MIPS eligible clinician for purposes of payment under the Quality Payment Program. Based on our experience, we have found that more often than not a MIPS eligible clinician was initially identified as a QP but did not in fact participate in an Advanced APM and, conversely, a MIPS eligible clinician who believes they had achieved QP status was not identified as such. The targeted review process allows for clinicians to bring these issues to our attention. Accordingly, the targeted review process is essential to compiling an accurate list of QPs, which is necessary for purposes of determining who receives the application of the higher PFS conversion factor (also known as ''qualifying APM conversion factor'') of 0.75 percent (versus non-QPs, who receive 0.25 percent).

Section 1848(q)(13)(A) of the Act does not specify a timeframe for targeted review, broadly requiring that we ''establish a process'' for informal review of our calculation of the MIPS adjustment factor. Section 1848(q)(13)(A) of the Act only requires that the targeted review process permit a MIPS eligible clinician to seek ''informal review of the calculation of the MIPS adjustment factor (or factors)'' applicable to the MIPS eligible clinician for a MIPS payment year. We believe this broad authority for establishing this targeted review process, and lack of specificity as to any timeframe required for such process, permits CMS to determine a reasonable time period for submission of a request for targeted review so long as a MIPS eligible clinician can submit a request after we have informed them of our calculation of their MIPS adjustment factor(s).

Therefore, we proposed to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year (88 FR 52601 through 52603). This proposal will allow for a total of approximately 60 days for the targeted review submission period (approximately 30 days before publication of the MIPS payment adjustments factors and 30 days thereafter). We believe this proposal provides us with the necessary time to adjudicate the targeted reviews and finalize the QP status list by October 1st. If finalized, we proposed to codify this modification to this policy at § 414.1385(a)(2).

In Figure 2, we illustrate our proposed change to the timeline of the targeted review. The text above the timeline reflects the current process for targeted review while the text below the timeline reflects the proposed process in Figure 2.

FIGURE 2: Current and Proposed Targeted Review Process



To further shorten the timeline of the targeted review process for the reasons outlined above, we also proposed to amend § 414.1385(a)(5) (88 FR 52601 through 52603). Specifically, we proposed to require that, if CMS requests additional information under the targeted review process, that the additional information must be provided to and received by CMS within 15 days of receipt of such request. This proposal will modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt.

In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we implemented a virtual groups participation option under MIPS. Since virtual groups are eligible to submit data to the MIPS program, we proposed to add virtual groups as being eligible to submit a request for targeted review (88 FR 52603). Finally, as discussed in section IV.A.4.d of the proposed rule, we also proposed to add subgroups as being eligible to submit a request for targeted review. We proposed to codify these additions at § 414.1385(a).

We invited public comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to allow virtual groups and subgroups to request a targeted review.

Response: We thank commenters for supporting our proposal to allow virtual groups and subgroups to request a targeted review.

Comment: Commenters opposed the shortened time for practices to review their payment adjustment information prior to the closing of the targeted review submission period. Most commenters urged CMS to preserve the 60-day targeted review period that allows for a minimum of 60-days after payment adjustments are released, noting that clinicians need sufficient time to fully evaluate their final MIPS scores and see how their adjustments may play out before requesting targeted review. Some commenters also opposed reducing the timeframe for clinicians to respond to CMS requests for additional information from 30 to 15 days, noting their concern that this does not allow enough response time for providers to review and gather the required information.

Response: We thank commenters for their feedback and understand the burdens MIPS eligible clinicians may face given the adjustments to the targeted review submission timeframe. In evaluating our options for implementing these operationally necessary adjustments to the targeted review submission timeframe, we considered the complexity of implementation, clinician burden, and ability to communicate this change clearly and effectively. While the proposed targeted review submission timeframe shortens the time in which a MIPS eligible clinician may request targeted review of a payment adjustment *after* receipt of their payment adjustment factors, it does not substantively shorten the total time for MIPS eligible clinicians to request targeted review, which will remain at 60 days. At this point in time, the targeted review process is sufficiently mature in that MIPS eligible clinicians are familiar with scoring, performance feedback, and the targeted review process to account for the proposed adjustments to the targeted review submission timeline.

We understand that MIPS eligible clinicians prefer to have their payment adjustment factors at the start of the targeted review submission timeframe. However, under our proposal, MIPS eligible clinicians may begin to request targeted reviews related to various elements essential to our final calculation of the MIPS payment

adjustment factors, such as their status as MIPS eligible clinicians versus QPs or Partial QPs, their scores on performance categories and their final scores, prior to the release of payment adjustment factors. We believe that starting the targeted review submission period with release of MIPS final scores provides sufficient notice of key information for the MIPS eligible clinician to evaluate whether they would like to request targeted review. As provided in section 1848(q)(6) of the Act and § 414.1405, the MIPS eligible clinician's final score, as compared to the established performance threshold for that MIPS payment year, generally indicates whether the MIPS eligible clinician will receive a positive, neutral, or negative payment adjustment.

Finally, to ease the burden associated with the adjustments to the submission timeline, CMS will ensure adequate, timely and clear communications with eligible clinicians and stakeholders.

Comment: One commenter asked CMS to clarify when CMS intends to release the MIPS final score and performance feedback reports.

Response: We expect to release MIPS final scores in early June, which, under our proposal, will correlate with the start of the targeted review submission timeframe. Currently, performance feedback reports will be released, along with the issuance of the MIPS payment adjustment factors, approximately 30 days after the release of the MIPS final scores. While we appreciate that MIPS eligible clinicians may benefit from reviewing their performance feedback reports before deciding whether to request targeted review, we believe 30 days should be sufficient time for such review before the targeted review submission period ends. We will continue to explore options to provide performance feedback reports as early in the process as is operationally feasible to do so.

Comment: One commenter noted their support for the proposed adjustment to the targeted review submission timeline so long as CMS can ensure clearer cost measure specifications and cost measure performance feedback reports, preferably at the time that MIPS final scores are released. The commenter noted that this information is essential to understanding the context of their final score. The commenter also requested that CMS consider extending the targeted review submission timeframe for eligible clinicians impacted by multiple promoting interoperability (PI) submissions to allow them to receive the PI category score from the highest scored collection type as required under CMS-finalized policy and to allow those who submitted a performance year 2022 targeted review due to this issue and were denied appropriate PI scoring to resubmit the targeted review.

Response: There are operational and budgetary constraints that limit our ability to issue these performance feedback reports earlier. However, we continue to explore options for providing more frequent and useful cost measure feedback data that MIPS eligible clinicians can use to analyze practice patterns that could lead to improved performance and would allow eligible clinicians to react during the performance period. As previously discussed in this section of the final rule, due to operational constraints, we cannot re-open or extend the targeted review submission timeline as requested. As stated in the regulation at § 414.1385(a)(7), ''Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.''

After consideration of public comments, we are finalizing our proposal with minor technical corrections to modify § 414.1385(a) to allow virtual groups and subgroups to request a targeted review. We refer readers to section IV.A.4.d of this final rule regarding our discussion of allowing subgroups to request targeted review.

We are also finalizing our proposal to adjust the targeted review submission timeframe to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year and to require that, if CMS requests additional information under the targeted review process, that the additional information must be provided to and received by CMS within 15 days of receipt of such request. We are revising the regulation text with minor technical corrections at § 414.1385(a)(2) and (5) to reflect this change.

k. Third Party Intermediaries General Requirements

(1) Codification of Previously Finalized Policy From Preamble

A third party intermediary is an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the Quality, Improvement Activities, and Promoting Interoperability performance categories (§ 414.1305). Many of the policies that apply to third party intermediaries were finalized through prior rulemaking, but not codified in the CFR. Among other things, this has made it challenging for third party intermediaries to track certain program requirements and has caused confusion for MIPS participants and third party intermediaries.

We have reviewed the previously finalized language and identified policies that we believe should be codified for these reasons. We describe these proposals and provide background throughout this section.

(2) General Requirements

(a) Background

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), the CY 2022 PFS final rule (86 FR 65538 through 65550), and the CY 2023 PFS final rule (87 70102 FR through 70109) for our previously established policies regarding third party intermediaries. Where we proposed to codify existing final policy, we incorporated the rationale described in these prior rules by reference.

In the proposed rule, in addition to codifying previously finalized policies and making technical updates for clarity, we proposed to: (1) Add requirements for third party intermediaries to obtain documentation; (2) Specify the use of a simplified self-nomination process for existing qualified clinical data registries (QCDRs) and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting; (6) Specify requirements for a transition plan for QCDRs and qualified registries; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add

failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify CMS's authority to terminate third party intermediaries that are on remedial action for 2 consecutive years; (14) Specify the process for publicly posting remedial action; and (15) Specify the criteria for audits (88 FR 52603 through 52610).

(b) Requirement To Obtain Documentation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 and 77385), we established requirements that QCDRs and qualified registries obtain signed documentation from clinicians and groups regarding their authority to handle and submit data on the clinician and group's behalf. We established that QCDRs and qualified registries must enter into appropriate Business Associate Agreements with MIPS eligible clinicians. QCDRs and qualified registries must obtain signed documentation that each holder of a national provider identifier (NPI) has authorized the third party intermediary to submit ''quality measure results, improvement activities measure and activity results, advancing care information objective results and numerator and denominator data or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation.'' The documentation should be annually obtained at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry. A group, subgroup, Virtual Group, or APM Entity may have their authorized representative give permission to the third party intermediary to submit their data. Additionally, in the CY 2018 Quality Payment Program final rule (82 FR 53812), we clarified that Business Associate Agreements must comply with the HIPAA Privacy and Security Rules. Records of the authorization must be maintained for 6 years after the performance period ends (81 FR 77370). We proposed to codify these requirements at § 414.1400(b)(3)(xii) and (xiii) (88 FR 52603).

We invited comments on this proposal.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed concern that a requirement for individual signatories for virtual group reporting creates unnecessary administrative burden and suggested that CMS should instead allow for documentation of submission authority for virtual groups to occur at either the TIN or clinician level.

Response: If data is reported at a group level, the practice admin can sign for the group. A direct signature from an individual clinician is only required if the individual clinician's data is reported to CMS as an individual.

After consideration of public comments, we are finalizing as proposed our proposal at § 414.1400(b)(3)(xii) and (xiii) to codify that QCDRs and qualified registries must enter into appropriate Business Associate Agreements with MIPS eligible clinicians and that they must maintain records of their authorization to submit data to CMS for the purpose of MIPS participation for each NPI whom they submit data to CMS for. The records must be annually obtained, be signed by an eligible clinician or by an authorized representative of the reporting group, and records of the authorization must be maintained for 6 years after the performance period ends.

(c) Requirement To Report in Form and Manner Specified

(i) Criteria for Data Submission

At § 414.1400(a)(2)(C), we required that all data submitted by a third party intermediary must be submitted in the form and manner specified by CMS. We specified that these requirements include the obligation for a third party intermediary to: (1) report the number of eligible instances (reporting denominator); (2) report the number of instances a quality service is performed (performance numerator); (3) report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification; (4) comply with a CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file; (5) be able to calculate and submit measure-level reporting rates or the data elements needed to calculate the reporting and performance rates by taxpayer identification number (TIN)/NPI and/or TIN; (6) be able to calculate and submit a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI or TIN reports; (7) provide the performance period start date the QCDR will cover; (8) provide the performance period end date the QCDR will cover; (9) report the number of reported instances, performance not met, meaning the quality actions was not performed for no valid reason as defined by the measure specification; and (10) submit quality, advancing care information, or improvement activities data and results to us in the applicable MIPS performance categories for which the QCDR is providing data (81 FR 77367 through 77369 and 77384 through 77385). These criteria for data submission are technical requirements of functioning QCDRs and qualified registries.

(ii) Reporting on All Patients, Including Non-Medicare Patients

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries are required to submit data on all patients, not just Medicare patients. In section IV.A.4.f.(1)(b) of the proposed rule, we proposed a revision to the definition of the term collection type to allow Shared Saving Program ACOs meeting the reporting requirements under the APP to report on a subset of patients that is partially defined by having the payer of Medicare (88 FR 52563). We proposed to codify our previously established requirement that data submitted by third party intermediaries must include data on all of the MIPS eligible clinician's patients regardless of payer, with the addition of the phrase ''unless otherwise specified by the collection type'' at § 414.1400(a)(3)(ii)(A) (88 FR 52604). We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(3) Requirements for QCDRs and Qualified Registries

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(B)(ii) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of certified EHR technology (CEHRT) and qualified clinical data registries.

We referred readers to § 414.1400(b)(4), the CY 2017 Quality

Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

As described at § 414.1305, a qualified registry is a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

We referred readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77382 and 77386), the CY 2018 Quality Payment Program final rule (82 FR 53815 and 53818), the CY 2019 PFS final rule (83 FR 59906), the CY 2020 PFS final rule (84 FR 63074 through 63077), the CY 2021 PFS final rule (85 FR 84944 through 84947), and the CY 2022 PFS final rule (86 FR 65539 through 65548) for previously finalized standards and criteria for qualified registries.

(b) Self-Nomination and Program Requirements

(i) Subgroup Reporting

In the CY 2022 Quality Payment Program final rule (86 FR 65544), we established the requirement that third party intermediaries must support subgroup reporting beginning with the CY 2023 performance period/2025 MIPS payment year. This requirement that third party intermediaries support subgroup reporting was finalized because it would allow for clinicians to meaningfully report MIPS Value Pathways (MVPs) given that subgroups will be implemented concurrently with MVPs. We proposed to add new language to codify this policy. We proposed to revise § 414.1400(b)(1)(iii) that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support subgroup reporting (88 FR 52604).

We invited comments on this proposal.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter suggested that third party intermediaries should only be required to support subgroups if they are reporting on MVPs since subgroups can only report through MVPs.

Response: We have announced our intention to eventually make MVP reporting mandatory (although an official start date has not been proposed yet), and therefore, believe that subgroup reporting will be an integral part of reporting in the future.

After consideration of public comments, we are finalizing our proposal as proposed at § 414.1400(b)(1)(iii) to codify that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support subgroup reporting.

(ii) Simplified Self-Nomination Process for Existing QCDRs and Qualified Registries in MIPS, That Are in Good Standing

In the CY 2018 Quality Payment Program final rule (82 FR 53811 through 53812 and 53817 through 53818), we established that beginning with the CY 2019 performance period/2021 MIPS payment year, QCDRs and qualified registries in good standing (that is, QCDRs and qualified registries that are not on probation or disqualified) (81 FR 77386 through 77389) that ''wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable'' (see also § 414.1400(b)(2)). When this is the case, third party intermediaries may use the simplified process. The goal of the simplified self-nomination form is to reduce the self-nomination burden for third party intermediaries in good standing by allowing them to self-nominate with a mostly pre-populated self-nomination form. The policy allows third party intermediaries to attest that sections of their application have no changes even if there are minimal changes or substantive changes in other parts of their application. An example of a minimal change is adding or removing MIPS quality measures. An example of a substantive change is the submission of new QCDR measures for consideration. For sections of an application that do require changes, the requirements are the same as those for the normal self-nomination process (82 FR 53808).

In the course of implementing this policy, we have learned that the text of § 414.1400(b)(2) has confused some third party intermediaries such that they have attested that their previously approved self-nomination form is still accurate and have not submitted self-nomination forms because they thought they did not need to do so if they had no changes. We proposed to revise § 414.1400(b)(2) to reflect that QCDRs and qualified registries are still required to submit their self-nomination form even if they utilize the simplified self-nomination process (88 FR 52604 through 52605). Even if a third party intermediary has no change to make to its form from the previous year, there may be new sections to fill out and they need to respond to attestations within the course of the application. We proposed to revise the last sentence of § 414.1400(b)(2) from ''For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period'' to state, ''For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the simplified self-nomination process during the self-nomination period, from July 1 and September 1 of the CY preceding the applicable performance period.'' This will ensure that third party intermediaries that have previously participated in MIPS and are in good standing can use the process to reduce the burden of self-nomination.

We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(iii) Measure Numbers and Identifiers and Titles for the Improvement Activity Performance Category, the Promoting Interoperability Performance Category, and MVPs

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must provide the measure numbers for the MIPS quality measures on which the QCDR and qualified registry is reporting. We proposed to codify this previously finalized provision at § 414.1400(b)(3)(ix). For completion and consistency, we also

need to receive identifiers for improvement activities, Promoting Interoperability, and titles for MVPs. This information is used to track which quality measures, improvement activities, Promoting Interoperability performance category measures and MVPs QCDRs and qualified registries support in a performance period. This information is available on the qualified postings that are published on the QPP Resource Library. We proposed that § 414.1400(b)(3)(ix) will additionally require QCDRs and qualified registries to submit to CMS the identifiers for the improvement activity performance category, the Promoting Interoperability performance category measures, and titles for MVPs (88 FR 52605).

We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(iv) Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that one criterion for data submission for QCDRs and qualified registries is that they must be able to submit results to CMS for at least six individual quality measures with at least one outcome measure during self-nomination. If an outcome measure is not available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure. We proposed to codify this previously finalized provision at § 414.1400(b)(3)(x) (88 FR 52605).

We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(v) Qualified Posting Attestation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must sign a document that verifies their ''name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report.'' As technology has progressed, we no longer need third party intermediaries to sign a document and instead require an attestation. We became aware that this requirement is not consistent with our established policy in describing the manner in which the QCDR or qualified registry documents this information. In order to align with current processes, we proposed to add § 414.1400(b)(3)(xiv), which would require that QCDRs and qualified registries attest that the information listed on the qualified posting is accurate. The qualified posting contains information to help clinicians, groups, subgroups, virtual groups, APM Entities determine the services, cost, reporting options, measures/activities, etc. that a CMS-approved intermediary supports. We publish it every performance period and update it, as needed. While we have used the term qualified posting since the inception of the Quality Payment Program, we have not previously defined this term, and therefore, we proposed to define qualified posting as the document made available by CMS that lists QCDRs or qualified registries available for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities at § 414.1305.

We invited comments on these proposals.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(vi) Data Access Capabilities

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS. We proposed to codify this previously finalized provision at § 414.1400(b)(3)(xv) (88 FR 52605).

We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(vii) Attestation of Data Access Capabilities

As was previously described, the CY 2017 Quality Payment Program rule finalized the requirement for third party intermediaries to comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS reporting requirements (81 FR 77367 through 77369 and 77384 through 77385). However, it did not require third party intermediaries to attest to their capabilities. Attestation during the self-nomination period emphasizes the importance of this capability for third party intermediaries even if the capability is not ultimately utilized later. We proposed to add § 414.1400(b)(3)(xvi)(A) to require that a QCDR or a qualified registry attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry (88 FR 52605). We also proposed to add § 414.1400(b)(3)(xvi)(B) to require that a QCDR or a qualified registry must attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in § 414.1400(b)(3)(xvi)(A) to CMS upon request to ensure that data can be accessed by the third party intermediary for auditing purposes. We have received correspondence from some third party intermediaries, stating that they do not have access to the data and depend on clinicians to do the audit (88 FR 52605).

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to consider the financial and administrative burden of requiring a QCDR or a qualified registry to attest that is has required each MIPS eligible clinician to permit the QCDR or qualitied registry to provide the information requested to CMS, and to provide resources QCDRs would need to implement the requirement.

Response: Existing policy already requires third party intermediaries comply with CMS requests to review data (81 FR 77367 through 77369 and 77384 through 77385). Attesting to the ability to require clinicians to provide documentation necessary to verify the accuracy of data submitted and to be able to submit that documentation to CMS should not be viewed as broadening the scope of this requirement as it would be a logical component of an audit. Therefore, we consider this to be a baseline requirement and not overly burdensome. CMS's ability to access the underlying documentation to verify the accuracy of the data submitted by clinicians is critical to ensuring that all data submitted is true, accurate, and complete.

Comment: One commenter suggested that the language be modified to require third party intermediaries to attest that they have access to the data to clarify that intermediaries are not expected to maintain all data necessary for an audit at all times.

Response: This requirement does not detail how intermediaries maintain the data but rather that the third party intermediary provide the documentation when CMS requests it.

After consideration of public comments, we are finalizing our

proposal as proposed at § 414.1400(b)(3)(xvi) that a QCDR or a qualified registry must attest that it has required each MIPS eligible clinician on whose behalf it reports to provide all documentation necessary to verify the accuracy of the data the eligible clinician submitted to the QCDR or qualified registry. Additionally, a QCDR or qualified registry must also attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in paragraph 414.1400(b)(3)(xviii)(A) to CMS upon request.

(viii) Third Party Intermediary Support of MVPs

In the CY 2022 PFS final rule (86 FR 65543), we finalized a new requirement at § 414.1400(b)(1)(ii) that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. This proposal was finalized because MVPs are beginning to be implemented in the CY 2023 performance period/2025 MIPS payment year, and third party intermediaries have the necessary experience reporting data to support MVP reporting.

To further clarify this finalized policy, we responded to a comment in the CY 2022 PFS final rule (86 FR 65543) by explaining that third party intermediaries who support MVPs are required to ''support all measures and activities available in the MVP across the quality, improvement activities, and Promoting Interoperability performance categories. The exceptions to this requirement are the cost measures and population health measures . . . [and] QCDR measures, which are only reportable through a QCDR. In instances where QCDR measures are included in an MVP, a qualified registry or health IT vendor will be expected to support all other quality measures included within the MVP.'' Some interested parties have expressed concern regarding this requirement as many MVPs include measures that may be reported by clinicians across multiple specialties, some of whom might be outside their intended customer base. We are concerned that continuing this strict requirement for MVP support could undermine adoption during the time in which MVP submission is an option under MIPS. Given that many third party intermediaries may not support measures for clinicians in all specialty areas that might report a MVP, we proposed to add a sentence at the end of § 414.1400(b)(1)(ii) that a QCDR or a qualified registry is required to support MVPs pertinent to the specialties they support (88 FR 52605 through 52606). The addition states that a QCDRs or a qualified registry must support all measures and improvement activities available in the MVP with two exceptions. The first exception to this requirement at § 414.1400(b)(1)(ii)(A) is that if an MVP includes several specialties, then a QCDR or a qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians. For example, if an orthopedic care MVP includes both surgery and physical therapy measures, and the third party intermediary caters specifically to physical therapists, they are not required to support the surgical measures. The second exception at § 414.1400(b)(1)(ii)(B) is that QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR does not own the QCDR measures in the MVP, the QCDR may only support the QCDR measures if they have the appropriate permissions.

We received public comments on these proposals. The following is a summary of the comments our responses.

Comment: Several commenters supported the proposed exception that if an MVP includes several specialties, then a QCDR or a qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians. One commenter appreciated the agency's recognition that there may be operational barriers to reporting all measures within an MVP that span multiple specialties indicating that a QCDR or qualified registry may not have access to all the necessary data, urging the agency to provide sufficient flexibility to registries when determining the precise scope of a specialty. A few commenters supported the proposed exception that QCDR measures are only required to be reported by the QCDR measure owner and in instances where a QCDR does not own the QCDR measures in the MVP, the QCDR may only support those QCDR measures with the appropriate permissions.

Response: We thank the commenters for their support.

Comment: One commenter warned that incorporating QCDR measures into MVPs and restricting their availability puts some practices at a disadvantage if they cannot afford to pay the fees associated with the QCDR registration.

Response: A QCDR measure incorporated into an MVP is not required to be reported on by an MVP participant or supported by QCDRs who are not the owners of the QCDR measures in the MVP. To the extent possible with the existing MIPS quality measure inventory, we aim to construct MVPs that include MIPS quality measures which are broadly available for as many clinicians as possible.

Comment: One commenter urged CMS to consider adding an exception for the requirement that QCDRs or qualified registries support all measures and activities within an MVP in situations in which the care setting associated with the measure or activity does not apply to the participants of the QCDR or qualified registry. One commenter requested CMS clarify that third party intermediaries are only expected to support the categories that are pertinent to the specialty of their clinicians (such as not supporting Promoting Interoperability in traditional MIPS if the clinicians are exempt).

Response: We are uncertain of an organized method to incorporate care setting location into the assessment of whether a QCDR or qualified registry is able to support all measures and activities within an MVP outside of measure specifications that are already included. In regards to the requirements to report the Promoting Interoperability performance category in situations in which the specialty supported is not subject to that performance category, we note that § 414.1400(b)(1)(i)(C) does allow for approval of a self-nomination of a QCDR or qualified registry that does not support the Promoting Interoperability performance category if the third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*), or (c)(2)(i)(C)(*1*) through (*7*), or (c)(2)(i)(C)(*9*)

Comment: One commenter requested broadening of the exclusion for situations that may be beyond the control of the qualified registry that would limit their ability to collect a measure, such as the timing of the receipt of pharmacy claims in measures that may incorporate this data.

Response: The intent of the policy is to recognize that the MVP area of focus may not align in its entirety with the focus of a third party intermediary which we understand often focus ozn a clinician specialty. We will continue to evaluate the environment to ensure clinicians have access to third party intermediaries while balancing the need to ensure that most clinicians are able

to report as many measures on MVPs as possible.

After consideration of public comments, we are finalizing at § 414.1400(b)(1)(ii) our proposal to clarify that that a QCDR or a qualified registry must support all measures and activities included in the MVP except if an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinician or if an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

(ix) Readiness To Accept Data

In the CY 2019 PFS final rule (83 FR 59761), we established that a QCDR or a qualified registry must be up and running by January 1st of the performance period so that they can accept and retain clinician data starting on January 1st. We proposed to codify at § 414.1400(b)(3)(xvii) the requirement that a QCDR or a qualified registry must be able to accept and retain data by January 1 of the applicable performance period (88 FR 52606).

We invited comments on this proposal.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(x) Duration of Services Provided

In the CY 2020 PFS final rule (84 FR 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(E) that the organization must provide services throughout the entire performance period and applicable data submission period. In section IV.A.4.k.(3)(b)(xi) of the proposed rule, we outlined the requirements for a transition plan for cases in which organizations are not able to provide services throughout the entire year. While we recognize and allow for cases in which organizations may find themselves unable to provide services throughout the course of an entire year, we would require that they indicate their intent to do so as part of program requirements. We proposed to modify this requirement to state the organization must certify it intends to provide services throughout the entire performance period and applicable data submission period (88 FR 52606). We proposed to make this change at § 414.1400(a)(2)(i)(C) as a result of our proposal to divide requirements for self-nomination from programmatic requirements as outlined in section IV.A.4.k.(7) of the proposed rule.

We invited comments on these proposals.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(xi) Transition Plan Requirements

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(F) that prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan. As part of an overall effort to divide self-nomination requirements from program requirements as discussed in section IV.A.4.k.(7) of the proposed rule, at § 414.1400, we proposed to redesignate and revise paragraph (a)(2)(i)(F) to paragraph (a)(3)(iv) that, prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS. We proposed to specify the contents required in the transition plan in paragraphs (a)(3)(iv)(A) through (E) (88 FR 52606). We proposed to add § 414.1400(a)(3)(iv)(A) to require that the transition plan state the issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period. We also proposed to add § 414.1400(a)(3)(iv)(B), which will require that the transition plan state the number of clinicians, groups, virtual groups, subgroups or APM entities inclusive of MIPS eligible, opt-in and voluntary participants that will need to find another way to report and as applicable, and identify any QCDRs that were granted licenses to QCDR measures which will no longer be available for reporting due to the transition. We further proposed to add paragraph (a)(3)(iv)(C) to state the steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in § 414.1400(a)(3)(iv)(B)(*1*) are notified of the transition in a timely manner and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable. At paragraph (a)(3)(iv)(D), we proposed to require that the transition plan include a detailed timeline of when the third party intermediary will take the steps identified in paragraph (a)(3)(iv)(C), including notification of affected clinicians, groups, virtual groups, subgroups, or APM Entities, the start of the transition, and the completion of the transition. Finally, we proposed to add at paragraph (a)(3)(iv)(E) that the third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline. The proposals would enable CMS to have documentation of the steps, actions, tasks, and timeline for completion of the transition of clients.

We invited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments our responses.

Comment: One commenter supported the proposal for a transition plan for QCDRs and qualified registries withdrawing from the program indicating this would help share the responsibility of clinician support, increase the speed and cooperation for data transfer, and ensure that all pertinent agreements and compliances are in place.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS specify how much time is permissible for a completed transition plan indicating that a minimum of 90-business days would allow a QCDR to complete the requirements, with a longer timeline approved by CMS depending on the size of the QCDR.

Response: The transition plan should be developed with the intent to cause as little disruption as possible to the clinicians participating with their third party intermediary. While we required a timeline within the transition plan, we did not include a specific timeframe for a completed transition plan.

Comment: One commenter recommended that CMS enable other QCDRs in the program be notified immediately upon CMS receiving the resignation notice, as well as the reasoning as this would allow participating QCDRs to anticipate and

accept those clinicians, especially if it is past their last day to accept new clients via the qualified posting deadline.

Response: We do update the qualified posting each month if a QCDR or Qualified Registry is terminated from the program or placed on remedial action. Third party intermediaries are encouraged to periodically review the updated qualified postings for this information.

After consideration of public comments, we are finalizing our proposal as proposed.

(c) Submission Requirements

(i) Risk-Adjusted Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77384 through 77385), we established that qualified registries ''submitting MIPS quality measures that are risk-adjusted . . . must submit the risk-adjusted measure results to CMS when submitting the data for these measures'' (88 FR 52606). We proposed to codify this previously finalized provision at § 414.1400(b)(3)(xi).

We did not receive public comments on this provision, and therefore, we are finalizing it as proposed.

(ii) Data Validation Audit Requirements

Section 414.1400(b)(3)(v) outlines the requirements for third party intermediary's annual data validation audits. As specified at paragraph (b)(3)(v)(E), the QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements: (1) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR or qualified registry may use a sample size of 50 TIN/NPIs. (2) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients. We finalized this policy (81 FR 77366 through 77367) to reflect the number of reporting entities, which may be individuals, as represented by TIN/NPIs, but are often compositions of TIN/NPIs as represented by groups, subgroups, or APM entities. Since these compositions represent a single unit of measurement, we believe that they should be considered as a single unit.

We have received questions about the required sampling methodology from interested parties who are confused by the references to TIN/NPI in the context of sample size and how they map to individual MIPS eligible clinicians, groups, virtual groups, subgroups or APM Entities. To reduce confusion among third party intermediaries regarding the data validation audit sample, we proposed to revise § 414.1400(b)(3)(v)(E)(*1*) and (*2*) to replace references to TIN/NPI with ''a combination of individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM Entities'' (88 FR 52607). The new text would state: (1) Uses a sample size of at least 3 percent of a combination of individual clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that if the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities, the QCDR or qualified registry may use a sample size of a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities; and (2) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

We invited comments on this proposal.

We received public comments on the proposal. The following is a summary of the comments and our responses.

Comment: One commenter supported the revision of wording to replace references to TIN/NPI but noted concern that the proposed wording of ''a combination of individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM Entities'' will make the regulation difficult to read and is confusing. The commenter suggested using the term ''submitter type'' defined in § 414.1305 instead. In addition, the commenter suggested removing the word ''may'' from the statement indicating sample size reading ''the QCDR or qualified registry may use a sample size of . . . 50'' stating the use of the word ''may'' means the QCDR or Qualified Registry may submit 50 but also more than 50.

Response: We appreciate the commenter's suggestion; however, we fear that acting on this suggestion would only cause more confusion. The term ''submitter type'' is not limited to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM entities. The term also includes third party intermediaries, which are not intended to be covered by this requirement. We note that the use of the term ''may'' is correctly interpreted by the commenter as we do not mandate a maximum sample size. We will monitor service center feedback to ensure that this policy is well understood by representatives from third party intermediaries, but do not believe we should change this terminology at this time.

After consideration of public comments, we are finalizing our proposal at § 414.1400(b)(3)(v)(E)(*1*) and (*2*) to modify the description of sample size as proposed.

(4) Requirements Specific to QCDRs

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(ii)(B) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of CEHRT and qualified clinical data registries.

We referred readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

(b) QCDR Measure Self-Nomination Requirements

(i) New QCDR Measures May Not Be Submitted After Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures

as part of the self-nomination process for an entity to become a QCDR. In the CY 2018 Quality Payment Program final rule (82 FR 53808), we established a process by which existing QCDRs that are in good standing could attest that certain aspects of their previous year's approved self-nomination have not changed. We intended for the self-nomination document to be comprehensive in terms of which QCDR measures would be submitted for consideration. However, we have received requests to add measures following the completion of the QCDR self-nomination process for the performance year. Our review process requires consideration of a complete self-nomination with all measures, so we proposed to add that the measure was submitted after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O) (88 FR 52607).

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed the proposal and stated their belief that it would discourage the development of new measures and potentially slow participation of QCDRs.

Response: It does not logically follow that establishing a deadline for the submission of measures as part of the self-nomination process would hamper the development or use of QCDRs in MIPS. As a practical matter, there is a point at which we can no longer accept the submission of measures in order for us to review a QCDR's complete application. QCDRs have generally met these requirements in the past, and adoption of this proposal would merely clarify for a QCDR what it must include at the time of its self-nomination.

Comment: A few commenters requested that CMS clarify whether all measures submitted after September 1 will be rejected for the reporting period or if only newly developed measures would be rejected. One commenter expressed concern that this may lead to the rejection of measures previously approved for use.

Response: A QCDR or Qualified Registry can add a MIPS quality measures after the September self-nomination deadline. CMS allows third party intermediaries to support additional MIPS quality measures until early May of the performance period and this date is communicated to third party intermediaries during monthly support calls for the given performance period. However, neither a new QCDR measure nor a previously approved QCDR measure that was not included in the third party intermediary's self-nomination can be accepted after the close of the self-nomination period on September 1st. Each QCDR measure that is self-nominated is evaluated and approved by CMS for its appropriateness and use in the MIPS program.

After consideration of public comments, we are finalizing our proposal to add that the measure was submitted after self-nomination closes to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O) as proposed.

(ii) Limitations on Number of QCDR Measures Submitted for Self-Nomination

In the CY 2017 Quality Payment Program final rule, we established at § 414.1400(b)(4)(i) that QCDRs must submit certain specifications for QCDR measures that would be considered for approval by CMS (81 FR 77374 through 77378). These measures would then be considered for approval or rejection under the requirements of § 414.1400(b)(4)(iii) and (iv). CMS reviews these measures carefully and each additional measure takes considerable time and effort to review. We have had experiences in which a single QCDR has submitted a large number of QCDR measures for consideration. While we are mindful that there may be a number of valid measure concepts, we are generally trying to focus measurement within the Quality Payment Program. In an effort to optimize resource allocation and encourage QCDRs to focus their submitted measures on those that have the highest value, we proposed to add at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration (88 FR 52607). We considered a lower limit given that clinicians in traditional MIPS are only required to report on 6 quality measures and clinicians reporting via MVPs may report even fewer. However, we recognize that some QCDRs serve more diverse clinical populations and could conceivably wish to submit this many as part of self-nominations. We noted that we would continue to evaluate individual measures on their merits as specified in our requirements at § 414.1400(b)(4)(iii) and (iv).

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration and suggested that it would reduce the likelihood of irrelevant measures being reported by a QCDR.

Response: We thank the commenter for their support.

Comment: A few commenters opposed our proposal and suggested that establishing this limit would not allow a QCDR to best report for all the subspecialty clinicians which report through that QCDR.

Response: We understand that some QCDRs serve diverse clinical populations and may wish to offer a large number of measure reporting opportunities to their clinicians. However, we also note that we are engaging in efforts such as the development of MVPs that would focus measures on those that are most relevant. We note that QCDRs have no limitation on the number of measures they report that are on the annual list of MIPS quality measures. Even a QCDR supporting diverse populations should have sufficient measures with this limit.

After consideration of public comments, we are finalizing our proposal at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration as proposed.

(iii) Requirements for Previous Data on QCDR Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77368), we established a requirement that for non-MIPS measures the QCDR must provide us, if available, data from years prior to the start of the performance period. We proposed to codify this previously finalized provision at § 414.1400(b)(4)(i)(C) (88 FR 52607 through 52608).

We did not receive public comments on this provision, and therefore, we are finalizing it as proposed.

(iv) Requirement for QCDR Measure Specifications To Remain Published Through the Performance Period and Data Submission Period

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77376), we established at § 414.1400(b)(4)(i)(B) that no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the QDCR must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS

with a link to where this information is posted. While we established when this posting was required, we did not establish a standard for the duration of this posting. We have become aware of situations in which QCDR measure owners have removed this documentation during the course of the performance period or before the closure of the submission period. We proposed to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period (88 FR 52608). Although it was not previously specified, it was our intention that this information be made available for the entirety of the time that the measure could be considered and reported by clinicians or groups as part of the Quality Payment Program. Measure specifications must be available throughout the duration of measure use for interested parties to understand the target population of the measure, how the measure is built and calculated, and to identify existing measure gaps. Clinicians may elect to begin collecting data at various times in the year and even if data collection has started, may need to consult specifications throughout the performance period to confirm that data collection is in concordance with the specifications. We stated that we believe this addition will prevent QCDRs from removing specifications following the initial required posting and increase transparency for participants. We also proposed to make a technical update to the language removing the reference to providing the NQF number due to changes in the contractor that CMS uses for measure endorsement (88 FR 52608).

We received public comments on the proposal. The following is a summary of the comments our responses.

Comment: One commenter opposed this proposal and suggested that it would discourage the development of new measures and potentially slow participation of QCDRs in MIPS.

Response: We note that this requirement merely specifies the length required before removal of a posted document. We believe that the specifications for a measure used in a public program should be publicly available while being used in that program. It is not clear how this proposal would discourage development of new measures or participation of QCDRs in the MIPS program.

After consideration of public comments, we are finalizing our proposal at § 414.1400(b)(4)(i)(B) that the approved QCDR measure specifications must remain published through the performance period and data submission period as proposed.

(5) Health IT Vendors

(a) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we established the category of health IT vendor in the Quality Payment Program, along with requirements for data submission. In the CY 2019 PFS final rule, we codified the definition of a health IT vendor as an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT) (83 FR 59907). In the CY 2022 PFS final rule (86 FR 65541), we finalized a reorganization of the regulatory text governing the third party intermediary section to improve clarity and readability. In that revised text, we established general requirements at § 414.1400(a), additional requirements for QCDRs and qualified registries at § 414.1400(b), and additional requirements for health IT vendors at § 414.1400(c).

(b) Proposal To Remove Health IT Vendor Category

In the CY 2021 PFS final rule, we established additional program safeguards regarding data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries. We noted (85 FR 84928 and 84929) that while we did not propose these additional requirements for health IT vendors, we had become aware of situations in which health IT vendors have submitted data that are inaccurate and unusable and that could result in improper payments or otherwise undercut the integrity of the MIPS program. In our review of comments in response to our solicitation on the future application of such requirements on health IT vendors, we observed that several commenters supported requirements for health IT vendors to perform data validation to align requirements with QCDRs and qualified registries and improve data integrity. We also observed that several commenters opposed additional data validation requirements for health IT vendors due to the associated cost, and that such a requirement would be duplicative of requirements of health IT vendors under the ONC regulatory framework.

Since the publication of the CY 2021 PFS final rule, we continue to have experiences with third party intermediaries submitting data that is inaccurate and unusable. We believe this necessitates a reconsideration of the lack of data validation requirements for health IT vendors in contrast to those requirements for QCDRs and qualified registries.

In the CY 2019 PFS final rule (83 FR 59747 through 59749), we established the definition of collection type, submitter type, and submission type. These definitions are intended to more precisely describe how data is collected and submitted for the Quality Payment Program. For the quality, Promoting Interoperability, and improvement activity performance categories, an approved third party intermediary may submit directly to the submissions application programming interface (API), or upload files via *qpp.cms.gov*. Historically, third party intermediaries are able to receive tokens by virtue of successful self-nomination as a QCDR or qualified registry or, for those technologies that use CEHRT, through a request to CMS.

In examining the different requirements for QCDRs and qualified registries and health IT vendors, we noted that the primary difference is the requirement for self-nomination at § 414.1400(b)(2) and requirements primarily related to data validation audits at § 414.1400(b)(3). We considered whether we should add a self-nomination requirement for health IT vendors or require data validation audits for health IT vendors or both. However, we noted that we believe that adding a self-nomination requirement or data validation audit requirements would essentially eliminate the difference between a health IT vendor and a qualified registry. We noted our observation that many vendors serve in capacities as qualified registries, QCDRs or health IT vendors with similar technology. Rather than establish identical or nearly identical requirements for different categories of vendors, we instead proposed to eliminate the health IT vendor category beginning with the CY 2025 performance period and by revising § 414.1400(a)(1)(iii) (88 FR 52608). Absent a self-nomination process for Health IT vendors, we do not believe we can establish a meaningful enforcement mechanism to ensure that the vendors are meeting the requirements as we have laid out.

We noted that our proposal to remove Health IT vendors from the definition of third party intermediary would not preclude the vendors from assisting MIPS eligible clinicians with reporting under the program. Instead, the vendors may still provide their technology for

clinicians to directly report under MIPS. We noted our belief that eliminating the category of Health IT vendor as a distinct type of third party intermediary will create a clearer distinction between those vendors that are submitting data to us for the purposes of MIPS and must meet the requirements of a qualified registry or QCDR and those vendors that work with clinicians through the sale and support of health IT that permits the clinician or group to submit the data.

We received public comments on the proposal. The following is a summary of the comments and our responses:

Comment: Several commenters supported our proposal to remove the Health IT vendor category, suggesting that this policy would improve clarity and set a consistent standard among third party intermediaries. A few commenters who supported the proposal to remove the Health IT vendor category suggested that CMS establish data validation standards for direct reporting of data for the purposes of MIPS in order to further improve consistency among submission types.

Response: We appreciate the support from the commenters for our proposal to remove Health IT vendors from the definition of a third party intermediary and agree it will improve clarity and establish a consistent standard. In response to concerns about data quality for those clinicians and groups that may directly submit data, we note that direct submitters are subject to the same requirements for data quality as data submitted through a third party intermediary and may be subject to audit.

Comment: A few commenters opposed our proposal to eliminate the health IT vendor category of third party intermediaries and suggested that this could limit the opportunity for clinicians to report MIPS data using their EHRs. One commenter recommended that CMS align data submission requirements with the Digital Quality Measure Roadmap and continue to build on existing eCQMs. One of the commenters suggested that CMS instead adopt corrective action plan requirements for health IT vendors that submit inaccurate data and adopt more stringent data validation strategies.

Response: Our proposal was made based on our observation that many EHRs can self-nominate to serve as registries or QCDRs under our existing requirements and that many others can also facilitate direct reporting of MIPS data by clinicians and groups. This proposal will not limit opportunities for clinicians to submit data and most clinicians and groups can continue to use the vendors they currently use to facilitate reporting. This change will improve clarity and ensure that there is clear understanding of what has been reviewed in the approval of a third party intermediary. As noted in the 2024 PFS proposed rule (88 FR 52608), a lack of self-nomination process has made it difficult to fully understand the nature of the health IT vendors and therefore made it difficult to properly identify and develop corrective action plans for those with data issues. We continue to emphasize the importance of digital measures in MIPS and throughout CMS quality programs.

Comment: A few commenters requested further clarification on how the organizations previously identified as health IT vendors could support MIPS-eligible clinicians. One commenter asked if those organizations could provide QRDA files for the improvement activity and Promoting Interoperability performance categories.

Response: The organizations previously identified as health IT vendors may complete self-nomination as registries or QCDRs and submit data, which would include measures and activities in the improvement activity and Promoting Interoperability performance categories which may be reported using QRDA. They may also facilitate the direct reporting of data by clinicians and groups which is reported via QRDA.

Comment: One commenter opposed this proposal and suggested that it would have a disproportionate effect on hospitals that treat disadvantaged patients.

Response: We offer a number of different options for clinicians who practice in environments in which they may be treating disadvantaged patients and are uncertain how such a policy would affect them disproportionately.

Comment: One commenter opposed our proposal because they stated that it may be difficult for some vendors to support the self-reporting by clinicians and groups and also difficult for these vendors to meet the requirements of a qualified registry or QCDR. One commenter suggested that technological solutions that are available such as OAuth are limited because they are assigned to individuals.

Response: Those organizations that served as health IT vendors that are unable to support self-reporting by clinicians and groups may be able to self-nominate to serve as a qualified registry or QCDR. We note that many organizations have successfully completed these requirements so we do not believe that they prevent a significant barrier.

Comment: One commenter requested that CMS require that health IT vendors that are serving as third party intermediaries be required to support a transition to another third party intermediary due to the elimination of the health IT vendor category.

Response: We will continue to offer as many resources as possible to help clinicians identify third party intermediaries that could facilitate data reporting for MIPS, as well as educate clinicians on opportunities to report data directly. In addition, it is important to note that this change will occur beginning with the CY 2025 performance period—thereby, providing clinicians and third party intermediaries additional time to prepare for the transition.

After consideration of the public comments, we are finalizing our proposal at § 414.1400(a)(1)(iii) to eliminate the health IT vendor category beginning with the CY 2025 performance period.

(6) Remedial Action and Termination of Third Party Intermediaries

(a) Background

We referred readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77389), the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), the CY 2022 PFS final rule (86 FR 65542 and 65550) and the CY 2023 PFS final rule (87 FR 70106 through 70109) for previously finalized policies for remedial action and termination of third party intermediaries.

(b) Additional Basis for Remedial Action

(i) Failure To Maintain Correct Contact Information

In the CY 2017 Quality Payment Program final rule, we established the process for self-nomination for QCDRs (81 FR 77364 through 77367) and qualified registries (81 FR 77383 through 77384). We also established the process for corrective action plans in the CY 2017 Quality Payment Program final rule (81 FR 77389). In our work with QCDRs and qualified registries, we experienced times when the QCDR or qualified registry did not respond to certain requests in a timely manner, thereby delaying program operations. In some cases, we had further correspondence with the QCDR or qualified registry and those organizations suggested that the contact information (generally an email address) submitted as part of the self-nomination

was not correct, so the request was never received. While we understand that personnel can change over time in an organization, such a change does not relieve the QCDR or qualified registry of its obligations under these rules. Therefore, we proposed an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence (88 FR 52609).

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed our proposal to add failure to maintain correct contact information to the list of reasons for corrective action plan and suggested that this proposal was too inflexible. One commenter suggested that the requirement for three separate contacts already provide an undue burden for smaller registries and that maintaining current information would add to that burden.

Response: We note that this policy does not require us to terminate a third party intermediary in all circumstances in which a third party intermediary fails to maintain current contact information; instead, it gives us the discretion to do so. Being able to contact a representative of a QCDR or Qualified Registry is a basic operational requirement.

After consideration of the public comments, we are finalizing our proposal at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence.

(ii) Consecutive Years on Remedial Action

In the CY 2017 Quality Payment Program final rule, we established a process for placing third party intermediaries on probation for not meeting requirements (81 FR 77387). Specifically, if a third party intermediary did not meet requirements for qualification, they could be placed on probation for the current performance period and/or the following performance period. We also established that after two years on probation, a third party intermediary would be disqualified for the subsequent performance year (81 FR 77387 through 77389). In the CY 2019 PFS final rule, policies relating to probation and disqualification were renamed and reorganized under remedial action and termination of third party intermediaries (83 FR 59908 through 59910). Additionally, we finalized reasons for terminating third party intermediaries including being placed on remedial action, not submitting a corrective action plan, and not promptly correcting data errors (83 FR 59908 through 59910). At that time, we did not propose any actions related to third party intermediaries on remedial action for multiple years, as had been established under our initial probation policy.

We noted that we continue to experience issues with third party intermediaries that require corrective action plans over multiple years. We believe that third party intermediaries that consistently require corrective action plans, whether for the same or unrelated issues, do not further the goals of the Quality Payment Program, which are to improve quality of care while limiting administrative burden. We believe allowing third party intermediaries that have consistently demonstrated failure to comply with CMS requirements such that they required corrective action plans undermine clinicians' and groups' efforts to improve quality and could result in increased administrative burden for those clinicians and groups. For this reason, we proposed to add at § 414.1400(e)(2)(v) that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years (88 FR 52609). We noted our belief that this proposal would minimize risk within the Quality Payment Program by terminating third party intermediaries that are consistently deemed as non-compliant.

We received public comments on the proposal. The following is a summary of the comments we received and our responses:

Comment: One commenter opposed our proposal that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years. The commenter suggested that CMS has had difficulty in determining if certain elements of the corrective action plan have been completed and further suggested that continuous years of corrective action could be a result of this lack of awareness.

Response: As part of our corrective action plans, we track and maintain status of progress on a monthly basis. Our policy to require third party intermediaries under a corrective action plan to communicate the final resolution of that plan, finalized in section IV.A.4.k.(6)(c) of this rule, will further facilitate awareness on our part of the resolution of a corrective action plan.

After consideration of public comments, we are finalizing our proposal at § 414.1400(e)(2)(v) that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years.

(c) Revised Corrective Action Plan Requirements

As described in § 414.1400(e)(1)(i), among the remedial actions that CMS may take against a non-compliant third party intermediary is a corrective action plan (CAP). Under paragraphs (e)(1)(i)(A) through (D), unless different or additional information is specified by CMS, the CAP must address the following issues: (A) the issues that contributed to the non-compliance; (B) the impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program; (C) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future; and (D) a detailed timeline for achieving compliance with the applicable requirements. In the CY 2023 PFS final rule, we finalized a policy at § 414.1400(e)(1)(i)(E) to require third party intermediaries to provide a communication plan for communicating the impact to the parties identified within the corrective action plan (87 FR 70107).

Based on our experience with corrective action plans from third party intermediaries through the years, we have identified a gap in our ability to determine if certain elements of the corrective action plan have been completed in the time and manner specified within the action plan. Therefore, we proposed to add at § 414.1400(e)(1)(i)(F) an additional requirement for a third party intermediary under a corrective action plan to communicate the final resolution to CMS once the resolution is complete, and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C) (88 FR 52609). We noted our belief that this additional step will ensure that third party intermediaries complete the required actions within the corrective action plan.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(d) Public Posting of Deficiencies

In the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77388), we established a remedial action that, in the event that a QCDR or qualified registry had data inaccuracies that affected more than 3 percent but less than 5 percent of the total number of MIPS eligible clinicians, we would have this information identified on the CMS public posting. We modified this requirement in the CY 2019 PFS final rule (83 FR 59909) that the data error rate would be publicly disclosed until the data error rate falls below 3 percent.

We proposed to modify this requirement. While we previously determined that a single, objective measure (that is, a 3 percent error rate) would support our goals of public notice, we noted our belief that the precise metric is not a meaningful indicator. Specifically, some errors may be minor in nature yet affect a large number of clinicians for whom the QCDR or qualified registry has reported data. Other errors, however, may be materially significant but may not affect 3 percent of the MIPS eligible clinicians due to the unique nature of the data point at issue.

We believe that there is significant value in informing the public and potential customers which QCDRs and qualified registries are under remedial action or are terminated. Therefore, we proposed to add a new provision at § 414.1400(e)(1)(ii)(B) that CMS may, beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary. We noted that this public disclosure would be limited to the presence of the corrective action plan and would not include any proprietary information from the QCDR or qualified registry (88 FR 52610). We also proposed to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(e)(1)(ii)(A) and ending this policy after the CY 2025 performance period/2027 MIPS payment year (88 FR 52610). We proposed to remove this policy because we believe it would be superseded by the proposal included in § 414.1400(e)(1)(ii)(B).

We received public comments on these proposals. The following is a summary of the comments we received and our responses:

Comment: A few commenters opposed our proposal to publicly post the existence of a corrective action plan for third party intermediaries, suggesting that this would make it more difficult for these third party intermediaries to participate in MIPS. One commenter suggested that the information only be released if the third party intermediary is unable or unwilling to address the issue.

Response: A third party intermediary is given the opportunity to address deficiencies in a corrective action plan. We again note that the nature of the corrective action plan would not be identified. We believe that those considering the use of these third party intermediaries should be aware if there is a current deficiency when considering options for reporting MIPS data.

After consideration of public comments, we are finalizing our policies to add a new provision at § 414.1400(e)(1)(ii)(B) that CMS may, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publicly disclose on the CMS website that we took remedial action against or terminated the third party intermediary. We also finalize our proposal to modify § 414.1400(e)(1)(ii) by redesignating it as paragraph (e)(1)(ii)(A) and end this policy after the CY 2025 performance period/2027 MIPS payment year.

(e) Considering Past Performance in Approving Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule, we established that third party intermediaries would be placed on probation status if they had not met criteria for qualification following self-nomination (81 FR 77386 through 77389). Under the terms of the probation policy, a corrective action plan could be required to address any deficiencies or prevent them from recurring. In addition, a third party intermediary that was on probation status for 2 years would be disqualified for the subsequent performance period. In the CY 2019 PFS final rule (83 FR 59909), we consolidated the corrective actions that we would take in the event of a deficiency or error on the part of a third party intermediary. This included the elimination of a policy of probation for third party intermediaries and the establishment of a policy of remedial action for third party intermediaries. We did not change the factors made to determine a remedial action or probation.

We have continued to experience issues related to data errors from third party intermediaries and these errors often extend over multiple years. We are concerned that some third party intermediaries fail to address deficiencies with regularity, and are required to perform remedial actions as defined in corrective action plans over the course of many years. This suggests that these organizations are not able to properly adhere to the criteria for qualification for third party intermediaries. While we have established criteria for approval of third party intermediary at § 414.1400(a)(2)(ii)(A) which state that our determination to approve a third party intermediary may take into account whether the entity failed to comply with the requirements for a previous MIPS payment year, we wish to clarify that the consideration of past compliance can also include remedial actions. While we already have the ability to consider whether the entity failed to comply with certain requirements, we do not believe that the existing requirements are explicit enough for third party intermediaries to understand that a history of remedial actions, even if addressed such that the third party intermediary was not terminated could result in CMS not approving future approval.

We did not receive public comments on this provision. We are finalizing this proposal as proposed.

(f) Terms of Audits

In the CY 2017 Quality Payment Program final rule (81 FR 77389 through 77390), we finalized that third party intermediaries submitting MIPS data must comply with auditing procedures as a condition to participate in MIPS. In the proposed rule, we did not establish the reasons we have for auditing a particular third party intermediary. We noted that we perform both random and targeted compliance audits based on a number of reasons and we wish to document those reasons for transparency to the public. Therefore, we proposed at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary (88 FR 52610). For example, areas of concern could include but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary. We also proposed to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(v) with minor changes in the text for clarity (88 FR 52610). We noted that this section refers to program requirements, which we

believe is a more appropriate characterization of these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the specific element of our proposal which referenced a continuing pattern of Quality Payment Program service center inquires or support call questions. The commenters suggested this could discourage third party intermediaries from engaging with the support center.

Response: We clarify that a third party intermediary would not be identified for an audit on the basis of communication between the service center and the third party intermediary. However, a pattern of particular third party intermediary users contacting the Quality Payment Program for issues could indicate that the third party intermediary was having trouble meeting our program requirements, which would be a basis for taking corrective action.

After consideration of public comments, we are finalizing our proposal at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. We are also finalizing our policy to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(v) with minor changes in the text for clarity.

(7) Technical Changes

In the course of reviewing the regulation for third party intermediaries, we identified areas in which certain language was used that is not as consistent or clear as it could be. We proposed to make the following changes to § 414.1400 to improve clarity as denoted below (88 FR 52610):

- At paragraph (a)(2), to clarify that an organization may only become a third party intermediary for the purposes of MIPS by meeting the approval criteria by replacing the term ''third party intermediary'' with ''organization''.
- Redesignate paragraph (a)(3) to delineate third party intermediary approval criteria from requirements for third party intermediaries as they participate in the Quality Payment Program. We proposed the following redesignations:
- § 414.1400(a)(3) redesignated as § 414.1400(a)(3)(i);
- § 414.1400(a)(2)(i)(C) redesignated as § 414.1400(a)(3)(ii);
- § 414.1400(a)(2)(i)(D) redesignated as § 414.1400(a)(3)(iii);
- § 414.1400(a)(2)(i)(F) redesignated as § 414.1400(a)(3)(iv); and
- § 414.1400 (a)(2)(iii) redesignated as § 414.1400(a)(3)(vi).

These reorganized sections also include minor changes to the text. Please note that we outlined new proposals related to these requirements in section IV.A.4.k.(3) of the proposed rule. There is also a conforming change to reference this section at § 414.1400(e)(1).

- At § 414.1400(e)(3) to remove the word ''total'' from the phrase ''total clinicians'' as this word was included in error.
- At § 414.1400(e)(4) to improve clarity and remove a paragraph.

We invited comments on these proposals.

We did not receive public comments on this provision. We are finalizing these technical changes as proposed.

l. Public Reporting on Compare Tool

Section 10331(a)(1) of the Affordable Care Act provides for the development of a Physician Compare internet website (''Physician Compare'') with information on physicians and other eligible professionals enrolled in Medicare who participate in the Physician Quality Reporting Initiative (PQRI). Section 1848(q)(9) of the Act, as added by section 101(c) of MACRA, aligned Physician Compare with the newly established Merit-Based Incentive Payment System (MIPS) by requiring the public reporting of MIPS performance information for MIPS eligible professionals through Physician Compare.

For previous discussions of public reporting of physician and clinician performance and information, we refer readers to the CY 2016 Physician Fee Schedule (PFS) final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2022 PFS final rule (86 FR 65550 through 65554), the CY 2023 PFS final rule (87 FR 70109 through 70113) and the Care Compare: Doctors and Clinicians Initiative web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*. We also note, that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466). (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*.) As finalized at § 414.1305, ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466).

(1) Telehealth Indicator

In the CY 2023 PFS final rule, we finalized the addition of an indicator to the profile pages of clinicians who furnish telehealth services (87 FR 70109 through 70111) to established processes and coding policies to identify such clinicians (*id.*). As discussed in the CY 2024 proposed rule (88 FR 52611), under our current policy, we would already be using the most current CPT codes for each telehealth indicator update; however, we would need to use annual rulemaking to update the POS and claims modifier codes used for telehealth indicator public reporting purposes. Adding coding flexibility for other codes, such as POS and claims modifiers, would both help avoid future regulatory burden and allow for more real-time accuracy of the telehealth information provided on Care Compare.

For these reasons, we proposed to update our policy for identifying clinicians furnishing telehealth services, such that we remain current with CMS coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using POS code 02, 10, or modifier 95 to identify telehealth services furnished for the telehealth indicator, we will use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. We proposed that at the time of such a data refresh we will publish the details of which codes are used for the telehealth indicator through education and outreach, such as via a fact sheet, listserv, and information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-*

initiative. We refer readers to the CY 2024 PFS proposed rule (88 FR 52611) for details on the Telehealth Indicator proposal.

The following is a summary of the comments on this proposal we received and our responses.

Comment: Commenters supported the use of the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. The commenters noted the importance of providing an accurate indicator of telehealth services on clinician profile pages. One commenter noted that providing meaningful information on care delivery options available could help to further access to care and health equity goals.

Response: We appreciate the commenters' support for updating the telehealth indicator process for identifying and updating telehealth service information on clinician profile pages. We agree that it is important to ensure accuracy in knowing whether a clinician offers services via telehealth to be useful to patients and caregivers, particularly for those who have access to care barriers.

Comment: One commenter recommended having a clinician review and correction process that would allow clinicians to update and correct the telehealth indicator and other information listed on their profiles if needed.

Response: Since claims are the data source for identifying telehealth services rendered by a clinician, we encourage clinicians to first look into any billing errors. However, as with any other questions or concerns regarding the information on clinician and group profile pages on the Compare tool, interested parties may contact the Quality Payment Program at 1–866–288–8292 or by email at *QPP@cms.hhs.gov*. Those who are hard of hearing can dial 711 to be connected to a Telecommunications Relay Service (TRS) Communications Assistant. We also encourage clinicians to ensure their information is current in the Provider Enrollment, Chain, and Ownership System (PECOS) and to visit the Doctors and Clinicians initiative page for more information *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Care-Compare-DAC-Initiative*.

After consideration of public comments, we are finalizing our proposal to use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth, as proposed.

(2) Publicly Reporting Utilization Data on Profile Pages

Section 104(a) of MACRA provides that, beginning with 2015, the Secretary shall make publicly available on an annual basis, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals, on items and services furnished to Medicare beneficiaries. Section 104(e) of the MACRA also requires that we integrate this data into the Compare tool. We finalized a policy to report the most recent available utilization data in downloadable format beginning in late 2017 (80 FR 71130). This information continues to be available today in the Medicare Provider Data Catalog (PDC) available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*. Separately, we have reported on the Compare tool clinician training information as well as a clinician's primary and secondary specialties.

In the CY 2023 PFS final rule (87 FR 70111 through 70113), and as discussed in the CY 2024 proposed rule (88 FR 52611 through 52612), we established a policy for publicly reporting procedure information on clinician profile pages to provide patients more information in their clinician searches in an understandable format, beginning no earlier than CY 2023.

We also established that priority procedures selected for utilization data public reporting will meet one or more of the following criteria:

- Have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research;
- Are affiliated with existing MIPS measures indicating importance to CMS;
- Represent care that a patient might shop for a clinician to provide; and/or
- Are an HHS priority.

We finalized that this data would be based on a 12-month lookback period, with data refreshes updated bi-monthly, as technically feasible, and we would not initially prioritize complex, rare procedures. We noted that the utilization data shown on profile pages would only reflect Medicare Fee-for-Service (FFS) claims data and would not include procedures performed for patients who have other types of insurance. To meaningfully categorize procedures, we finalized the policy of using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System to collapse Healthcare Common Procedure Coding System (HCPCS) data into procedural categories, and when no Restructured BETOS categories are available, procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures.

Consumer testing showed that publicly reporting utilization data on patient-facing clinician profile pages and using plain language, is helpful for patients and caregivers to make informed healthcare decisions, since it allows them to find clinicians who have performed specific types of procedures. Consumer testing results showed that patients and caregivers understand this language, would not select a health care provider based on this information alone, and find the information helpful but would like the procedure volume to also reflect patients with other insurance if possible. Our data analyses have confirmed the availability of Medicare Advantage (MA) data increasing the representativeness of the procedure (that is, utilization) data, as discussed later in this section.

(a) Updating the Provider Data Catalog (PDC) Utilization Data Policy

As discussed in the CY 2024 PFS proposed rule (88 FR 52611 through 52612), we historically have published a PDC file that is a subset of the most commonly performed procedures in the PUF. With the upcoming release of the initial procedural utilization data, we will publish a second utilization file in the PDC that will reflect the procedure category information on clinician profile pages. That is, consistent with what will be publicly reported on profile pages, the second PDC file will aggregate like procedures and include an indication of low volume counts, in accordance with the CMS small cell size policy, in which counts below 11 cannot be publicly reported, to protect patient privacy.

It would be of greater use for the PDC to only have one utilization downloadable file that reflects the same subset of data, in the same format, as what will be publicly reported on clinician profile pages. Doing so aligns the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages and will assist researchers in analyses of utilization data on clinician profile pages.

Therefore, we proposed revising the policy to publicly report a subset of the Medicare PUF on the PDC to instead provide a single downloadable dataset including the procedure utilization data that would appear on clinician profile pages. We proposed to remove the PUF subset file from the PDC and only keep the utilization data file that reflects the information on clinician profile pages in the PDC. We refer readers to the CY

2024 PFS proposed rule (88 FR 52612 through 52613) for details on the PDC Utilization Data File proposal.

We solicited comment on all aspects of this proposal, including any concerns about technical feasibility; our approach to aligning the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages; ways in which we inform researchers on the location of the full CMS PUF for continued use; and any other considerations.

The following is a summary of the comments on this proposal we received and our responses.

Comment: One commenter supported providing a single downloadable dataset including the procedure utilization data that would appear on clinician profile pages, noting the importance of access to the data for research purposes.

Response: We appreciate the commenter's support and agree that maintaining a single downloadable dataset that reflects the same procedure utilization data that will appear on clinician profile pages will be useful to researchers and clinicians interested in this information.

After consideration of public comments, we are finalizing the PDC Utilization Data File Policy as proposed. We will remove the PUF subset file from the PDC and only keep the utilization data file that reflects the information on clinician profile pages in the PDC.

(b) Procedure Grouping Policy for Publicly Reporting Utilization Data

As mentioned earlier in this section, in the CY 2023 PFS final rule, we finalized using Restructured BETOS and procedure code sources used in MIPS when no Restructured BETOS categories are available, such as the procedure categories already defined for MIPS measures to meaningfully categorize procedures for public reporting (87 FR 70111). However, since finalizing this policy, we identified some commonly sought procedures, such as hysterectomy, that do not have a procedure category specified in the Restructured BETOS categorization system or a relevant code set in any MIPS quality or cost measures.

In the CY 2024 PFS proposed rule (88 FR 52613), we proposed to define meaningful categories using subject matter expert (for example clinician) input in instances where a procedure category is unavailable under the Restructured BETOS or MIPS measures, if a code category exists but is not suitable for public reporting, or in instances where a procedure category does not exist, to create new, clinically meaningful, and well-understood procedure categories as needed. Added flexibility in grouping HCPCS codes to create procedure categories meaningful to patients and caregivers will allow users of the Compare tool to better assess a clinician's volume and scope of experience with a particular procedure and inform healthcare decision making.

To implement this, we proposed to modify the existing policy such that, in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS), we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. If we develop new procedure categories for publicly reporting utilization data on clinician profile pages, we proposed to engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, such as listserv emails, listening sessions, and focus groups to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible. We refer readers to the CY 2024 PFS proposed rule (88 FR 52613) for details on methods to solicit feedback on new procedure categories planned for future utilization data releases, as appropriate and technically feasible.

The following is a summary of the comments on the proposal we received and our responses.

Comment: Two commenters supported the proposal to modify existing procedural categorization policy to use alternate sources to create clinically meaningful and appropriate procedural categories.

Response: We appreciate the commenters' support and agree that the ability to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists will allow users of the Compare tool to better assess a clinician's volume and scope of experience with a particular procedure and inform healthcare decision making.

Comment: One commenter expressed concerns that BETOS is outdated, has broad categories and, as a result, may lead to errors that mislead patients. The commenter additionally stated there is no standard or systematic way to group procedures by Common Procedural Terminology (CPT) or HCPCS codes beyond the BETOS system and expressed concern that Restructured BETOS does not contain all procedure codes.

Response: In response to the concern that BETOS is outdated, we clarify that we do not use original BETOS. We use Restructured BETOS, which is updated on an annual basis, the most recent of which are from 2022. We discuss the differences between the two categorization systems in the CY 2023 PFS final rule (87 FR 70111 through 70113). We also recognized limitations with Restructured BETOS, which was why in the CY 2023 PFS final rule we also finalized that we would utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures, for procedures in which no Restructured BETOS categories are available. However, we have since identified the need for additional flexibility in defining procedure categories, as proposed in the CY 2024 PFS proposed rule (88 FR 52613).

Comment: One commenter noted that specialty societies could provide helpful feedback to aid CMS in making accurate determinations in the creation of new, clinically meaningful, and well-understood procedure categories.

Response: We appreciate the support specialty societies and other subject matter experts may provide in the development of additional procedure categories in future years.

Comment: One commenter cautioned against expanding the list of publicly reported procedures to include services such as reproductive health care and gender-affirming care citing safety concerns for physicians who furnish such services.

Response: We appreciate the commenter raising this concern and will take it into consideration as we expand procedure categories in the future.

After consideration of public comments, we are finalizing the Procedure Grouping Policy for Publicly Reporting Utilization Data as proposed. Specifically, in addition to Restructured BETOS and code sources used in MIPS, we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. We will engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, including but not limited to listserv emails, listening sessions, or focus groups to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible.

(c) Incorporating Medicare Advantage (MA) data into Public Reporting

As discussed in the CY 2024 proposed rule (88 FR 52613 through 52614), between the time of the CY 2023 PFS

proposed and final rules, our Medicare FFS claims data analyses showed that for the initial 13 priority procedures identified, approximately 50 percent of clinician-procedure combinations fall into the low volume category, which meant that, based on Medicare physician and ancillary service (carrier) claims in the past 12 months, we could only publish an indicator that a clinician has experience with the procedure rather than specific counts. Under the small cell size policy, we prohibit the use of specific procedure or patient counts in cases where the count is below ten. The high number of clinicians with a low volume indicator is partly due to not including data for patients with other coverage, such as MA plans or other payers, for whom a given clinician has also performed such procedures. As such, we are currently limited in our ability to contextualize low volume clinician experience with procedures in a way that is useful and easily understandable for patients and caregivers who may be looking for a clinician with experience performing a specific procedure.

As we identify more priority procedures for public reporting, more procedures may be subject to the small cell size policy using Medicare FFS data alone, which would prevent us from publicly reporting health care provider experience with such procedures for patients and caregivers to use in their healthcare decisions. Based on public comments and consumer testing, including other payer data would help prevent this issue. Consumer testing findings have also shown that patients and caregivers would like procedure information to reflect all procedures performed, since it better represents clinicians' experience.

While we agreed with comments received on the CY 2023 PFS proposed rule, we were unable to finalize the possibility of using other payer data as appropriate and technically feasible at that time. However, we have subsequently determined through analysis of MA encounter data submitted to CMS that it is technically feasible to integrate MA encounter data into procedure category counts and that adding such data adds to the representation of some clinicians' scope of care.

Therefore, we proposed to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to Medicare FFS utilization data, given that we have determined it is appropriate and technically feasible. Section 104(a) and (b) of MACRA provides for the public reporting of items and services furnished to Medicare beneficiaries under title XVIII of the Act, including, at a minimum, information on the most frequent services or groupings of services furnished by physicians or other eligible professionals under part B of title XVIII of the Act. This provision authorizes the publication of information on the items and services furnished to ''Medicare beneficiaries under Medicare by physicians and certain other professionals.'' Notably, the statute authorizes the disclosure of information on all items and services furnished to Medicare beneficiaries under the Medicare Act; that is, the statute does not limit the disclosure to a particular subset of Medicare services. Indeed, section 104(c)(1) of MACRA provides that the information made available must include ''at a minimum'' certain information on Part B services. This does not limit the disclosure authorized by section 104(a) of MACRA to information on Part B items and services; instead, it specifies the minimum information that CMS must disclose, leaving additional disclosures under section 104(a) of MACRA to CMS' discretion. MA plans cover Part A and Part B benefits (excluding hospice services, acquisition costs for kidneys used for transplants, and, for a limited period, certain services under new National Coverage Determinations and changes in legislation) for Medicare beneficiaries that elect to enroll in an MA plan; this coverage is also under Title XVIII of the Act. Section 104(a) of MACRA thus authorizes the disclosure of certain information about items and services provided as benefits under an MA plan and furnished by a physician or other eligible professional.

Separately, section 10331(b)(4) of the Affordable Care Act provides for the Secretary to, in developing and implementing his plan to make information as determined appropriate by the Secretary available on Physician Compare, include data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent practicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance. Thus, the inclusion of MA encounter data is consistent with the relevant statutory provisions regarding the disclosures on the Care Compare website.

Per section 1853(a)(3)(B) of the Act, CMS has required MA organizations to submit the data necessary to characterize the context and purposes of each item and service provided to a Medicare beneficiary enrolled in an MA plan to use for risk adjusting payments by CMS to MA plans. Per the MA regulation at § 422.310(f)(1)(vii), CMS may use this risk adjustment data, which includes MA encounter data, for activities to support administration of the Medicare program and for purposes authorized by other applicable law. The MA regulation at § 422.310(f)(2) allows CMS to release encounter data for any of the purposes specified in § 422.310(f)(1) in accordance with applicable Federal laws and CMS data sharing procedures, subject to protections of beneficiary confidentiality and commercially sensitive data. Finally, § 422.310(f)(3) imposes restrictions on when the data is available for release. We proposed to rely on § 422.310(f), as well as section 104 of the MACRA and section 10331 of the Affordable Care Act, for using and releasing the MA encounter data as part of the Care Compare website. To accomplish this, we also proposed to amend § 422.310(f)(3) to permit the release of the MA encounter data on the timeframe(s) used for disclosure and release of the data on the Care Compare website. We stated in the proposed rule that this proposal would ensure that there is no confusion about our ability to use and release the MA encounter data for the Care Compare website and downloadable files and permit release of MA encounter data when necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

Using and analyzing MA encounter data as part of the aggregated information disclosed through the Care Compare website will more completely fulfill the public reporting required by section 104 of the MACRA and section 10331 of the ACA and using the MA encounter data in implementing these statutory provisions supports administration of the Medicare program. In addition, it is also consistent with administering the Medicare program overall to provide appropriate and helpful information to beneficiaries in selecting a provider. Thus, the use and disclosure of the MA encounter data here are within the scope of § 422.310(f)(1)(vii) without any amendment to § 422.310(f)(1)(vii).

The aggregated utilization data we proposed to include in the Compare tool meets the additional requirements to protect beneficiary and commercially sensitive information at § 422.310(f)(2) because only identifying information about healthcare providers and types of procedures performed within a specific time period were proposed to be disclosed on the website and available for release in the PDC downloadable files. The disclosure and release of these

portions of the MA encounter data are consistent with CMS data sharing procedures, which are applied to the Medicare FFS data already displayed and available for download on the Care Compare website. However, when releasing the MA encounter data under § 422.310(f)(2), the timing limitations at § 422.310(f)(3) prohibit releasing the encounter data before the applicable payment year's reconciliation has been completed except for in specified circumstances, none of which apply here. Because we proposed to use information from the MA encounter data, in combination with FFS claims data, over a 12-month rolling period, but risk adjustment reconciliation occurs no sooner than 13 months after the end of the year that services were provided, the timing of the release of the MA encounter data is not within the scope of the timing requirements in § 422.310(f)(3).

MA organizations submit encounter data continuously, but do not have the same timeliness requirements for submission that FFS providers have for submitting claims. In the August 22, 2014 final rule entitled, ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program'' (79 FR 49854), CMS adopted § 422.310(f)(3) to address concerns that the need to update or correct MA encounter data prior to the final submission deadline could mean that the MA encounter data was not sufficiently complete or fully reliable for public release. However, since that time, which was during the first few years of submission of MA encounter data to CMS, submissions of MA encounter data have improved. In particular, the provider identifying information and procedure codes required for the Compare tool are well reported. Furthermore, including utilization and limited provider-identifying data from MA encounters prior to the data being reconciled by the MA organization would substantially improve the Compare tool and, thereby, the administration of the Medicare program overall by providing patients and caregivers with more useful and easily understandable information about procedures performed by providers in their search for a clinician. Therefore, we proposed to amend § 422.310(f)(3) to include an additional exception at paragraph (f)(3)(iv) that permits CMS to release aggregated risk adjustment data before the reconciliation for the applicable payment year has been completed if CMS determines that releasing aggregated data is necessary and appropriate for the purposes specified in § 422.310(f)(1)(vii).

Based on our analyses, the inclusion of data about utilization in the MA program will reduce the low volume procedure counts subject to the small cell size policy, in which precise counts less than ten procedures or patients cannot be publicly reported. This will allow us to more accurately report the types of services that Medicare clinicians provide. Based on the public comments in our prior rulemakings about the Care Compare website and consumer feedback, aggregating utilization data from the Medicare FFS and MA program will also enhance patient use of the information. Although the initial release of publicly reported utilization data on the Compare tool is limited to clinicians' Medicare FFS claims, publicly reporting utilization data that includes Medicare FFS and MA would also be more consistent with MIPS quality information submitted via health IT vendors or registries that include other payer data. Lastly, adding MA data to the counts in the existing Medicare FFS utilization data file will mitigate interested party concerns that information available through the Compare tool does not fully reflect the physician's/clinician's scope of practice. Including MA data with the FFS data will provide more information about a physician's/clinician's experience and scope of practice. We refer readers to the CY 2024 PFS proposed rule (88 FR 52613 through 52615) for details on incorporating MA data to FFS procedure counts.

The following is a summary of the comments on these proposals we received and our responses.

Comment: Three commenters supported the proposal to incorporate Medicare Advantage data to FFS procedure counts without any concerns. The commenters stated it is important to include MA data so that beneficiaries receive accurate information regarding what procedures are conducted by a specific clinician. One commenter noted this proposal directly addressed their concerns expressed in the CY 2023 PFS proposed rule public comment period that publicly reporting utilization data did not reflect the clinician's full scope of experience. Two commenters also encouraged CMS to continue exploring expanding the data to include Medicaid, Veterans Affairs, and private payers to provide a fuller representation of clinicians' experience. One commenter provided similar suggestions but also stated that utilization data that only reflects Medicare FFS and MA would not be meaningful to beneficiaries.

Response: We agree that publicly reporting additional sources, such as Medicare Advantage data, provides more accurate information on procedures performed by a clinician. We appreciate the suggestion to look into adding other types of payer data. We also note that our consumer testing has found patients and caregivers would find utilization data based only on Medicare FFS and MA data to be helpful, even if it does not cover clinicians' full scope of practice.

Comment: Several commenters expressed concerns related to patient understanding of the information. Two commenters were concerned patients could incorrectly equate higher volume of procedures to higher quality of care and better outcomes, particularly in the absence of quality information on profile pages. Another commenter expressed concern regarding the number of clinicians with low-volume counts as still too high and that, as a result, procedure volume could be misleading to patients.

Response: Prior to the CY 2023 PFS proposed rule public comment period and the CY 2023 PFS final rule (87 FR 70109 through 70113), we conducted comprehensive user testing with patients and caregivers to see if they accurately understand the information. Plain language text included explanations that: the data do not reflect all procedures the clinicians perform; the information shown only reflects procedures performed on patients with Medicare (Original Medicare and Medicare Advantage); and that the utilization data on their own are not the only indicator of quality. Findings show that patients and caregivers: understood that higher volumes may not be a consistent indicator of quality; would not select a provider based on utilization data information alone; and found the information helpful but would like the procedure volume to also reflect patients with other insurance if possible. We also found that low volume counts are well understood, perceived as an indicator that the clinician has experience performing the procedure, and that patients would not rely on utilization data alone to inform clinician selection.

Comment: Two commenters noted that ''incident to'' billing may limit procedure attribution for certain clinicians, such as nurse practitioners (NPs) and physician assistants (PAs).

Response: We agree that if a clinician, such as a NP or PA, bills Medicare incident to a physician, then we would attribute a procedure billed in this way to the physician listed on the claim. However, we believe such attribution is appropriate, since the billing physician supervised and is accountable for the procedure billed. Additionally, we note that the attribution concern is a non-issue for clinicians who only bill Medicare incident to a supervising physician since these clinicians would not have a Compare tool profile page through which we could display utilization data specific to that clinician. Furthermore, due to an operational update since the time of the previous final rule, utilization data will not currently be publicly reported on NP and PA profile pages.

Comment: One commenter expressed concerns that the encounter data are incomplete and that options for validating the data are limited. Given these concerns, the commenter requested CMS to publish the methodology used to calculate counts of procedures from the encounter data; which encounter data files were used to identify procedures (for example, physician, outpatient, inpatient, etc.); how procedures were attributed to individual clinicians (including whether any edits or data-cleaning procedures were applied to the NPI field); and what deduplication procedures were applied to the data. Two other commenters expressed concerns with potential data inaccuracies. One commenter noted difficulty in maintaining accurate counts on a routine basis, and another noted inaccurate encounter data might skew portrayals of clinician performance. One additional commenter provided a suggestion to release Part C utilization encounter data in a manner similar to how Part B data is released to allow for greater evaluation of how utilization differs between Part B and Part C.

Response: Regarding concerns that the encounter data are incomplete or inaccurate and options for validating the data are limited, MA plans are required to submit encounter data records for all items and services provided to their enrollees. CMS regularly undertakes analyses to understand what data MA organizations may have challenges submitting. CMS also provides guidance and technical assistance to MA organizations to help resolve these challenges. We continually monitor the accuracy and completeness of the encounter data and take steps to remedy identified issues as appropriate. In using the MA encounter data for this purpose, we identify the procedures using physician/supplier Medicare Part C non-institutional encounters on certain services and procedures and will group them using Restructured BETOS categories or utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures, for procedures in which no Restructured BETOS categories are available in the same way in which we finalized in the CY 2023 final rule for Medicare Part B non-institutional claims (87 FR 46331). We note that, similar to Part B non-institutional claims, Part C physician/supplier non-institutional encounters use clinician NPIs, so there is no further attribution process. We may also use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists, which we are finalizing as proposed in section IV.A.4.l.(2)(b) of this final rule. According to § 422.310(d)(5), MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance. Procedures are then attributed to individual clinicians using their individual NPI, specifically the rendering clinician and procedure code are listed on the same line. Regarding edits or data-cleaning applied to the NPI field, we are limiting what procedure data is publicly reported on clinician profile pages based on Medicare's definition of a physician. Procedure data for other types of clinicians would be reported in the PDC only. Lastly, deduplication procedures are applied at the clinician, patient, date of service, and procedure category level.

Comment: Two commenters expressed concerns regarding the proposal to publicly report aggregated claims data of both Medicare Advantage and FFS. One commenter noted the MA encounter data may not be complete, having found in their analysis that some MA enrollees had inpatient, home health, and dialysis services not reported in the MA encounter data, and that it may be more appropriate to publish the data separately when there are sufficient sample sizes for each. Another commenter stated that it is not appropriate to report the aggregated data before reconciliation given that CMS has stated in other contexts that pre-reconciled encounter data is not always complete and accurate and referenced section 104 of MACRA as not being supportive of using unreconciled encounter data for this purpose.

Response: We disagree that section 104 of MACRA pertains only to items or services provided under Medicare part B. We refer the commenter to the CY 2024 PFS proposed rule (88 FR 52613 through 52615), where we discussed in detail the legal basis for using Medicare Advantage encounter data, including our interpretation of the scope of section 104 of MACRA.

Regarding the suggestion to report FFS and MA data separately, the proposal to include encounter data in the procedure count is intended to reduce the number of instances when data could not be reported due to small cell sizes. That is, to describe the types of Medicare covered services that a provider has performed as accurately as possible. Presenting separate counts of the services for a clinician would not aide this goal as, when separated, each count may be too small to be reported. We do not believe consumers would make a meaningful distinction between the two sources, nor is it clear why they should do so. For this reason, reporting counts separately may cause unnecessary confusion.

We have determined that reporting the aggregated data before reconciliation is appropriate for the following reasons. First, since the adoption of § 422.310(f)(3) to address concerns that the need to update or correct MA encounter data prior to the final submission deadline could mean that the MA encounter data was not sufficiently complete or fully reliable for public release, MA organizations' data submission processes have matured and are well-established. MA encounter data submissions have improved compared to the early years of encounter data collection, such that data are submitted more timely and comprehensively. In addition, CMS maintains several checks and edits in the encounter data system to minimize duplicate, incomplete or inappropriate data stored in the encounter data system. Moreover, because using the data submitted before reconciliation might result in the under counting of procedures (for example, if encounter data records are updated to include more procedures as the data becomes more complete), including procedures from encounter data records is not likely to misinform consumers.

We proposed to amend § 422.310(f)(3) to include an additional exception at paragraph (f)(3)(iv) that permits CMS to release aggregated risk adjustment data before reconciliation for the applicable payment year has been completed if CMS determines that releasing

aggregated data is necessary and appropriate for the purposes specified in § 422.310(f)(1)(vii). When releasing aggregated encounter data for Medicare program administration before risk adjustment reconciliation, CMS will evaluate the potential for the release to misinform or otherwise result in undesirable consequences. CMS will not release aggregated encounter data before risk adjustment reconciliation unless we have determined releasing the data is necessary and appropriate.

For the Compare tool, including utilization and limited provider-identifying data from the MA encounter data prior to risk adjustment reconciliation is necessary in that the Compare tool's utility is substantially improved by including the data, and as noted before, is appropriate because there is limited risk that consumers will be misinformed if the MA encounter data are included. Rather, including the encounter data will provide patients and caregivers with more useful and easily understandable information about procedures performed by providers in their search for a clinician.

After consideration of public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing both the proposal to incorporate Medicare Advantage data to FFS procedure volume counts and the proposal to amend § 422.310(f)(3) to add a new paragraph (iv) authorizing CMS to release aggregated risk adjustment data before the reconciliation for the applicable payment year has been completed if CMS determines that releasing aggregated data is necessary and appropriate for activities to support administration of the Medicare program, as proposed.

(d) Request for Information: Publicly Reporting Cost Measures

In the CY 2024 PFS proposed rule (88 FR 52615 through 52617), we included a Request for Information (RFI) to evaluate ways to publicly report MIPS eligible clinicians' performance on measures under the MIPS cost performance category (cost measures). Specifically, we sought public comment on ways to publicly report performance on cost measures on clinician and group profile pages and signaled our intent to propose in future rulemaking to publicly report cost measures in CY 2026 beginning with data from the CY 2024 performance period/2026 MIPS payment year. We believe public reporting of these data would assist patients and caregivers in making healthcare decisions.

Additionally, in the proposed rule, we noted that we have not publicly reported any cost measure information from the MIPS cost performance category since the inception of MIPS. (88 FR 52615). As one of the reasons for this current status, we stated ''[W]e have not had cost measures available for public reporting because of the COVID–19 Public Health Emergency (PHE), during which we reweighted the cost performance category to zero percent for MIPS eligible clinicians' final scores in the CY 2019 performance period/2021 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2019*.'' (88 FR 52615). As stated in section IV.A.4.g.(1) of this final rule, we clarify that the reweighting of the cost performance category to zero percent began in CY 2020 and not 2019.

We thank commenters for their feedback on this RFI, which may be considered in future rulemaking.

m. Overview of QP Determinations and the APM Incentive

(1) Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. The Secretary has also adopted the closely related goal that all people with Original Medicare will be in an accountable care relationship by 2030, so that their needs are holistically assessed and their care is coordinated within a broader total cost of care system. Our vision for increased participation among clinicians in Advanced APMs is driven by the belief that integrating individuals' clinical needs across a spectrum of providers and settings will improve patient care and population health.

As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs. For example, in this section, we had proposed to calculate QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. As discussed further in the proposal, we believe that this change would provide a more accurate measure of the actual engagement of individual clinicians participating in Advanced APMs. Accuracy is important for administration of the Quality Payment Program incentives and could help us better identify and understand the motivating factors and indicators of clinician readiness for greater adoption of Advanced APMs.

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any such snapshot date is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for eligible clinicians in an APM Entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List for more than one APM Entity, but who do not to achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual-level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

(2) Individual QP Determination

Under the current policy at § 414.1425(b), QP determinations for most eligible clinicians participating in Advanced APMs are made at the APM Entity-level. In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we contemplated that ''as with any group assessment, there will be some situations in which individual Threshold Scores would differ from group Threshold Scores if assessed separately. This could lead to some

eligible clinicians becoming QPs when they would not have met the QP Threshold individually (a 'free-rider' scenario) or, conversely, some eligible clinicians not becoming QPs within an Advanced APM Entity when they might have qualified individually (a dilution scenario).'' At that time, we believed that the benefits of performing QP determinations at the APM Entity-level for groups outweighed these potential scenario concerns. However, as we previously indicated in a Request for Information in the CY 2023 PFS proposed rule (87 FR 46337 through 46339), we started to believe that the effects of these types of scenarios, including effects that we had not intended or foreseen in the 2017 rule, were outweighing the benefits of performing QP determinations at the APM Entity-level.

First, it has been brought to our attention that our policy to conduct most QP determinations at the APM Entity-level may have inadvertently discouraged some APM Entities from including certain types of eligible clinicians, particularly in multi-specialty APM Entities such as ACOs, leading those clinicians to be excluded from participation in Advanced APMs. Because the APM Entity Threshold Scores (using the payment amount and patient count methods) that are used to make APM Entity-level QP determinations are based on an aggregate calculation across all eligible clinicians participating in the APM Entity group, eligible clinicians in the APM Entity group who furnish proportionally fewer services that lead to attribution of patients or payment amounts to the APM Entity are likely to lower the APM Entity's Threshold Score. Many Advanced APMs attribute patients to APM Entity groups based in part on the provision of primary care services, but not all eligible clinicians furnish primary care services. For example, primary care physicians may furnish proportionally more evaluation and management (E/M) (office visit) services, which, as we explain more in the next section, are frequently the basis for attribution of patients and payment amounts to the numerator of the APM Entity's Threshold Score, whereas specialist physicians may furnish proportionally more diagnostic tests and surgical procedures, which are not usually part of the attribution basis to the APM Entity.

We have received reports from Advanced APM participants and specialty societies that some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating Threshold Scores for APM Entity-level QP determinations. For reasons stated above, this action typically would lead to the exclusion of certain specialists from the APM Entity.

However, there are also benefits to the APM entity of including specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. For example, in both the Medicare Shared Savings Program and in models tested by the Innovation Center that meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is helpful for achieving this goal. A comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.[502] The methodology used in beneficiary assignment for the Shared Savings Program is deliberately constructed such that assignment is largely based on primary care, rather than specialty care, which results in specialists contributing proportionately less in terms of payment amounts and patient counts to the numerator of the ACO's Threshold Score calculation used for APM Entity-level QP determination. Moreover, it was not our intent to create a policy whereby eligible clinicians who see most or all their Medicare patients through an Advanced APM to remain unable to achieve QP status because the APM Entity with which they participate in the Advanced APM includes eligible clinicians who furnish very few services through the Advanced APM. It has always been one of the goals of the APM track of the Quality Payment Program for the availability of QP status to incentivize eligible clinicians to join Advanced APMs. But under our current policy to make most QP determinations at the APM Entity-level, there is the potential that eligible clinicians who individually fully engage with an Advanced APM may still be unable to earn QP status because it is calculated at the entity-level. We carefully considered our policy to make most QP determinations at the APM Entity-level, and believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and their full participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we stated that ''the statute consistently refers to an eligible clinician throughout section 1833(z) of the Act and clearly identifies that the QP determinations are to be made for an eligible clinician,'' then noted that ''in section 1833(z)(3)(B) of the Act, the definition of an eligible clinician includes a group of such professionals.'' While the statutory scheme provides for the flexibility to establish policies that apply for groups of eligible clinicians, it does not require that approach. When we proposed the policy to calculate Threshold Scores at the APM Entity-level, we based this policy in part on ''a premise that positive change occurs when entire organizations commit to participating in an Advanced APM and focusing on its cost and quality goals as a whole.'' While we continue to believe in this premise, we also recognize that, if APM Entities are removing or otherwise excluding eligible clinicians who may technically contribute less to the APM Entity-level Threshold Score, such actions may impede other worthy goals of the Advanced APM (such as increased care coordination among all providers caring for a patient), in which case that larger positive change we were seeking to foster is not being achieved.

Conversely, we are concerned that, under our current policy to make most QP determinations at the APM Entity-level, in situations where an APM Entity does achieve QP status, some eligible clinicians who furnish relatively fewer services through that APM Entity may receive a QP designation despite limited Advanced APM participation because their QP status was achieved as a result of the care furnished by other eligible clinicians in the APM Entity while their APM Incentive Payment is calculated based on all of the covered professional services that the individual eligible clinician furnishes during the base year, including services that were not furnished through an Advanced APM. Our policy to make most QP determinations at the APM Entity-level allows these anomalies because we calculate the Threshold Scores using the aggregate of payment amounts or patient counts for attributed patients based on Medicare Part B covered professional services furnished by all the eligible

[502] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/sharedsavingsprogram/about.*

clinicians in the APM Entity, whether an individual eligible clinician furnished a few or many such services. When an eligible clinician receives QP status for a year, the individual QP will receive an APM Incentive Payment for covered professional services across all their TINs in the base year. This can enable an eligible clinician with minimal Advanced APM participation to receive an APM Incentive Payment, which we do not believe aligns with the intent of the Quality Payment Program.

As a result, we proposed to amend § 414.1425(b) so that, beginning with the QP Performance Period for CY 2024, we would make all QP determinations at the individual-level. We note that we already make some QP determinations at the individual level. Under §§ 414.1425(b)(2) and 414.1425(c)(4) we currently calculate Threshold Scores at the individual level when the Advanced APM includes eligible clinicians only on an Affiliated Practitioner List, and further, under § 414.1425(c)(4) we also make QP determinations individually when the eligible clinician participates in multiple Advanced APMs and does not achieve QP status at the APM Entity-level. The proposal would not have changed our policy for these determinations but would have changed the way we make QP determinations for all other eligible clinicians. Under the proposal, we would have calculated Threshold Scores for QP determinations at the individual-level for each unique NPI associated with an eligible clinician participating in an Advanced APM. We would have calculated a Threshold Score for each NPI based on all covered professional services furnished across all Tax Identification Numbers (TINs) to which the eligible clinician has reassigned their billing rights. This individual Threshold Score would have provided a more specific measurement of each eligible clinician's participation in an Advanced APM. This proposed methodology would have ensured that those eligible clinicians who individually meet a QP threshold would receive QP status and its commensurate financial incentives and other benefits. At the same time, it would have removed the incentive for APM Entities to exclude certain types of eligible clinicians from their Participation Lists, because the success or failure of the APM Entity's eligible clinicians to reach QP status no longer would be collective. Because each eligible clinician on the APM Entity's Participation List would have been evaluated individually at the NPI level, eligible clinicians with lower proportions of payments and payments through the Advanced APM Entity would not have affected the QP status of other eligible clinicians on the APM Entity's Participation List.

We solicited comment on this proposal to amend § 414.1425(b) so that, beginning with the QP Performance Period for CY 2024, we would make all QP determinations at the individual-level.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported our approach to move to QP determinations at the individual-level. One of these commenters stated that certain APM entities may be excluding specialists in order to meet the QP threshold. This commenter supports efforts that promote accurate attribution and increased inclusion of specialists in APMs.

Response: We appreciate these comments.

Comment: Many commenters suggested we keep the APM Entity-level determinations for QP status. These commenters stated that the proposed change would make it very difficult for individual specialists to qualify for QP status. They also stated it would negatively impact specialists' participation in ACOs and APMs.

Response: We appreciate this comment and are taking these concerns seriously. As we detail in the previous section, while APM Entity-level determinations have been used in some circumstances since the beginning of the Quality Payment Program, we have identified conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and the goal to build participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care. We also believe that when QP determinations are made at the APM Entity level, some eligible clinicians who furnish relatively fewer of their services through that APM Entity would receive a QP status that is not reflective of their individual participation in the APM. The intent of our proposal was to mitigate these conflicting issues, which we recognize are difficult.

Comment: Many commenters either opposed or expressed concern with our proposed change to make QP determinations at the individual-level. These commenters stated they believed that even after making the change, our proposal would still serve as a disincentive for specialists to participate in Advanced APMs because it would still be difficult for them to achieve QP status. Several commenters stated the change would make it challenging or nearly impossible for specialists to achieve QP status. Some of these commenters also stated that making the change at the same time that QP thresholds are scheduled to increase could result in the opposite effect despite this change in policy, and make it still even more difficult for eligible clinicians to achieve QP status because they would be depending on their own participation activities. A few commenters expressed concern for the impact on certain other health professionals whose services are in part, or largely, billed incident to the services of a physician or practitioner with whom they work.

Response: We share the commenters' goal of making the participation of all health professionals in APMs as straightforward as possible, including specialists. Our proposal was intended to eliminate the incentive for APM Entities to reduce the number of certain specialists or exclude them simply for financial considerations as sometimes occurs under our current policy of making QP determinations at the APM Entity-level. In this scenario, specialists themselves often lack control over whether they have the option to participate in the APM Entity. While we understand that specialists face certain challenges in achieving QP status, and therefore, may choose not to engage with Advanced APMs, we believe it is important to avoid having their participation precluded or terminated by the APM Entity. In addition, the proposed change to make QP determinations at the individual level was intended to prevent the assignment of QP status to eligible clinicians who have furnished relatively few of their services through the Advanced APM.

We appreciate the commenters' point that the increase in the QP threshold, required by statute, will make it more challenging for certain eligible clinicians to achieve QP status, and we share the goal of allowing more specialists the opportunity to participate in Advanced APMs.

Comment: Several commenters stated that the proposal to make QP determinations at the individual level does not support transition to value-based arrangements and will negatively impact specialists in particular. A few commenters suggested that the proposal will negatively affect team-based care or care coordination needed for patient-centered care because the incentive will no longer encourage collaboration. A few commenters stated that the proposal is not consistent with providing accountable care. Several commenters

expressed concern that APM Entities, particularly ACOs, could become responsible for both coordinating MIPS measure submissions and administering an Advanced APM, which would be unduly burdensome. Several commenters also stated the proposed changes would increase the administrative burden on individual physicians, both specialists and primary care.

Response: We believe the current policy of making QP determinations at the APM Entity level creates conflicting incentives for APM Entities between their eligible clinicians' interest in achieving QP status, and their participation in an Advanced APM that includes providers that deliver an appropriate spectrum of services. We continue to be concerned that the current policy may have inadvertently created incentives for APM Entities to make decisions about which eligible clinicians to include in their organization based on the clinicians' likely contribution to achieving QP status rather than providing a comprehensive continuum of patient-centered care. We share the commenters' goal of designing payment incentives that support the delivery of the appropriate spectrum of services, allowing APM Entities to focus on what is best according to their Advanced APM's goals and their own organizational goals relating to the provision of patient-centered care.

Comment: Many commenters suggested that rather than moving to QP determinations at the individual level, CMS should make QP determinations at both the APM Entity level and the individual level, and then select the most favorable result for each clinician.

Response: We do not believe this approach would adequately address our concerns related to specialist participation in Advanced APMs. While such an approach might avoid decreases in nominal specialist participation, it would do so without encouraging more intensive Advanced APM participation by individual eligible clinicians, perpetuating the issue of QP status for eligible clinicians with minimal participation in an Advanced APM.

Comment: A few commenters suggested that not enough analysis has been conducted to estimate the impact of the proposal on clinicians participating in Advanced APMs and their QP status. These commenters suggested that more modeling and data analysis is needed to look at the impact it will have particularly on specialists before any policy change is implemented. Some of these commenters also suggested that the impact of the proposal on different types of specialties should be conducted. One commenter stated that our impact analysis did not breakdown the effect on different types of specialties.

Response: We have conducted an analysis to estimate the impact of this policy on QP status, and presented the results in the proposed rule that was available for commenters' review (88 FR 52718). In short, we anticipated that implementing our proposal would have led to a decrease in the total number of eligible clinicians achieving QP status but would reflect improved attribution of APM participation. We will consider conducting additional analysis in the future.

Comment: One commenter stated that certain specialists are restricted in the number of ACOs they are allowed to participate in, while others do not face such restrictions. That commenter suggested that CMS change the requirements and allow all types of specialists to participate in as many ACOs as they choose, which would help them to achieve QP status. That commenter also suggested that we work more closely with the Physician Technical Advisory Committee to design more models for specialist.

Response: The Quality Payment Program does not restrict the number or type of Advanced APMs in which specialists may participate. Different Advanced APMs are available to different provider types and patient populations, and provider options are available.

Although we continue to believe that our proposal to make all QP determinations at the individual level has strong merit, and that it would be broadly beneficial for APM Entities and eligible clinicians participating in Advanced APMs, after consideration of public comments, we are not finalizing our proposal for the CY 2024 QP performance period. Meaningful participation in Advanced APMs by a broad range of providers remains a goal that we share with many of the commenters, and we are committed to implement policies in the future that address undue QP determinations. However, we recognize the concerns raised by commenters, especially with respect to specialist participation in Advanced APMs, and that the changes in incentives and the interactions between them, combined with the anticipated statutory increases in QP thresholds, would create significant uncertainty among specialist communities. Given the comments we received expressing concerns about the potential impact of the new policies, we have concluded that it would be appropriate to conduct further consultation and analysis to evaluate the expected impact of these policies on eligible clinicians, especially specialists, participating in Advanced APMs. We plan to share our findings with interested parties when information becomes available so that the impact of the policies is better understood throughout the provider community. We will also consider the results of this analysis before potentially revisiting these proposed policy changes in future rulemaking. Our current policy of making QP determinations at the APM-Entity will remain in place for 2024.

(3) Payment Amount and Patient Count Methods

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457) we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''attributed beneficiaries'' to ''attribution-eligible beneficiaries, as defined at § 415.1305.[503]

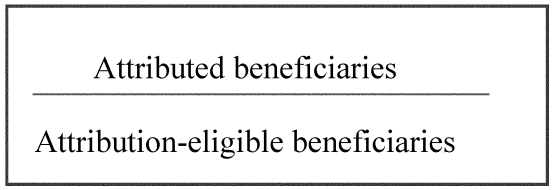
Attributed beneficiaries are those who are attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. Attribution-eligible beneficiaries generally are those who, during the QP Performance Period, meet six criteria specified in the definition of that term at § 414.1305 and described in section IV.A.4.m.(3) of the proposed rule.

When making QP determinations at the APM Entity-level or individual eligible clinician level, we begin by calculating Threshold Scores using the payment amount and patient count methods. These Threshold Scores are percentages based on the ratio of the payment amounts or patient counts for attributed beneficiaries to the payment amounts or patient counts for

[503] For technical information on the QP calculation methodology, see the ''QP Methodology Fact Sheet'' that we publish annually, which can be found as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip.*

attribution-eligible beneficiaries during the QP performance period. If the Threshold Score (using either the payment amount or patient count method) for the eligible clinician or APM Entity, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinician or clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) achieve QP status for such year.

FIGURE 3: QP Determination Calculation



The regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4), that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. This means that beneficiaries who have been attributed to one APM Entity and are thus barred under the terms of an Advanced APM from attribution to another APM Entity are removed from the denominator of both the payment amount method and patient count method in QP Threshold Score calculations for the APM Entity to which they cannot be attributed (in other words, we do not penalize an APM Entity in the QP Threshold Score calculation by including a beneficiary in its denominator when the terms of an Advanced APM do not permit such beneficiary to be attributed to such APM Entity).

(a) Attributed beneficiary:

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be attribution-eligible beneficiaries because the QP performance period does not coincide with the Advanced APM's performance period or attribution period, or for other reasons. There may be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. We exclude these beneficiaries from our Threshold Score calculations because they do not meet criteria to be attribution-eligible beneficiaries. Although APMs may have reconciliation processes in place to address changes in beneficiary status at various intervals, those processes do not necessarily coincide with the timeframe of QP determinations. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of attributed beneficiaries any beneficiaries who do not meet the criteria to be attribution-eligible beneficiaries at that point in time.

(b) Attribution-eligible beneficiary:

An attribution-eligible beneficiary is a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

Our stated intent when we finalized the definition of attribution-eligible beneficiary (81 FR 77451 through 77452) was to have a definition that would, for purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. For Most Advanced APMs, we chose to refer to E/M services because many Advanced APMs use E/M services to attribute beneficiaries to their participant APM Entities. Over time, we have updated the list of services that are considered to be E/M services for purposes of identifying attribution-eligible beneficiaries and have published this list as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip*.

We also included an exception in this sixth criterion to allow an alternative approach for Advanced APMs that do not base attribution exclusively on E/M services, and thus for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for and E/M

service. To date, we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify attribution-eligible beneficiaries for these Advanced APMs in the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip*.

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which attribution is based on services other than E/M services, the attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible beneficiary populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations is appropriate for such Advanced APMs. That said, our thinking at the time that we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. A key lesson we have learned over time as we have implemented the APM track of the Quality Payment Program is that, by affording sufficient flexibility within the program, we can both foster innovation in Advanced APMs and simplify our execution of the program. By having a more narrowly-defined default approach to beneficiary attribution (relying on E/M services), we frequently needed to exercise flexibility to determine an appropriate attribution methodology for Advanced APMs that fell into the exception, which meant that we identified several individually-tailored ways of performing the attribution methodology for each specific Advanced APM. As such, we have come to believe that application of our current regulations may result in increased complexity over time if, as we anticipate, Advanced APMs continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services.

Further, as we noted in our discussion of the proposal to calculate QP status at the individual NPI level, primary care practitioners generally furnish a higher proportion of E/M services than do specialists with the same beneficiary, and as for the Threshold Score calculations described previously, the emphasis on E/M services in our beneficiary attribution policy may have inadvertently encouraged APM Entities to exclude specialists from their Participation Lists. Under our current policy, if one or more eligible clinicians on the APM Entity's Participation List furnish covered professional services to a beneficiary but none of those services are among the E/M services we use for attribution, that beneficiary would not be attribution-eligible, and therefore, would not be included in our QP determination calculation, even though the beneficiary is actually receiving covered professional services from an eligible clinician on the APM Entity's Participation List.

We proposed to change the definition of ''attribution-eligible beneficiary'' at § 414.1305 so that a single definition using covered professional services will be applied regardless of the Advanced APMs in which the eligible clinician participates. We believe that this complemented our proposal to make QP determinations at the individual eligible clinician level. We are also concerned that retention of the current policy where E/M services are the default basis for attribution, and where special processes are required for Advanced APMs that use a different attribution basis, could result in a complex set of unique attribution approaches for Advanced APMs.

To create a uniform basis for beneficiary attribution across all Advanced APMs, we proposed to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying E/M services as the default attribution basis in the sixth criterion, we also eliminate the need for flexibility to use a different attribution basis that ties attribution-eligibility to a specific Advanced APM's attribution methodology. This would have simplified and streamlined the attribution methodology by making attribution based on covered professional services across all Advanced APMs

The proposal to base attribution eligibility on the receipt of a covered professional service also would have addressed the issue discussed earlier in this section whereby, under our current policy, beneficiary attribution for purposes of QP determinations is contingent upon the beneficiary receiving an E/M service, and as a result, beneficiaries who are actually being provided covered professional services by eligible clinicians on an APM Entity's Participation List are not attribution-eligible if none of the services provided are E/M services. Under our proposal, because we would consider all covered professional services for attribution, and not solely E/M services, we would have been able to include as attributed beneficiaries those who are receiving only other (non-E/M) covered professional services through the Advanced APM. We believe this proposal will result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflects eligible clinicians' actual participation in Advanced APMs.

We note that the proposal will not change the dates of service used for purposes of QP determinations. As such, QP determinations at any given snapshot date (March 31, June 30, and August 31, respectively) will be made by including all covered professional services furnished during the QP Performance Period for January 1 through the applicable snapshot date.

We believe that this change will more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made, particularly when considered in conjunction with the proposal to make QP determinations at the individual eligible clinician level. We further believe that this proposal will simplify and streamline QP determinations and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services.

We solicited comment on this proposal to modify the sixth criterion in the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include a beneficiary who has a minimum of one claim for a covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity at any determination date during the QP Performance Period.

We received public comments on the proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters expressed support for our proposal to change the definition of ''attribution-eligible beneficiary''. One of these commenters suggested we implement this change as a better alternative to our proposal to change QP determinations at the individual level.

Response: We appreciate the comments. We believe our proposal to change the definition of ''attribution-eligible beneficiary'' would complement QP determination at the individual level in terms of the policy objectives we are pursuing and would work best if it is implemented at the same time.

Comment: Two commenters noted that our proposal to change the definition of ''attribution-eligible beneficiary'' to base attribution on covered professional services would be applied regardless of the Advanced APMs in which the eligible clinician participates. These commenters expressed concern with making the change, particularly as we proposed to change QP determinations to the individual-level.

Response: We continue to believe the proposed change in the definition of ''attribution-eligible beneficiary'' would complement the change to make all QP determinations at the individual level. The change would expand the scope of services that could lead to attribution to include services that are more often furnished by specialists, which would lead to relatively higher Threshold Scores for specialist eligible clinicians. We also believe that the definition change would create a uniform, predictable, understandable basis for beneficiary attribution across all Advanced APMs. Further, it would simplify and streamline the attribution methodology by making attribution based on covered professional services across all Advanced APMs.

As with our proposal to make QP determinations at the individual level, we continue to believe that our proposal to modify the definition of ''attribution-eligible beneficiary'' has strong merit, but after consideration of public comments, we will not implement either of these proposals for the CY 2024 QP performance period. Modifying the definition of ''attribution-eligible beneficiary'' is closely tied to the proposal to make QP determinations at the individual level and we do not believe it would be productive to implement one without the other. Our current definition of ''attribution-eligible beneficiary'' will remain in place for 2024.

(4) QP thresholds and Partial QP thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance year 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance year 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

Section 4111(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) amended section 1833(z)(2) of the Act by extending for payment years 2024 and 2025 (performance years 2022 and 2023) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2024 (performance year 2022) to payment year 2025 (performance year 2023). Additionally, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to require that, for payment year 2025, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. As such, the Medicare Option QP thresholds for payment year 2025 will remain at 50 percent for the payment amount method and 35 percent for the patient count method. Section 4111(b) of the CAA, 2023, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2025 the Partial QP thresholds that were established since payment year 2021 under the Medicare Option. Therefore, the Partial QP thresholds for payment year 2025 (performance year 2023) will remain at 40 percent for the payment amount method and 25 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for payment year 2025 (performance year 2023) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2025 will be 40 percent for the payment amount method and 25 percent for the patient count method. To become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2025 (performance year 2023), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option to become a QP is 25 percent for the payment amount method or 20 percent for the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 20 percent for the payment amount method or 10 percent for the patient count method.

To conform our regulation with the amendments made by the CAA, 2023, we proposed to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with the CAA, 2023 amendments.

The proposed revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds are as follows:

- Paragraph (a)(1)(iv) to state that for 2025 the amount is 50 percent, and paragraph (a)(1)(v) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (a)(2)(iv) to state that for 2025 the amount is 40 percent, and paragraph (a)(2)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(3)(iv) to state that for 2025 the amount is 35 percent, and paragraph (a)(3)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(4)(iv) to state that for 2025 the amount is 25 percent, and paragraph (a)(4)(v) to state that for 2026 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(A) to state that for 2021 through 2025 the amount is 50 percent, and paragraph (b)(1)(i)(B) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(A) to state that for 2021 through 2025 the amount is 40 percent and paragraph (b)(2)(i)(B) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (b)(3)(i)(A) to state that for 2021 through 2025 the amount is 35 percent, and paragraph (b)(3)(i)(B) to

state that for 2026 and later, the amount is 50 percent.

- Paragraph (b)(4)(i)(A) to state that for 2021 through 2025 the amount is 25 percent, and paragraph (b)(4)(i)(B) to state that for 2026 and later, the amount is 35 percent.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

TABLE 61: QP Threshold Score Updates

Medicare Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Payment Amount Threshold	50		50		50		75	
Partial QP Payment Amount Threshold	40		40		40		50	
Medicare Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35		35		35		50	
Partial QP Patient Count Threshold	25		25		25		35	
All-Payer Combination Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

(5) APM Incentive Payment

Prior to amendments made by the CAA, 2023, section 1833(z)(1) of the Act provided for APM Incentive Payments for eligible clinicians who are QPs with respect to a year in each payment year from 2019 through 2024. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is a QP for such year, there is an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year (which we defined as the ''base year''). Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act).

In the CY 2017 Quality Payment Program final rule (81 FR 77445), we established a policy that, beginning with the 2017 QP Performance Period, the QP Performance Period would be the calendar year that is 2 calendar years before the payment year for the APM Incentive Payment. Thus, we established that the first QP Performance Period would begin on January 1, 2017, the first ''base year'' (established at 81 FR 77481 and 77482) for which we would use claims for professional services to calculate the 5 percent APM Incentive Payment amount would be in 2018, and the first payment year for the APM Incentive Payment would be in 2019 as required by the statute. Under our previously finalized policies, the QP Performance Period, base year, and payment year continue in this fashion on a rolling basis through payment year 2024, which was the final year for which the statute authorized an APM Incentive Payment. In the CY 2023 PFS final rule (87 FR 70114 through 70116), we explained that, beginning in payment year 2025, which correlates with performance year 2023, the statute

did not provide for any type of payment incentive for eligible clinicians who become QPs.

Section 4111(a) of the CAA, 2023 amended section 1833(z)(1) of the Act to provide that eligible clinicians who are QPs with respect to payment year 2025 (performance year 2023) will receive an APM Incentive Payment equal to 3.5 percent of their estimated aggregate payment amounts for Medicare Part B covered professional services in the preceding year. In effect, this statutory change extends the APM Incentive Payment for one additional year, at a new percentage of 3.5 percent rather than 5 percent.

Accordingly, we proposed to incorporate the change made by the CAA, 2023, by amending the regulation text at § 414.1450 to add the payment year 2025 APM Incentive Payment amount of 3.5 percent of covered professional services payments. We proposed to amend paragraph (b)(1) to state that the amount of the APM Incentive Payment for payment years 2019 through 2024 is equal to 5 percent and, for payment year 2025, 3.5 percent, of the estimated aggregate payments for covered professional services furnished during the calendar year immediately preceding the payment year.

We also noted that the CAA, 2023, did not extend the APM Incentive Payment beyond payment year 2025. Beginning for the 2026 payment year, which relates to the 2024 QP Performance Period, section 1848(d)(1)(A) of the Act specifies that there shall be two separate PFS conversion factors, one for items and services furnished by a QP (the qualifying APM conversion factor), and the other for other items and services (the nonqualifying APM conversion factor). Each conversion factor will be equal to the conversion factor for the previous year multiplied by the applicable update for the year specified in section 1848(d)(20) of the Act. The update specified for the qualifying APM conversion factor will be 0.75 percent, while the update for all others will be 0.25 percent.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

(6) Targeted Review of QP Determinations

In the CY 2021 PFS final rule (85 FR 84952), we finalized a policy to provide an opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made that could have resulted in the omission of an eligible clinician from a Participation List used for purposes of QP determinations, and for us to review and make corrections if warranted. We also finalized that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period. We noted that, consistent with section 1833(z)(4) of the Act, and as provided under § 414.1455(a) of our regulations, there is no right to administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the determination that an eligible clinician is a QP or Partial QP under § 414.1425, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

In the CY 2021 PFS final rule (85 FR 84953), we finalized our proposal to align the timing and procedures for this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities.

In light of the transition in incentives for eligible clinicians who are QPs for a year, as provided in statute, from an APM Incentive Payment to the differentially higher PFS conversion factor beginning with the 2024 QP performance period and 2026 payment year, we proposed at section IV.A.4.j. of the proposed rule to adjust the Targeted Review period in order to meet operational timelines to ensure that we can meet statutory requirements for the application of the differential conversion factors, and the resulting differential PFS payment rates, to eligible clinicians who are, and are not, QPs for the year. As discussed in section IV.A.4.j. of the proposed rule, we believe that adjusting the Targeted Review period will enable us to meet our statutory obligation to apply the differentially higher QP conversion factor beginning on January 1 of each payment year beginning with CY 2026. We encourage readers to review section IV.A.4.j. of the proposed rule.

n. Advanced APMs

(1) General Overview

In this section, we address policies regarding several aspects of the Advanced APM criterion for CEHRT use at § 414.1415(a). We proposed to amend the definition of CEHRT at § 414.1305 that applies to Advanced APM participants, and to modify the Advanced APM CEHRT use criterion at § 414.1415(a) to recognize the CEHRT that is relevant to the clinical practice of participants in the Advanced APM.

We believe the Quality Payment Program must be responsive to, and supportive of, innovation in technology and in a provider organization. It is our goal to encourage not only provider ownership of health information technology (health IT), but full adoption and integration of the most advanced health IT into clinical practice. We developed these proposals to modify the CEHRT that is required for Advanced APMs with this goal in mind, and we will continue to monitor advancements and opportunities in the health IT space to better prepare and align our program and APMs with the most cutting-edge technologies and innovative provider arrangements, for the benefit of APM Entities and eligible clinicians, and the Medicare beneficiaries we serve.

(2) Background

(a) Advanced APM CEHRT Use Criterion

Under section 1833(z)(3)(D)(i)(I) of the Act, Advanced APMs are those APMs that (among other things) require participants to use CEHRT. We codified this CEHRT use criterion for Advanced APMs at § 414.1415(a)(1). As such, the CEHRT use criterion under § 414.1415(a)(1) states that, to be an Advanced APM, the APM must require at least a certain percentage of eligible clinicians in each participating APM Entity group, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers. In the CY 2017 Quality Payment Program final rule, we specified at § 414.1415(a)(1)(i) that an Advanced APM is one that requires at least 50 percent of eligible clinicians in each APM Entity group to use CEHRT to document and communicate clinical care to their patients or health providers (81 FR 77410). In the CY 2019 PFS final rule (83 FR 59918), we amended § 414.1415(a)(1) to increase the required percentage from 50 percent to 75 percent.

(b) Definition of CEHRT

Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

In implementing the definition of CEHRT at § 414.1305 for the MIPS track of the Quality Payment Program, we adopted the definition of CEHRT used

for the Medicare EHR Incentive Program (also known as ''Meaningful Use'') at § 495.4 (81 FR 77211 through 77213). In the CY 2017 Quality Payment Program final rule, we explained that we intended ''to maintain continuity for MIPS eligible clinicians and health IT vendors who may already have CEHRT or who have begun planning for a transition to technology certified to the 2015 Edition based on the definition of CEHRT finalized for the EHR Incentive Programs in the 2015 EHR Incentive Programs final rule'' and ''to maintain consistency with the EHR Incentive Programs CEHRT definition at 42 CFR 495.4'' (81 FR 77212).

For the Advanced APM track of the Quality Payment Program, we in turn adopted the definition of CEHRT for MIPS under § 414.1305 (81 FR 77409 through 77410). We explained that applying the same definition of CEHRT for purposes of both the MIPS and Advanced APM tracks of the Quality Payment Program would reduce administrative costs and confusion among eligible clinicians and maintain consistency across programs, permitting eligible clinicians to use shared CEHRT systems to participate in either MIPS or Advanced APMs (81 FR 77409 through 77410).

Consequently, the MIPS and Advanced APM tracks of the Quality Payment Program share the same definition of CEHRT at § 414.1305. Since the CY 2019 performance period, this has generally meant EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and that has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition of CEHRT at § 414.1305. The currently applicable definition of CEHRT at § 414.1305 specifically requires that the EHR technology has been certified to the following 2015 Edition health IT certification criteria: (1) family health history at 45 CFR 170.315(a)(12); (2) patient health information capture at 45 CFR 170.315(e)(3); and (3) as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) and clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) (and optionally (c)(4)) and can be electronically accepted by CMS.

Because our definition of CEHRT at § 414.1305 ultimately derives from the definition of CEHRT used for the Meaningful Use Program, our Advanced APMs have required their participants to use CEHRT that is capable of meeting all requirements of a qualified EHR. As such, Advanced APMs generally require participants to use CEHRT that meets requirements for the 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. When we adopted the same definition of CEHRT at § 414.1305 for purposes of MIPS and Advanced APMs in the CY 2017 Quality Payment Program final rule, we acknowledged that such a policy may include some requirements not directly applicable to the APM Entities' practice. Specifically, we stated at that time that ''we understand this proposed CEHRT definition may include some EHR functionality used by MIPS eligible clinicians which may be less relevant for an APM participant and likewise APM participants may use additional functions that are not required for MIPS participation'' (81 FR 77409). At the time, we reasoned that ''using the same CEHRT definition for both MIPS and Advanced APMs would allow eligible clinicians to continue to use shared EHR systems and give eligible clinicians flexibility of participation as a MIPS eligible clinician or an eligible clinician in an Advanced APM without needing to change or upgrade EHR systems'' (81 FR 77409).

Although we acknowledged that this CEHRT definition may impose more rigorous requirements on APM participants than necessary, we nonetheless maintained that ''we generally want APMs to retain the flexibility to require activities performed using CEHRT that may vary from those prescribed under the advancing care information performance category in MIPS'' (81 FR 77412).[504] We also recognized that aligning the CEHRT definition for Advanced APMs with MIPS ''would go beyond what the statute requires'' (81 FR 77412). When we adopted the CEHRT definition for MIPS and Advanced APMs, one commenter suggested that our proposed CEHRT criterion for Advanced APMs was narrow, and that ''a strong, broad health IT infrastructure should be a key element used to identify Advanced APMs rather than the narrow proposed CEHRT criteria'' (81 FR 77410). We agreed that ''Advanced APMs need a strong health IT infrastructure as a foundation for communicating and delivering comprehensive and coordinated care to their patients,'' but at that time we wanted to prioritize continuity between the two tracks of the Quality Payment Program to maximize flexibility for eligible clinicians. However, we indicated that we would be prepared to update this definition as needed in the future.

(3) Proposal To Update CEHRT Definition and CEHRT Use Criterion for Advanced APMs

After several years of experience with the uniform definition of CEHRT for purposes of MIPS and Advanced APMs and based on input we have received from interested parties, we now believe that the standard for CEHRT use for Advanced APMs may have been unnecessarily burdensome, imposing unwarranted barriers to organization of and participation in Advanced APMs, and not clinically relevant for many prospective and current participants in Advanced APMs. As previously discussed, our policy at § 414.1415(a)(1)(i) currently requires that at least 75 percent of eligible clinicians in each participating APM Entity group, and for APMs in which hospitals are APM Entities, each hospital, to use CEHRT, as defined in § 414.1305, to document and communicate clinical care to their patients or health care providers. By referring in the Advanced APM CEHRT use criterion to CEHRT, as defined in § 414.1305, Advanced APMs have required participants to adopt and implement health IT that is capable of meeting all requirements of a qualified EHR, which means CEHRT that meets all requirements for 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. We have heard from many interested parties that our CEHRT use requirements for Advanced APMs are

[504] Section 1848(q)(2)(A)(iv) and (B)(iv) of the Act requires that the Secretary assess MIPS eligible clinicians' performance with respect to the ''meaningful use of certified EHR technology'' in accordance with the requirements set forth at section 1848(o)(2) of the Act as one of the four performance categories for MIPS. In the CY 2017 Quality Payment Program final rule, we named this required MIPS performance category the ''advancing care information performance category.'' (81 FR 77010). We have since renamed this MIPS performance category, requiring the meaningful use of CEHRT, as the ''Promoting Interoperability performance category.'' (85 FR 84820 through 84821).

falling short of some of our intended goals. Specifically, we have heard from many interested parties that our current requirements for use of CEHRT have led Advanced APMs to apply an inflexible standard that does not allow them to take into account whether certain CEHRT modules are relevant for, and applicable to, the specific clinical practice areas of their intended or actual participants. By placing a broad set of requirements for use of CEHRT, particularly regarding the criteria the health IT must be certified as meeting to satisfy our definition of CEHRT at § 414.1305, interested parties report that we are needlessly burdening some potential and actual participants in Advanced APMs because they must adopt health IT modules that are not always clinically relevant across provider types that would participate in an Advanced APM. Specifically, interested parties noted that the CEHRT definition used for our Advanced APM criterion means that the APM must require participants to use health IT certified as meeting criteria necessary to report on objectives and measures of the MIPS Promoting Interoperability performance category, even when such health IT is not clinically relevant for or applicable to APM participants' practice, is needlessly burdensome and a barrier to innovation and participation in APMs. To support their position, interested parties noted as an example that application of our current Advanced APM CEHRT use criterion and associated CEHRT definition has required specialists in the Kidney Care Choices (KCC) Model or providers in the ACO Realizing Equity, Access, and Community Health (REACH) Model to purchase certified Health IT Modules beyond those required as part of the 2015 Edition Base EHR definition at 45 CFR 170.102 that are not immediately necessary or applicable to their clinical practice.

We have learned that Advanced APMs have not had the flexibility to require certified health IT that is tailored to their specific participants' practice areas. Likewise, we could envision a scenario where, to comply with the Advanced APM CEHRT use criterion under our current policy, an APM or APM Entity would exclude from participation specialists or other eligible clinician types, such as pathologists, for whom compliance with our current CEHRT requirements beyond the Base EHR definition would be burdensome and beyond the scope of their typical practice, even though participation of such eligible clinicians would be relevant and beneficial to the goals of the APM.

For Advanced APMs, we believe that it is important both to apply a rigorous standard for use of CEHRT and to allow sufficient flexibility to Advanced APMs to specify CEHRT modules that are clinically relevant for their participants. We believe that our current CEHRT use requirements meet the former goal (application of a rigorous standard), but not the latter (allowing sufficient flexibility).

Further, our current CEHRT use criterion specifies that 75 percent of participants in the APM must use CEHRT as defined in § 414.1305 and allows for 25 percent of participants to not have or use CEHRT. This policy establishes a minimum percentage of Advanced APM participants that must use CEHRT, but without consideration of which eligible clinicians in each participating APM Entity (or hospital) must use CEHRT, or whether it is clinically appropriate for any of those eligible clinicians to not use CEHRT. As such, this policy could allow eligible clinicians who could and should be using CEHRT to forego CEHRT use solely because enough of their colleagues are using CEHRT to meet the requirement of the Advanced APM. Additionally, we have heard from interested parties that, for most Advanced APM participants, CEHRT use among eligible clinicians is close to 100 percent. Given this information and the fact that the 75 percent CEHRT use standard has been in effect for almost five years, we believe it is appropriate to re-evaluate our approach to the application of the CEHRT use requirement to Advanced APMs and their participants. We want to maintain the rigor of our CEHRT use criterion for Advanced APMs while providing Advanced APMs flexibility to require CEHRT use that is applicable for the practice areas of their participants and their eligible clinicians. Further, we believe any exceptions to CEHRT use that are permitted under the Advanced APM should be based on clinical appropriateness, rather than on generalized application of percentages.

First, we proposed to amend the definition of CEHRT at § 414.1305 by adding a new paragraph (3) to specify that, for purposes of the Advanced APM CEHRT use criterion under § 414.1415(a)(1), beginning with CY 2024, CEHRT means EHR technology certified under the ONC Health IT Certification Program that meets: (1) the 2015 Edition Base EHR definition, or any subsequent Base EHR definition (as defined in at 45 CFR 170.102); and (2) any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice areas involved, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

We believe our proposal to revise the definition of CEHRT for Advanced APMs at § 414.1305 would provide flexibility to each APM to determine what CEHRT functionalities are relevant to the model and its participant APM Entities and eligible clinicians. We believe that providing Advanced APMs with the greater flexibility permitted by the statute with respect to requiring CEHRT use will foster innovation in model design and diversity in APM participation. Specifically, we believe our amendment to the CEHRT definition at § 414.1305 will facilitate innovation in APM design, and enable a broad range of participants and their eligible clinicians to meet Advanced APM CEHRT use requirements by adopting health IT that satisfies the 2015 Edition Base EHR definition, or subsequent Base EHR definition, at 45 CFR 170.102 and is certified as meeting other ONC health IT certification criteria adopted, or updated in 45 CFR 170.315, as is clinically relevant to their practice, without unnecessarily obtaining other health IT, such as the health IT necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category.

We note that participation in an Advanced APM does not automatically exclude eligible clinicians from MIPS. Eligible clinicians in an Advanced APM who do not achieve Qualifying APM Participant (QP) status or Partial QP status, or who are not otherwise excluded or exempt from MIPS (for example, on the basis of low Medicare volume, new Medicare enrollment, or eligible clinician type), remain subject to the MIPS reporting requirements and payment adjustment. Accordingly, under our proposal, eligible clinicians in Advanced APMs will still need to be prepared to report to MIPS, including using CEHRT as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, in the event that they do not achieve QP or Partial QP status or are not excluded or exempt from MIPS on another basis.

In section IV.A.4.f.(4) of the proposed rule, we also proposed other

modifications to the CEHRT definition at § 414.1305 to be more flexible in reflecting any changes ONC may make to its Base EHR definition, certification criteria, and other standards for health IT at 45 CFR part 170. Our proposed amendment to the CEHRT definition under paragraph (3) at § 414.1305 for Advanced APMs is consistent with our other amendments to the CEHRT definition, which we are finalizing as set forth in section IV.A.4.f.(4) of this final rule.

Second, we proposed to amend our current Advanced APM CEHRT use criterion at § 414.1415(a)(1). Specifically, we proposed to amend the regulation to end the current 75 percent CEHRT use requirement at § 414.1415(a)(1)(i) with the CY 2023 QP performance period. Then we proposed to add a new paragraph at § 414.1415(a)(1)(iii) to specify that, to be an Advanced APM, the APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use CEHRT that meets our proposed new paragraph (3) of the CEHRT definition at § 414.1305. In essence, we proposed to no longer specify a minimum number of eligible clinicians that an Advanced APM must require to use CEHRT, and instead, simply specify that the Advanced APM must require all participating eligible clinicians to use CEHRT that meets our proposed modified, and more flexible, definition. We also proposed to revise § 414.1415 by making non-substantive technical edits to paragraphs (a)(1)(i) and (ii) to improve clarity.

This policy, which we proposed and are finalizing with modification as discussed herein, is consistent with section 1833(z)(3)(D)(i)(I) of the Act, which generally requires that Advanced APMs require their participants to use CEHRT as defined in section 1848(o)(4) of the Act. We believe this amendment to the Advanced APM CEHRT use criterion will further enhance innovation in Advanced APM development and diversity in participation, allowing for novel APM Entity compositions, because Advanced APM participants will no longer have to concern themselves with the percentage of eligible clinicians that meet our current CEHRT requirements. We further believe that, under our more flexible CEHRT definition and Advanced APM CEHRT use criterion, Advanced APMs could create their own CEHRT use requirements, potentially beyond what we currently require, tailored to the various types of clinicians and practice areas the Advanced APM intends to include in its model. We believe our proposal will permit Advanced APMs to recruit and retain participants that represent a variety of practice types, and to require different types of EHR technologies certified under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, or subsequent Base EHR definition, at 45 CFR 170.102 and additional ONC health IT certification criteria adopted and updated in 45 CFR 170.315 as specifically applicable to different types of clinical practice.

We sought comment on this proposal.

The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for the proposal to amend the definition of CEHRT at § 414.1305, noting their appreciation for the greater flexibility it would afford, as well as for making permanent references to ONC regulations such that CMS rulemaking will not be necessary to incorporate future updates to ONC health IT certification criteria within the definition of CEHRT.

Response: We thank commenters for their support.

Comment: One commenter expressed concern about changing the CEHRT definition to be ''edition-less,'' citing concerns with respect to smaller practices being able to meet deadlines for updating EHRs. This commenter noted they believe additional flexibility is warranted to give time to these practices to keep up with CEHRT requirements as they change. Another commenter expressed concern about the timing of our proposal to modify our CEHRT definition with respect to ONC's proposed rule that proposes to modify definitions and certification requirements in ONC's regulations that our CEHRT definition references and recommended that we wait until ONC's rule is finalized before modifying our definition.

Response: We appreciate a desire to meet the needs of smaller practices. We note that section 1833(z)(3)(D)(i)(I) of the Act specifies that Advanced APMs are those that require participants to use CEHRT, and that the definition of CEHRT references health IT certification criteria established by ONC, which in turn is implemented under regulations promulgated by ONC. The CEHRT definition used for purposes of the Advanced APM criterion must inherently, and at a minimum, require technology to meet certification criteria established by ONC. As such, we believe our regulatory definition of CEHRT must be flexible to reflect any changes ONC proposes and finalizes regarding its own definition of Base EHR and its certification criteria to ensure our Advanced APM standard aligns with ONC's regulations as required by our statute. We believe that waiting to revise our CEHRT definition, based on whether ONC finalizes its proposals (88 FR 23757 through 23762), would increase regulatory burden and complexity. Rather, this final policy would incorporate the timelines ONC adopts through notice and comment rulemaking for health IT developers to update and provide certified technology to their customers. While our proposals have been informed by the ''edition-less'' approach and related proposals described by ONC (88 FR 23757 through 23762), we believe that our final policies will simplify participation and reduce confusion for CMS program participants whether or not ONC finalizes its proposals. However, we do recognize that smaller practices may face additional burden to keep up with changes, and we will continue to examine the ability of small practices to meet CEHRT requirements in Advanced APMs, including through the examining the potential use of flexibilities described in greater detail below.

Comment: One commenter supported our proposal to replace the 75 percent CEHRT use threshold with a requirement that Advanced APMs require the use of CEHRT.

Response: We thank the commenter for their support.

Comment: Most commenters opposed our proposal to remove the current 75 percent CEHRT use requirement at § 414.1415(a)(1)(i) and requested that we retain this aspect of the current regulations, noting that the threshold provides flexibility, and citing concerns that requiring Advanced APMs to require all eligible clinicians to have CEHRT is unforgiving. One commenter cited that a single clinician could fail to use CEHRT for reasons such as ''travel, sickness, or injury,'' and expressed concern that this could make the entire Advanced APM fail to meet our proposed standard. One commenter encouraged us to instead look at data other Federal Agencies collect on the levels of CEHRT adoption, such as ONC's ''Insights Condition'' data from its most recent proposed rule. One commenter indicated that we should be encouraging clinicians not currently using CEHRT to join APMs. One commenter specifically expressed concern relating to the ability of smaller practices to participate in Advanced APMs.

Response: We understand commenters' concerns that requiring all eligible clinicians to use CEHRT is an

exacting standard on its face. We believe that the flexibilities introduced in our proposed amendment to the definition of CEHRT at § 414.1305 would allow Advanced APMs to establish requirements for CEHRT use that are reasonable expectations for Advanced APM participants. As discussed in the proposed rule, our original definition of CEHRT was one that we recognized would not necessarily be relevant to all practice areas. Under the new definition, Advanced APMs can consider clinical practice when establishing their CEHRT use requirements, and thereby establish a standard that would be reasonable to expect participating APM Entities and eligible clinicians in relevant clinical practice areas to be capable of meeting.

As we discussed in the proposed rule, the use of a CEHRT use threshold without consideration of which eligible clinicians in each participating APM Entity (or hospital) must use CEHRT, or whether it is clinically appropriate for any of those eligible clinicians to not use CEHRT, would potentially allow for eligible clinicians who could and should be using CEHRT to forego CEHRT use solely because enough of their colleagues are using CEHRT to meet the requirement of the Advanced APM. We note that section 1833(z)(3)(D)(i)(I) of the Act does not specify the use of any threshold for purposes of the Advanced APM CEHRT use criterion, whereas the statute does specify the use of, and sometimes also level for, thresholds for other provisions (such as the level of Advanced APM participation necessary to achieve QP status). After several years of experience applying the threshold-based CEHRT use criterion, we do not believe it is serving as a sufficiently meaningful approach for measuring eligible clinicians' adoption of clinically appropriate CEHRT.

In describing the proposal, we stated that we expect Advanced APMs to require all eligible clinicians to use CEHRT (88 FR 52627). Specifically, our proposal was that Advanced APMs would have to require participants to use CEHRT that meets the (current or subsequent) Base EHR definition at 45 CFR 170.102 and could require CEHRT to meet additional certification criteria under 45 CFR 170.315 as clinically appropriate. As further outlined below in this response, we believe that it is reasonable to expect all Advanced APM participants to have technology that is capable of meeting at least the Base EHR definition. However, we do not expect that this would occur entirely without exceptions across all possible circumstances. As we stated in the proposed rule, we believe that any exceptions permitted under the Advanced APM should be based on clinical appropriateness, rather than the provision of a generalized application of percentages to CEHRT use (88 FR 52626).

We also note that we apply the Advanced APM criteria and identify Advanced APMs before the beginning of each QP performance period based on the structure of the APM and, in the case of CEHRT use, what health IT technology the APM requires of its participant APM entities and eligible clinicians. We would not anticipate removing Advanced APM status from an APM under circumstances such as a single eligible clinician failing to use CEHRT; and we recognize that Advanced APMs may provide for, and have reasons to apply, exceptions from time to time. In the example of travel, illness, or injury, that one commenter cited, an Advanced APM may have in place and choose to apply an exception based on significant hardship or an Extreme and Uncontrollable Circumstance (EUC) policy, and we would work with that Advanced APM with respect to the application of such an exception to the Advanced APM criteria, including CEHRT use. For example, in the spring of 2020, we recognized that, as part of CMS's COVID–19 response to reduce burden or ease financial strain, Advanced APMs might apply exceptions to their requirements to the extent permitted by the terms of each Advanced APM, and did not consider removing Advanced APM status on the basis of any such decisions that may have affected one or more of the Advanced APM criteria. If a circumstance were to arise in which we were to determine that a particular Advanced APM or its participants were not in compliance with one of the Advanced APM criteria, including the CEHRT use criterion, we first would seek to identify steps for the Advanced APM and/or its participants to remediate the identified problem such that Advanced APM status could be maintained. In the event that we determine that the removal of Advanced APM status would be necessary, such a removal would apply to future performance years and would involve a process for notice to its participants and the public that the APM no longer would be an Advanced APM for the upcoming performance period.

Additionally, as one commenter noted, CEHRT may be a barrier for smaller practices to participate in Advanced APMs. We acknowledge that this may be the case, and will consider whether greater flexibility in our CEHRT use criterion is warranted, for example, if a particular APM were designed to include smaller practices and identified a reason why time- or situation-limited exceptions to the CEHRT use criterion for those small practices may be appropriate as a matter of the APM's design. In general, we believe that taking specific circumstances into account in the context of APM design is a better approach for CEHRT use requirements in contrast to applying a blanket threshold, which leaves room for eligible clinicians in Advanced APMs to not engage meaningfully in CEHRT use for no real reason. To the extent that we identify in the future that further rulemaking may be warranted or necessary to establish specific criteria for exceptions, we would update our rules accordingly through notice-and-comment rulemaking. At this time, we believe that the Advanced APM should lead the way in identifying the potential appropriateness of any exceptions, and we would consider those exceptions when determining or reviewing Advanced APM status.

We expect that Advanced APMs readily can require that their participants use CEHRT that meets at least the 2015 Edition Base EHR definition, or subsequent Base EHR definition at 45 CFR 170.102, because these participants would use CEHRT that meets at least this Base EHR definition under several Medicare programs. First, as we noted in the CY 2024 PFS proposed rule, the current Advanced APM CEHRT use criterion is that the APM must require 75 percent of eligible clinicians participating in the APM to use CEHRT that meets both the Base EHR definition at 45 CFR 170.102 and the ONC health IT certification criteria at 45 CFR 170.315 to satisfy Meaningful Use requirements and MIPS Promoting Interoperability performance category requirements (88 FR 52626). Second, MIPS eligible clinicians, who may also participate in an Advanced APM, use CEHRT (§ 414.1375(b)(1)) as defined at § 414.1305, meeting both the Base EHR definition at 45 CFR 170.102 and specific certification criteria at 45 CFR 170.315 for reporting applicable measures and activities, for purposes of the MIPS Promoting Interoperability performance category. Although these requirements vary with respect to what additional ONC health IT certification criteria at 45 CFR 170.315 the CEHRT must meet, both the Advanced APM CEHRT use criterion and MIPS expect eligible clinicians to use CEHRT that at least meets the Base EHR definition at 45 CFR 170.102. As discussed herein, we are finalizing our proposal to revise

the definition of CEHRT that Advanced APMs must require to mean CEHRT that meets the Base EHR definition at 45 CFR 170.102 and any additional ONC health IT certification criteria set forth in 45 CFR 170.315 that the Advanced APM determines applicable, considering certain factors. Given this revision, we believe that Advanced APM participants who are using CEHRT already under the more strenuous requirements should be able to ensure their CEHRT continues to meet the Base EHR definition at 170.102.

The only gap we expect in CEHRT use are Advanced APM participants who have not been required to use CEHRT to date either under MIPS, such as due to application of exceptions or reweighting policies, or the Advanced APM CEHRT use criterion at § 414.1415(a)(1)(i). However, as we noted in the CY 2024 PFS proposed rule, we have heard from interested parties that CEHRT use among eligible clinicians in Advanced APMs is close to 100 percent (88 FR 52626). Therefore, we believe that given the opportunity for a transition year as described further below in this section, and our ability under the revised definition to consider a potential exception that a particular Advanced APM believes is clinically appropriate, as a general matter we can reasonably expect that by 2025, all eligible clinicians participating in Advanced APMs should have CEHRT that meets at least the Base EHR definition.

We believe that adopting a flexible definition of CEHRT, as proposed, would permit Advanced APMs to select more specific CEHRT requirements (for instance, specifying which certification criteria under 45 CFR 170.315 should be incorporated into CEHRT requirements beyond the applicable Base EHR definition) that their participating eligible clinicians must meet and use to document and communicate their clinical care to patients and other health care providers. CMS collaborates with ONC regarding certification criteria for health IT referenced in the CEHRT definition, including relevant capabilities for Advanced APMs, and we agree that the examination of available data from ONC (and other Federal partners) is relevant in decision-making; that is, we believe that these types of data are most useful when considered at the individual Advanced APM level, as the purpose of a specific Advanced APM and the practice areas of its participants will be relevant drivers of the specific ONC health IT certification criteria required by that Advanced APM, and is likely to be different between Advanced APMs.

Comment: One commenter expressed support for increasing the current 75 percent threshold to 100 percent ''over the next few performance years,'' but expressed concern that removing the 75 percent threshold by QP performance period 2024 does not give participants sufficient time to work with or remove eligible clinicians that do not currently use CEHRT. This commenter notes that CMS's deadline to remove participating TINs from the Shared Savings Program (CMS's largest Advanced APM) was September 5, 2023, which was before the proposed rule would be finalized and therefore prior to participant ACOs knowing what policies would be in place for QP performance period 2024. Similarly, another commenter requested that we consider finalizing the proposal for QP performance period 2025 rather than 2024 because, while its organization's CEHRT use is close to 100 percent, it is not quite there, and the additional year would provide a sufficient glide path to full compliance either through adoption of CEHRT by the remaining few that do not have it or removal of those participants from the organization. One commenter did not express outright support or opposition to the proposal to end the 75 percent CEHRT use threshold, but recommended that we incorporate a transition period and delay ending the 75 percent threshold until a later QP performance period.

Response: After further reflection, we agree that a transition period would be appropriate, and agree with the commenters that indicated that some participants had to make decisions about 2024 participation without certainty about what rules would be in place for that QP performance period or having much time to work with members that may be using technology that does not currently meet the CEHRT definition. Our information pertaining to CEHRT use by Advanced APM participants indicates readiness to meet the new standard, but we recognize that a transition period would be helpful to address potential circumstances on which we may not have information, such as the CEHRT readiness of practices that may have been considering joining Advanced APMs in the near future, and give current and future potential participants the ability to make participation decisions for a particular QP performance period with full knowledge of the policies that will be in place for that year. We note that, because the definition of CEHRT that we are finalizing in this rule will allow for Advanced APMs to tailor their CEHRT requirements to clinical practice, it is possible that technology that eligible clinicians currently have that did not meet the existing CEHRT definition will meet the new definition. We encourage Advanced APMs to evaluate the CEHRT their eligible clinicians use with that new definition in mind (for example by determining if at least the Base EHR definition at 45 CFR 170.102 is met). We believe that providing an additional year should afford sufficient time for such an evaluation and we encourage participants to further use the time to work with their participant membership who do not have technology meeting the CEHRT definition to adopt it, as opposed to simply removing those clinicians from participation. We also believe that a transition year will allow us time to address concerns about the proposed new standard that were expressed in the previous comment. Accordingly, we will delay removal of the 75 percent threshold for CEHRT use until the CY 2025 QP performance period. We encourage Advanced APM participants to work with their Advanced APMs to understand what requirements apply to them.

After consideration of public comments, we are finalizing our proposal to amend the definition of CEHRT at § 414.1305 by adding a new paragraph (3) to specify that, for purposes of the Advanced APM criterion under § 414.1415, beginning with CY 2024, CEHRT means EHR technology certified under the ONC Health IT Certification Program that meets: (1) the 2015 Edition Base EHR definition, or any subsequent Base EHR definition (as defined in at 45 CFR 170.102); and (2) any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice areas, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM. We are also finalizing our proposal with modification to add a new paragraph at § 414.1415(a)(1)(iii) to specify that beginning with the CY 2025 QP performance period, to be an Advanced APM, the APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use CEHRT that meets our proposed new paragraph (3) of the CEHRT definition at § 414.1305. Finally, we are finalizing, with modification, our

proposal to amend § 414.1415(a)(1)(i) to end the current 75 percent CEHRT use requirement with the CY 2024 QP performance period, instead of the CY 2023 QP performance period.

(4) All Payer Advanced APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77459), we proposed policies, effective beginning for performance year 2021, that would allow eligible clinicians to earn QP status through participation in a combination of Medicare Advanced APMs and other payment arrangements designed and implemented by other payers (Other Payer Advanced APMs). The statute includes a CEHRT use criterion for Other Payer Advanced APMs as it does for Medicare Advanced APMs, and we finalized the same CEHRT use criterion for Other Payer Advanced APMs as for Medicare Advanced APMs (81 FR 77463). Likewise, in this rule, we proposed to amend the Other Payer Advanced APM criteria at § 414.1420(b) to conform with the changes we proposed for Medicare Advanced APMs, and to be reflected in amendments to § 414.1415(a)(1)(i), to remove the 75 percent minimum CEHRT use requirement for Advanced APMs, and replace it with a more flexible CEHRT use requirement based on our revised definition of CEHRT for purposes of Advanced APM determinations. We also proposed to revise § 414.1420(b) by making additional non-substantive technical edits to improve clarity.

The changes we proposed for Medicare Advanced APMs are designed to require use of technologically sufficient EHRs consistent with the ONC Base EHR definition at 45 CFR 170.102, while affording Advanced APMs the ability to tailor additional CEHRT use requirements to those features or capabilities that are clinically relevant to the APM and its participants. We believe that this same flexibility should be afforded in the context of Other Payer Advanced APMs. The All-Payer Combination Option through which we consider the participation of eligible clinicians in Other Payer Advanced APMs offers an additional pathway to achieve QP status for eligible clinicians participating in both Medicare Advanced APMs and Other Payer Advanced APMs. Under the All-Payer Combination Option, we consider the combined participation of eligible clinicians in Medicare and Other Payer Advanced APMs. Similar to the statutory CEHRT use requirement for Advanced APMs under section 1833(z)(3)(D)(i)(I) of the Act, section 1833(z)(2)(iii)(II)(bb) of the Act specifies that Other Payer Advanced APMs are those under which CEHRT is used. Since the All-Payer Combination Option for QP determinations involves the same eligible clinician as the Medicare Option and, considers their participation in both Medicare Advanced APMs and Other Payer Advanced APMs, we believe we should continue to apply the same CEHRT use standard for both Medicare and Other Payer Advanced APMs. Further, we believe the same need exists for flexibility in the CEHRT that is required to be used in Other Payer Advanced APMs. This will allow Other Payer Advanced APMs to structure their CEHRT use requirements to be clinically relevant to the APM and participating eligible clinicians and avoid the need for participants to obtain clinically unnecessary technology simply for purposes of meeting what we now believe to be an overly restrictive CEHRT use criterion.

We sought comment on this proposal.

We did not receive public comments on this provision. However, one key goal of ours in implementation of Medicare Advanced APM and Other Payer Advanced APM policies is to align them wherever appropriate, and with that alignment in mind, because we are delaying the removal of the 75 percent threshold for Medicare Advanced APMs, and we also are finalizing the Other Payer Advanced APM proposal with a one-year delay. As such, we are finalizing that the conforming changes we proposed in § 414.1420(b) to remove the 75 percent CEHRT use threshold and instead require the use of CEHRT will be finalized with an effective date of QP Performance Period 2025. We note that because the definition for CEHRT at 414.1305 will be finalized as proposed, the more flexible definition will be in place for Other Payer Advanced APMs, as well as for Medicare Advanced APMs.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements.

Comments received are summarized under each relevant section.

A. Wage Estimates

Private Sector: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2022/oes_nat.htm*). In this regard, Table 62 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 62: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43-3021	21.54	21.54	43.08
Business Operations Specialists	13-1000	40.04	40.04	80.08
Computer System Analysts	15-1211	51.70	51.70	103.40
Financial Specialists	13-2000	44.37	44.37	88.74
General and Operations Manager	11-1021	59.07	59.07	118.14
Licensed Practical and Licensed Vocational Nurses	29-2061	26.86	26.86	53.72
Medical and Health Services Managers	11-9111	61.53	61.53	123.06
Secretaries and Administrative Assistants	43-6014	20.87	20.87	41.74
Nurse Practitioners	29-1171	59.94	59.94	119.88
Physician Assistants	29-1071	60.23	60.23	120.46

For our purposes, BLS' May 2022 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we are using an average conglomerate wage of $274.44/hr as demonstrated below in Table 63.

TABLE 63: National Occupational Employment and Wage Estimates (Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	145.66	145.66	291.32
Family Medicine Physicians	29-1215	107.91	107.91	215.82
General Internal Medicine Physicians	29-1216	108.30	108.30	216.60
Obstetricians and Gynecologists	29-1218	133.33	133.33	266.66
Orthopedic Surgeons, Except Pediatric	29-1242	178.56	178.56	357.12
Pediatric Surgeons	29-1243	174.51	174.51	349.02
Pediatricians, General	29-1221	97.71	97.71	195.42
Physicians, All Other	29-1229	114.76	114.76	229.52
Psychiatrists	29-1223	118.92	118.92	237.84
Surgeons	29-1240	162.49	162.49	324.98
Surgeons, All Other	29-1249	167.25	167.25	344.50
Total				3,018.80
Average Physician Wage (3,018.80/11)				274.44

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual

Framework and Best Practices [505] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,059 [506] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr × 0.17), resulting in the post-tax hourly wage rate of $21.98/hr ($26.48/hr − $4.50/hr). Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

1. ICRs Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts (§ 414.940)

The following changes will be submitted to OMB for approval under control number 0938–1435 (CMS–10835).

As discussed in section III.A. of this final rule, as a part of implementing section 1847A(h) of the Act, as added by section 90004 of the Infrastructure Act, the Secretary is authorized to recognize, through notice and comment rulemaking, drugs with unique circumstances that justify an increase of the applicable percentage greater than 10 percent. In section III.A.3.d of this final rule, we finalized modifications to § 414.940 to establish an application process for drug manufacturers to request an increased applicable percentage for an individual drug product based on its unique circumstances.

To request we consider increasing the applicable percentage for a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug, or, if the drug is not yet approved, documentation of the FDA acceptance or filing of the NDA or BLA submission; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification can include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study. We are also finalizing that for manufacturers that do not have FDA approval for their product by February 1, the product must be FDA-approved label by August 1 and the manufacturer must notify and submit the approved labeling to CMS no later than September 1 for their application to be complete and eligible for consideration for an increased applicable percentage based on unique circumstances.

As discussed in section VI.E.4. of this final rule, our estimates show a projected 27 billing and payment codes meeting the definition of refundable single-dose container or single-use package drug with more discarded units than their respective applicable percentage, (that is, 10 percent for those not increased through rulemaking, as specified in section 1847A(h)(3) of the Act, or 26, 45, or 90 percent, as finalized in section III.A. for certain drugs). Therefore, we anticipate a similar number of drugs could owe a refund under section 90004 of the Infrastructure Act. Since 22 of those billing codes have an estimated annual refund obligation of over $50,000, we expect that, initially (that is, the first year the application process is available), the manufacturers of those 22 drugs to submit an application for consideration of an increased applicable percentage based on unique circumstances.

Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer will not need to apply again. We clarify in section III.A. of this final rule, that unique circumstances and increased applicable percentage for an individual drug, once finalized through rulemaking, are permanent, unless modified through subsequent rulemaking. Therefore, subsequent years we will expect a smaller number of applications. When evaluating the approval dates of these 22 drugs, we find that there is a range of 0 to 4 drugs per year approved that will be expected to owe a refund of more than $50,000 per year. From 2010 through 2020, the mean number of such approvals is 1.45 per year. Rounding that figure up, we estimate that we will typically receive 2 applications per year subsequent to the initial application year.

We estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. As we anticipate no more than 22 applications in the initial year that applications are available, we estimate a one-time first year burden of 110 hours (22 applications × 5 hr) at a cost of $4,591 ($41.74/hr × 110 hr). For subsequent years, we estimate an annual burden of 10 hours (2 applications × 5 hr per respondent/applicant) at a cost of $418 ($41.74/hr × 10 hr).

2. ICRs Regarding the Clinical Laboratory Fee Schedule: Data Reporting by Laboratories

As described in section III.D. of this final rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories,'' and we revised the regulations at § 414.504(a)(1) to account for a delay in reporting until January 1, 2024 through March 31, 2024. As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any requirements or burden for public review and OMB approval as prescribed under the PRA. Please refer to section VI.E.7. of this final rule for a discussion of the impacts associated with the changes described in section III.D. of this final rule.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the preamble. Please refer to section VI.E.10. of this final rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this final rule.

4. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program

In section III.L. of this final rule, we finalized the proposed policy to extend specific Medicare Diabetes Prevention Program (MDPP) flexibilities allowed during the PHE for the COVID–19 1135 waiver event by 4 years. In addition, we finalized the policies necessary to update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the

[505] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[506] *https://fred.stlouisfed.org/series/LEU0252881500A.*

diabetes risk reduction performance payments. Finally, we are finalizing the provision to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition as well as remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We expect the policies will increase the number of eligible organizations willing to enroll as MDPP suppliers. We also anticipate that the extended PHE flexibilities will make MDPP more marketable to both suppliers and beneficiaries due to the continued flexibility in how the MDPP set of services are delivered live, either in-person or virtually (or a combination of the two). We anticipate the payment structure changes will motivate suppliers to retain participants due to more frequent payments. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions.

5. Appropriate Use Criteria for Advanced Diagnostic Imaging

As discussed in section III.J. of this final rule, we are finalizing our proposal to pause efforts to implement the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services program for reevaluation and to rescind and reserve for future use the current AUC program regulations at § 414.94. The program was established in the Protecting Access to Medicare Act of 2014 (PAMA) and we have used rulemaking over the ensuing years to stand up the program in phases while aiming for a clinically useful and least provider-burdensome approach. At this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we have determined in section III.J. of this final rule to pause implementation of the AUC program for reevaluation and rescind the current AUC program regulations from § 414.94.

The following collection of information requests are affected by this rule's final decision to rescind the AUC program regulations from § 414.94: CMS–10570 (OMB 0938–1288), CMS–10624 (OMB 0938–1315), and CMS–10654 (OMB 0938–1345). Given that the AUC program regulations, which include these information collection requirements, will be rescinded, all three collections are no longer needed.

CMS–10570 (OMB 0938–1288) relates to the application and qualification process for provider-led entities (PLEs). Since we are finalizing the proposal and will rescind the AUC regulations at § 414.94, we are discontinuing this collection of information. Table 64 scores the impact of discontinuing the requirements and burden that are currently active and approved by OMB under the aforementioned control number, showing an expected 10 re-applications per year. We note however, that because we received less than 10 applicants in each year 2017–2022, there have been and will continue to be fewer than 10 re-applicants each year. In fact, the number of PLEs has overall decreased as qualified PLEs exit the program, choosing not to re-apply. In 2022 we expected all seven PLEs approved in 2017 to reapply; however, only two submitted re-applications and were re-qualified. For 2023, we froze the re-application process, continuing the approval of the three PLEs that had initially qualified in 2018. If we were not pausing the AUC program and rescinding the current regulations at § 414.94, then we would expect one re-application in 2024 and no re-applications in 2025.

At the time of the last approval in 2021, we expected the burden for PLEs re-applying for qualification to be half the burden of the initial application process. In the explanation below, we continue to use the previously approved number of responses, respondents and time, while updating the labor cost to reflect May 2022 BLS wages. As previously estimated, the PLEs would be able to make modifications to their original application which should result in a burden of 10 hours at $80.08/hr for a business operations specialist (occupation code 13–100) to compile, prepare and submit the required information, 2.5 hours at $123.06/hr for a medical and health services manager (occupation code 11–911) to review and approve the submission, and 2.5 hours at $242.3/hr for a physician (occupation code 29–1210) to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of $1,714.2 per organization. In aggregate, we estimate 150 hours (15 hr × 10 submissions) at $17,142 ($1,714 × 10 submissions).

TABLE 64: Burden of Pausing AUC Program Implementation Efforts for Reevaluation and Rescinding § 414.94

Regulation Section(s)	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
§ 414.94(c)(2) (reapplication)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)

CMS–10624 (OMB 0938–1315) relates to the application and qualification process for Clinical Decision Support Mechanisms (CDSMs). This collection of information is no longer active. CMS–10624 was first approved on March 6, 2017, and was associated with the CY 2017 Physician Fee Schedule final rule (November 15, 2016; 81 FR 80170). CMS–10624 last expired on March 31, 2020. In June 2020, CMS filed a request to discontinue CMS–10624 (OMB 0938–1315).

CMS–10654 (OMB 0938–1345) relates to the consultation of AUC through a qualified CDSM by an ordering professional or clinical staff acting under the direction of the ordering professional. While this collection of information is no longer active, the impact of discontinuing the requirements and burden is addressed in this final rule RIA (*see* section VII.

Regulatory Impact Analysis of this final rule).

6. ICRs for Medicare Provider and Supplier Enrollment

None of this rule's Medicare and Medicaid provider enrollment provisions include any new, revised, or removed information collection requirements or burden. Regarding the finalization of our policy to reduce the timeframe for reporting practice location changes from 90 days to 30 days, this change will not alter the requirement for disclosing the change via the applicable Form CMS–855 or Form CMS–20134. It will only revise the timeframe in which the change must be reported. Hence, there will be no change in the ICR burden.

7. ICRs Regarding the Medicare Ground Ambulance Data Collection System (GADCS) (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we did not set out any burden estimates under this section of the rule.

We did not receive any public comments on our claim that the provision is exempt from the PRA and are finalizing that claim as proposed.

8. ICRs Related to the Changes in the RHC/FQHC CfCs and Hospice CoPs

a. Permitting MFT and MHCs to Furnish Services in RHC/FQHCs

The following changes will be submitted to OMB for approval under control number 0938–0344 (CMS–R–38).

In section III.C. of this final rule, we implement section 4121 of the CAA by conforming changes at § 491.8(a)(3) and (6) that would add MFT and MHCs to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an RHC or FQHC provides services furnished by an MFT or MHC, they will be required to update their patient care policy, as set out in section § 491.9(b)(2) of the CfCs.

The existing requirement at § 491.9(b)(2), *Patient care policies,* requires that policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners, with at least one member who is not a member of the clinic or center staff. The patient care policies must describe the services the clinic or center furnishes directly, through agreement or arrangement, guidelines for medical management of health problems, and rules for the storage, handling, and administration of drugs and biologicals.

As we proposed to include MFTs and MHCs as professionals who can provide services in an RHC and FQHC, there will be a burden associated with the existing requirement at § 491.9(b)(3)(i). This requirement states that policies include ''A description of the services they provide directly or through agreement or arrangement.'' Therefore, if an RHC or FQHC provides services furnished by an MFT or MHC they must update their policies to include a description of the services provided.

We note that the time and effort required to conduct this activity will vary depending on if a clinic or center chooses to provide services furnished by an MFT or MHC. We also believe that some RHCs and FQHCs may already provide services furnished by an MFT or MHC. State Medicaid programs can cover ambulatory care services (including mental health and substance use disorder services) under a number of different mandatory Medicaid benefits such as outpatient hospital services, physician services, RHC and FQHC services, as well as optional benefits such as rehabilitative services, and services of other licensed practitioners.

The National Association of Community Health Center's 2017 policy assessment suggests that 21 State Medicaid programs cover services provided by MFTs, and 25 State Medicaid programs cover services provided by licensed professional counselors.[507] Due to approximately half of the State's Medicaid programs already covering services furnished by an MFT or MHC and the assumption that some centers and clinics will not provide these services, we believe only 50 percent of RHCs and 50 percent of FQHCs will incur this burden. The total RHCs and FQHCs who will have to meet this 1-time burden is 2,643 clinics and 5,643 centers, or 8,286 combined.[508] [509]

Each clinic or center is required by the existing requirement at § 491.9(b)(2) to have at least one physician/administrator at $274.44/hr and one advanced practice provider (nurse practitioner or physician assistant) at $120.17/hr ($119.88 + $120.46/2) reviewing and updating the policies. We estimate that it takes existing RHCs and FQHCs 4 hours every 2 years for clinical staff to review and make changes to all patient care policies. Based on this, we estimate that adding MFT and MHC services (as necessary) to the patient care policies would take approximately 15 minutes (0.25 hr) for each clinical professional. In aggregate, we estimate an annual burden of 4,143 hours (0.50 hr × 8,268 RHC and FQHCs) at a cost of $817,631.92 [(2,072 hr × $274.44/hr) + (2,072/hr × $120.17/hr)].

We did not receive public comments on this provision; and therefore, we are finalizing as proposed.

b. ICRs Related to Permitting MFTs and MHCs To Serve as Members of the Interdisciplinary Group (IDG) in Hospices (§ 418.56 and § 418.114)

In section III.O. of this final rule, we will implement subtitle C, section 4121 of the CAA 2023 by conforming changes at § 418.56(a)(1)(iii) that will permit MFTs or MHCs, in addition to social workers, to serve as members of the IDG. The conforming change will require hospices to include one SW, MFT or MHC to serve as a member of the IDG. Hospices will have the flexibility to determine which discipline(s) are appropriate to serve on the IDG. We believe that with the introduction of MFT and MHC into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114.

In this rule we also proposed to add both MFT and MHC to the provider requirements under 42 CFR subpart B (Medical and Other Health Services) at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we proposed to add both MFT and MHC to the requirements at § 418.114(b)(9) and (10) and referencing the new requirement at §§ 410.53 and 410.54, respectively.

[507] *https://www.nachc.org/wp-content/uploads/2019/03/BH-Fact-Sheet-3.20.19.pdf.*

[508] *https://qcor.cms.gov/active_nh.jsp?which=12&report=active_nh.jsp&jumpfrom=#pagetop.*

[509] *https://qcor.cms.gov/active_nh.jsp?which=11&report=active_nh.jsp&jumpfrom=#pagetop.*

In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the revisions to the requirements at §§ 418.56(a)(iii) and 418.114(b)(9) and (10) are exempt from the PRA. We believe permitting hospices the ability to select one of these disciplines (SW, MFT or MHC) to serve as a member of the IDG and the addition of both MFT and MHC to the personnel requirements with reference to the new requirement at §§ 410.53 and 410.54 respectively, is reasonable and customary business practice. We state such in the information collection request that is currently approved under OMB control number: 0938–1067 ((CMS–10277). Therefore, we did not propose to seek OMB's approval for any information collection or recordkeeping activities that may be conducted in connection with the revisions to §§ 418.56(a)(1)(iii) and 418.114(b)(9) and (10), but we requested public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and this time and effort would be incurred by hospice staff even absent this regulatory requirement.

The following is a summary of the comments we received and our responses.

Comment: A commenter questioned if the hospice would need to document how a decision was made to assign the MFT, MHC, or SW to the patients IDG. They also stated that this may cause additional administrative burden if hospices are required to prove how they chose the MFT, MHC or SW to serve on the patients IDG.

Response: We appreciate the clarification question on how the IDG is to show the decision on which provider (MFT, MHC, or SW) to serve as a member of the patients IDG. We have removed the proposed requirement ''depending on the needs and preferences of the patient'', Therefore, the hospice will not be required to show the decision on which provider (MFT, MHC, or SW) would serve as a member of the patients IDG. It is important for the hospice to assess and determine, along with the input from the patient and family, which care and services best align with the needs of the patient. Therefore, we expect that the hospice would include the patient's needs as part of the patient assessment and care planning process. This information would be included in the patients' medical record and discussed at the IDG team meeting just as other important care aspects are discussed and documented by the IDG, including any changes to care delivery. We believe the IDG documentation is reasonable and customary business practice, therefore no additional burden on the provider.

After consideration of public comments on this provision, we are finalizing § 418.56 with one modification of the proposed language. We are deleting ''depending on the needs and preferences of the patient.'' The inclusion of an MFT and MHC as members of the hospice IDG helps to accommodate the patient's needs. We believe that this action strengthens our response to the need for increased access to behavioral and mental health services.

9. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

Please note that this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we did not seek proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We noted that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we noted that we will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement will be required or sought. All submissions become U.S. Government property and will not be returned.

10. Basic Health Program (BHP) Provisions

a. Information Collection Requirements (ICRs)

We did not receive any public comments on the collection of information requirements for the BHP provisions; and therefore, we are finalizing as proposed. The following finalized provisions will be submitted to OMB for approval under OMB control number 0938–1218 (CMS–10510).

(1) ICRs Regarding the BHP Blueprint (§ 600.125)

We finalized at § 600.125(a)(1) through (3) that Blueprint revisions must be submitted to reflect: (1) changes in Federal laws, regulations, policy interpretations or court decisions that affect provisions in the certified Blueprint; (2) significant changes that alter core program operations or the BHP benefit package; or (3) changes to enrollment, disenrollment, and verification policies described in the certified Blueprint. We noted that only § 600.125(a)(1) is a new requirement. The requirements under § 600.125(a)(2) and (3) are existing. We finalized at § 600.125(b) that a State may submit revisions to its certified Blueprint at any time within the same quarter of the proposed effective date of revised Blueprint. We finalized at § 600.125(c) that HHS must review the revised Blueprint within 90 calendar days or provide the State written notice of disapproval or additional information it needs to make a final determination.

We estimated that, on average, a State operating a BHP will submit one revised Blueprint in response to § 600.125(a)(1)

annually. Because only two States are currently certified to operate a BHP, we provided the burden estimate for two States. We estimated that the provision under § 600.125(a)(1) will increase State burden. We estimated that the provisions under § 600.125(b) and (c) will have no impact on State burden. We estimated that, on average, it will take a State 4 additional hours at $80.08/hr for a Business Operations Specialist and 2 additional hours at $118.14/hr for a General Manager to meet the new Blueprint requirements under § 600.125(a)(1). In aggregate, we estimated an increased burden of 12 hours (2 States × 6 hr/State) at a cost of $1,113 [2 States × ((4 hr × $80.08/hr) + (2 hr × $118.14/hr))]. We noted that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

(2) ICRs Regarding the Operation of a BHP (§§ 600.145(a), 600.145(f)(2), and 600.330(f))

We finalized at § 600.145(a) that a State must implement its BHP in accordance with: (1) the approved and full certified State BHP Blueprint; or (2) the approved suspension application (see ICR section 3 below).

We finalized at § 600.145(f)(2) that the State operating a BHP must perform eligibility and health services appeals as specified in § 600.335.

The ongoing burden associated with the requirements under § 600.145 is the time and effort it would take each participating State to perform the recordkeeping and reporting portions of the core operating functions of a BHP including eligibility determinations and appeals as well as enrollment and disenrollment, health plan contracting, oversight and financial integrity, consumer assistance, and if necessary program termination or suspension.

Because only two States are currently certified to operate a BHP, we provided the burden estimate for two States. We estimated that it would take a business operations specialist 4 additional hours at $80.08/hr to meet these new recordkeeping and reporting requirements for health services appeals. In aggregate, we estimated an increased burden of 8 hours (2 States × 4 hr/response) at a cost of $641 (2 States × 4 hr × $80.08/hr). We noted that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

We finalized at § 600.330(f), BHP eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency. These notices must be developed and processed in a coordinated fashion with other insurance affordability programs which have the same accessibility standards at 45 CFR 155.230(b). As such, we estimated no additional burden for the BHP for the noticing requirement.

(3) ICRs Regarding Suspension of a BHP (§§ 600.140(b) and 600.170(a)(2))

We finalized at § 600.140(b)(1) if a State decides to suspend its BHP or requests a suspension extension, a State must submit to the Secretary a suspension application or suspension extension application. We finalized at § 600.140(b)(3) that a State must submit written notices to all BHP enrollees and participating standard health plan offers at least 90 days prior to the effective date of the suspension. We finalized at § 600.140(b)(4) that the State must submit to HHS within 12 months of the suspension effective date the data required by § 600.610 needed to complete the financial reconciliation process with HHS. We finalized at § 600.140(b)(5) that the State must submit the annual report required by § 600.170(a)(2). We finalized at § 600.140(b)(6) that the State must annually remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period. We finalized at § 600.140(b)(7) that the State must submit a transition plan to HHS that describes how the State will reinstate its BHP or terminate the program.

Two States are currently certified to operate a BHP; therefore, we provided the burden estimate for two States.

We estimated that, on average, it will take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a suspension application to the Secretary. In aggregate, we estimated a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We estimated that, on average, it will take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a suspension extension application to the Secretary. In aggregate, we estimated a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimated that, on average, it will take a Business Operations Specialist 32 hours at $80.08/hr to prepare and submit notification to all participating standard health plans and enrollees. In aggregate, we estimated a one-time burden of 64 hours (2 States × 32 hr/response) at a cost of $5,125 [2 States × (32 hr × $80.08/hr)].

We estimated that it would take a Business Operations Specialist 25 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to compile and submit data required for quarterly financial reconciliation. In aggregate, we estimated an annual burden of 232 hours (2 States × 29 hr/response × 4 responses/yr) at a cost of $19,796 [2 States × 4 responses/yr ((25 hr × $80.08/hr) + (4 hr × $118.14/hr)).

We estimated that, on average, it will take a Financial Specialist 8 hours at $88.74/hr to remit annually the interest accrued on the balance of the BHP trust fund while in suspension. In aggregate, we estimated an annual burden of 16 hours (2 States × 8 hr/response) at a cost of $1,420 [2 States × (8 hr × $88.74/hr)].

We estimated that it will take a Business Operations Specialist 20 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a transition plan to reinstate its BHP or terminate the program. In aggregate, we estimated a one-time burden of 48 hours (2 States × 24 hr/response) at a cost of $4,148 [2 States × ((20 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimated that, on average, it will take a Business Operations Specialist 40 hours at $80.08/hr and 4 hours at $118.14/hr for a General Manager to complete and submit the State's annual report, for a total annual burden of 88 hours at a cost of $7,352 [2 States × ((40 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We noted that these costs will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

b. Burden Summary

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TABLE 66: Summary of Requirements and Burden Estimates

Regulation Section(s)/ ICR Provision	OMB Control No./ CMS-ID	Year	Number of Respondents	Number of Responses	Time per Response (hrs)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
600.125(a)(1)	0938–1218 (CMS-10510)	2024	2	2	6	12	Varies	1,113	1,113	N/A
600.145(a) and 600.145(f)(2)	0938–1218 (CMS-10510)	2024	2	2	4	8	80.08	641	641	N/A
600.140(b)(1) (suspension application)	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(1) (extension application	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(3)	0938–1218 (CMS-10510)	2024	2	2	32	64	80.08	5,125	5,125	N/A
600.140(b)(4)	0938–1218 (CMS-10510)	2024	2	4	29	232	Varies	19,796	19,796	N/A
600.140(b)(5) and 600.170(a)(2)	0938–1218 (CMS-10510)	2024	2	2	44	88	Varies	7,352	7,352	N/A
600.140(b)(6)	0938–1218 (CMS-10510)	2024	2	2	8	16	88.74	1,420	1,420	N/A
600.140(b)(7)	0938–1218 (CMS-10510)	2024	2	2	24	48	Varies	4,148	4,148	N/A
Total					Varies		Varies	51,155	51,155	

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11. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Final Rule)

The following QPP-specific ICRs reflect changes to our currently approved burden due to policy changes in this CY 2024 final rule as well as adjustments to the policies that have been previously finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131, respectively) due to revised assumptions based on updated data available at the time of the publication of this final rule.

a. Background

(1) ICRs Associated With Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In the following sections, we discuss a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the policies discussed in the CY 2024 PFS final rule and the revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The estimated burden will be submitted to OMB under control number 0938–1314 (CMS–10621). The estimated burden for the CAHPS for MIPS Survey discussed in sections V.B.11.c.(5), V.B.11.e.(8), and V.B.11.e.(9) of this rule was submitted under OMB control number 0938–1222 (CMS–10450). We noted that we have received approvals for the collection of information associated the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(2) Summary of Changes for the Quality Payment Program: MIPS

We have included the change in the estimated burden for the CY 2024 performance period/2026 MIPS payment year due to the policies and information collections in this final rule. The policies in this final rule impact the burden estimates for the CY 2024 performance period/2026 MIPS payment year.

The following five MIPS ICRs show changes in burden due to the policies in

this final rule: (1) Quality performance category data submission by Medicare Part B claims collection type; (2) Quality performance category data submission by qualified clinical data registry (QCDR) and MIPS CQM collection type; (3) Quality performance category data submission by eCQM collection type; (4) MIPS Value Pathways (MVP) quality performance category submission, and (5) MVP registration. In aggregate, we estimate the policies will result in a net decrease in burden of 4,147 hours and $477,101 for the CY 2024 performance period/2026 MIPS payment year. The remaining changes to our currently approved burden estimates are adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this final rule. As discussed in section VI.E.23.a.(2) of this final rule, we based our estimates on submission data from the CY 2022 performance period/2024 MIPS payment year.

In the CY 2024 PFS proposed rule (88 FR 52636), we proposed to add two new ICRs, ''QCDR full self-nomination process'' and ''qualified registry full self-nomination process'' to distinctly capture the burden for the number of QCDRs and qualified registries submitting applications for the simplified and full self-nomination process. We noted that the addition of these ICRs is not due to finalizing the policies discussed in section IV.A.4.k. of this final rule. It is a change in our approach in representing the estimated burden for the third-party intermediary self-nomination process due to availability of updated data. We discuss the details of these changes in sections V.B.11.c.(2) and V.B.11.c.(3) of this final rule.

We proposed to remove one ICR, ''nomination of Promoting Interoperability measures,'' in the CY 2024 PFS proposed rule (88 FR 52636). We note that the removal of the ICR is not due to finalizing the policies discussed in section IV.A.4.f.(4) of this final rule. It is due to a consistent decline in the number of submissions received for the ICR.

We did not propose any changes or adjustments to the following ICRs (88 FR 52636): Registration for virtual groups; OAuth credentialing and token request process; Quality Payment Program identity management application process; subgroups registration; nomination of MVPs; and opt-out of performance data display on Compare Tools for voluntary participants. We note that we have received updated data for this final rule and adjusted the estimated burden as applicable. See section V.B.11. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted by two primary factors. First, we are unable to predict with absolute certainty who will be a Qualifying APM Participant (QP) for the CY 2024 performance period/2026 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2024 performance period/2026 MIPS payment year compared to the CY 2022 performance period/2024 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data. Additionally, we will continue to update our estimates annually as data becomes available.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), we did not implement any changes to currently approved burden estimates for the CY 2024 performance period/2026 MIPS payment year. Therefore, we did not propose any changes to the Partial QP elections; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of Data for QP determinations under the All-Payer Combination Option (88 FR 52636).

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 67 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. In Table 67, MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS may submit data as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted. Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in an MVP. We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS. We finalized in the CY 2022 PFS final rule that a subgroup reporting measures and activities in an MVP will submit its affiliated group's data for the Promoting Interoperability performance category and in the scenario that a subgroup does not submit its affiliated group's data, the subgroup will receive a zero score for the Promoting Interoperability performance category (86 FR 65413 through 65414).

Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used to calculate the scores for the cost performance category is not represented in Table 67.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule that the APM Performance Pathway is available for both Accountable Care Organization (ACO) participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2024 performance period/2026 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in the CY 2022 PFS final rule (86 FR 65259

through 65263), the CMS Web Interface collection type is available through the CY 2024 performance period/2026 MIPS payment year only for clinicians participating in the Shared Savings Program. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. Additionally, we finalized the introduction of a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70087 and 70088). For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we established that, for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM Entity receives less than the maximum improvement activities performance category score, to date all MIPS APM Entities have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844).

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TABLE 67: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician

Type of Data Submitted	Category of Clinician
Quality Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Subgroup reporting is only available for clinicians participating in MVP reporting.
Promoting Interoperability Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Each eligible clinician in an APM Entity could report data for the Promoting Interoperability performance category at the individual level, or as part of their group TIN, or under their APM Entity TIN. The burden estimates for this final rule assume group TIN-level reporting.
Improvement Activities Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.
Reweighting Applications for extreme and uncontrollable circumstances and significant hardship or other exceptions	Clinicians who submit an application may be eligible for a reweighting of the approved performance category to zero percent under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or another type of exception. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category as described in § 414.1380(c)(2)(i)(A)(4).
MVP and Subgroup Registration	An MVP participant, as described at § 414.1305, electing to submit data for the measures and activities in an MVP must register. Clinicians who choose to participate as a subgroup for reporting an MVP must also register.
Partial QP Election	Eligible clinicians who attain Partial QP status and choose to participate in MIPS would need to submit a partial QP election form.
Registration for the CAHPS for MIPS Survey	Groups electing to use a CMS-approved survey vendor to administer the CAHPS for MIPS survey must register.
Virtual Group Registration	Virtual groups must register via email. Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.
APM Performance Pathway	Clinicians in MIPS APMs electing the APM Performance Pathway. The burden estimates for this final rule assume that ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option (available through the CY 2024 performance period/2026 MIPS payment year), and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an APM Entity.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131), and continued in this final rule create some additional data collection requirements not listed in Table 67. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–

10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs related to MIPS third-party intermediaries (see sections V.B.11. c. and V.B.11.d. of this final rule):

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning qualified registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314)
- Third party intermediary plan audits
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 through 84970).

Additional ICRs related to the data submission and the quality performance category (see section V.B.11.e. of this final rule):

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs related to the Promoting Interoperability performance category (see section V.B.11.g. of this final rule):

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities (see sections V.B.11.j, V.B.11.f, V.B.11.k., and V.B.11.h. of this final rule):

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314).
- Nomination of Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).

Additional ICRs related to MIPS (see section V.B.11.o. of this final rule):

- Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections V.B.11.m. and V.B.11.n. of this final rule):

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

We did not propose any new or revised collection of information requirements or burden related to the virtual group election for the CY 2024 performance period/2026 MIPS payment year. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any changes under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As discussed above in section V.B.11.a.(2) of this final rule, we proposed to add two new ICRs, ''QCDR simplified self-nomination process'' and ''qualified registry self-nomination process'', to represent the estimated burden for the third party intermediaries submitting applications for the simplified self-nomination process. We discuss the details of these changes in the below sections.

As discussed in section IV.A.4.k. of this final rule, we are finalizing our proposals to: (1) add requirements for third party intermediaries to obtain documentation of their authority to submit on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or an APM Entity; (2) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (3) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) add a requirement for QCDRs and qualified registries to attest that information contained in the qualified posting about them is correct; (5) modify requirements for QCDRs and qualified registries to support MVP reporting to increase flexibility for measures supported; (6) specify requirements for a transition plan for QCDRs and qualified registries withdrawing from the program; (7) specify requirements for data validation audits; (8) add additional criteria for rejecting QCDR measures; (9) add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (9) eliminate the Health IT vendor category; (10) add failure to maintain updated contact information as criteria for remedial action; (11) revise corrective action plan requirements; (12) allow CMS to terminate third-party intermediaries that are on remedial action for 2 consecutive years; (13) specify the process for publicly posting remedial action; and (14) specify the criteria for audits. In the CY 2024 PFS proposed rule (88 FR 52639), we noted that the policy to eliminate the health IT vendor category beginning with the CY 2025 performance period/2027 MIPS payment year will not have any impact on the estimated burden for third party self-nomination process in the CY 2024 performance period/2026 MIPS payment year. We discussed that the removal of health IT vendor category beginning with the CY 2025 performance period/2027 MIPS payment year could encourage some existing health IT vendors to complete the requirements under the qualified registry self-nomination process. However, we did not propose any adjustments in the number of qualified registries that will submit applications for the qualified registry self-nomination process during the CY 2024 performance period/2026 MIPS payment year because we believe that many third party intermediaries serve as both health IT vendors and qualified registries for the purposes of submitting data for MIPS eligible clinicians.

We assume that the changes to codify previously finalized preamble language related to third party intermediaries in the regulatory text will result in modifying the regulatory text to reflect previously finalized policies for third party intermediaries or provide additional clarification of the previously finalized policies. We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to finalizing the above policies and therefore, we are not making any adjustments to the currently approved burden estimates for third party intermediaries. We refer readers to

section IV.A.4.k. of this rule for additional details on the finalized policies for third party intermediaries. Additionally, we refer readers to section VI.E.23.e.(2)(a) of this rule where we discuss the details in our impact analysis for these policies.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[510] The processes for self-nomination of entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

As described below in this section, we proposed to separate the burden for the number of QCDR self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year (88 FR 52639 through 52642). In the CY 2023 PFS final rule (87 FR 70137 through 70139), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full QCDR self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we proposed to add a new ICR to capture the burden for the simplified QCDR self-nomination process. We note that the change in estimated burden is not due to finalizing the policies discussed in section IV.A.4.k. of this rule. To accurately represent the estimated burden incurred by the QCDRs for the simplified and full self-nomination process, we discuss the burden under separate ICRs.

As discussed later in this section, we are updating our estimates for the simplified and full QCDR self-nomination process based on the number of applications received during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year. Specifically, we are updating our estimates for: (1) the number of QCDRs that will submit applications under the simplified and full self-nomination process; (2) the number of measures (existing or borrowed and new measures) submitted by a QCDR; (3) the average time required for a QCDR to submit the measure information; and (4) the time required for the simplified and full QCDR self-nomination process.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 through 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969, 86 FR 65569 through 65573, and 87 FR 70138 through 70139, respectively) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

(a) Simplified Self-Nomination Process and Other Requirements

Based on updated data for the number of applications received during the CY 2023 QCDR self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 44 existing QCDRs will submit applications under the simplified self-nomination process. We continue to estimate that each QCDR will submit 12 measures, on average, however, based on the number of QCDR measure submissions received during the CY 2023 QCDR self-nomination period, we are adjusting our estimates for the number of new and existing or borrowed measures discussed in the CY 2023 PFS final rule (87 FR 70138). We note that we are not revising or adjusting our estimated per response time for a QCDR to submit a new measure (2 hr/response) and an existing or borrowed measure (0.5 hr/response). For the QCDRs that submit measures for consideration during the self-nomination process, we estimate that we will receive approximately 2 new measures and 10 existing or borrowed measures on average per QCDR. Due to this change, we are also adjusting the estimated weighted average time required for each QCDR to submit a measure from 0.63 hours to 0.75 hours [((2 new measure $\times$ 2 hr) + (10 existing or borrowed measures $\times$ 0.5 hr))/total # of measures (12)]. We note that we are not making any changes to the currently approved time of 0.5 hours required for existing QCDRs that do not submit measures under the simplified self-nomination process. For existing QCDRs that submit measures as part of their self- nomination process, due to the estimated decrease in the number of existing or borrowed QCDR measures and an increase in the number of new QCDR measures submitted with the self-nomination application discussed previously in this section, we estimate that it will take 9.5 hours [0.5 hr for the simplified self- nomination process + (12 measures $\times$ 0.75 hr/measure for QCDR measure submission)] for a QCDR to submit an application under the simplified self-nomination process. We note that this will result in an overall increase of 1.4 hours from the estimated time the currently approved time of 8.1 hours required for the simplified QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

As shown in Table 68, we assume that the staff involved in the simplified QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response will be $982.30 (9.5 hr $\times$ $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified QCDR self-nomination process will be 418 hours (44 responses $\times$ 9.5 hr) at a cost of $43,221 (44 applications $\times$ $982.30/application).

[510] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

TABLE 68: Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Simplified QCDR Self-Nomination Applications submitted (a)	44
Annual Hours Per QCDR for Simplified Process (b)	9.5
Total Annual Hours for Self-nomination (c) = (a) * (b)	**418**
Cost per Application at Labor Cost for computer systems analysts at $103.40/hr (d)	$982.30
Total Annual Cost (**e**) = (a) * (d)	**$43,221**

In Table 69, the addition of this new ICR for the CY 2024 performance period/2026 MIPS payment year will result in an increase of 418 hours at a cost of $43,221 for the simplified QCDR self-nomination process. We note that the increase in burden is due to separating the estimated burden for the simplified QCDR self-nomination process.

TABLE 69: Change in Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS final rule (b) (See Table 68, row (c))	418
Difference (c) = (b) - (a)	**+418**
Total Currently Approved Annual Cost (d)	0
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 68, row (e))	$43,221
Difference (f) = (e) - (d)	**+$43,221**

We did not receive any comments on our proposed requirements and burden estimates for the simplified QCDR self-nomination process. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52639 through 52641) due to the availability of updated data.

(b) Full QCDR Self-Nomination Process and Other Requirements

Based on the number of applications that we received during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 12 new QCDRs would submit applications under the full self-nomination process. This is a decrease of 51 respondents from the currently approved estimate of 63 for the QCDR self-nomination process (87 FR 70139). We continue to estimate that each QCDR will submit 12 measures, on average, however, based on the number of QCDR measure submissions received during the CY 2023 QCDR self-nomination period, we are adjusting our estimates for the number of new and existing or borrowed measures discussed in the CY 2023 PFS final rule (87 FR 70138). We note that we are not revising or adjusting our estimated per response time for a QCDR to submit a new measure (2 hr/response) and an existing or borrowed measure (0.5 hr/response). For the QCDRs that submit measures for consideration during the self-nomination process, we estimate that we will receive approximately 2 new measures and 10 existing or borrowed measures on average per QCDR. Due to this change, we are also adjusting the estimated weighted average time required for each QCDR to submit a measure from 0.63 hours to 0.75 hours [((2 new measure × 2 hr) + (10 existing or borrowed measures × 0.5 hr))/total # of measures (12)]. We note that we are not making any changes to the currently approved time of 0.5 hours required for the QCDRs that do not submit measures under the simplified self-nomination process. For new QCDRs that submit measures as part of their self-nomination process, due to the estimated decrease in the number of existing or borrowed QCDR measures and an increase in the number of new QCDR measures submitted with the self-nomination application discussed above, we estimate that it will take 11.5 hours [2.5 hr for the full self-nomination process + (12 measures × 0.75 hr/measure for QCDR measure submission)] for a QCDR to submit an application under the full self-nomination process. We note that this will result in an overall increase of 1.4 hours from the estimated time the currently approved time of 10.1 hours required for the full QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 70, we assume that the staff involved in the full QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $1,189.10 (11.5 hr × $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full QCDR self-nomination process will be 138 hours (12 applications × 11.5 hr)

at a cost of $14,269 (12 applications × $1,189.10/application).

TABLE 70: Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Full QCDR Self-Nomination Applications submitted (a)	12
Annual Hours Per QCDR for Full Process (b)	11.5
Total Annual Hours for Full Self-nomination (c) = (a) * (b)	138
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$1,189.10
Total Annual Cost (e) = (a) * (d)	$14,269

In Table 71, we use the currently approved burden as the baseline for calculating the net change in burden for the full QCDR self-nomination process. We note that we discussed the estimated burden for the full QCDR self-nomination process under ''maximum burden'' in Table 108 in the CY 2023 PFS final rule (87 FR 70139). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above in this section results in a decrease of 498 hours and $51,524 for the full self-nomination process. We also note that the decrease in burden accounts for the change due to separating the estimated burden based on the simplified and full self-nomination process.

TABLE 71: Change in Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	636
Total Annual Time (hr) for Respondents in CY 2024 PFS final rule (b) (See Table 70, row (c))	138
Difference (c) = (b) - (a)	**-498**
Total Currently Approved Annual Cost (d)	$65,793
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 70, row (e))	$14,269
Difference (f) = (e) - (d)	-$**51,524**

We did not receive any comments on our proposed requirements and burden estimates for the full QCDR self-nomination process. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52641 through 52642) due to the availability of updated data.

(c) QCDR Measure Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures as part of the self-nomination process for an entity to become a QCDR.

As discussed in section IV.A.4.k.(4)(b)(i) of this final rule, we are finalizing our proposal to add that the measure being submitted after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O). We will not revise or adjust our burden estimates because the policy only clarifies requirements for rejecting a QCDR measure and will not substantively change the estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

As discussed in section IV.A.4.k.(4)(b)(ii) of this final rule, we are finalizing our proposal at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration. We will not revise or adjust our burden estimates as result of this change because limiting the number of measures submitted during the QCDR self-nomination process will not substantively change the estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

As discussed in section IV.A.4.k.(4)(b)(iv) of this final rule, we are finalizing our proposal to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period. We will not revise or adjust our burden estimates as result of this change because establishing a standard for the duration of posting the approved QCDR measure specifications would not substantively change the estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(b)(2) which states that entities seeking to

qualify as a qualified registry for the applicable performance period must complete a self-nomination process to be considered for approval.

As described in the CY 2024 PFS proposed rule, we proposed to separate the burden for the number of qualified registry self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year (88 FR 52642 through 52644). In the CY 2023 PFS final rule (87 FR 70139 through 70140), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full qualified registry self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we proposed to add a new ICR to capture the burden for the qualified registry self-nomination process. We note that the change is not due to finalizing the policies discussed in section IV.A.4.k. of this final rule. With the addition of a new ICR, we believe that we will be able to accurately represent the estimated burden incurred by the qualified registries for both the simplified and full self-nomination process.

(a) Simplified Qualified Registry Self-Nomination Process

Based on the number of applications received during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 84 qualified registries will submit applications under the simplified self-nomination process. We note that we are not making any changes to the currently approved time of 0.5 hours required for the simplified qualified registry self-nomination process (87 FR 70140).

Based on the above assumptions, we provided an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 72, we assume that the staff involved in the simplified qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response will be $51.70 (0.5hr × $103.40/hr) for the simplified self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified qualified registry self-nomination process will be 42 hours (84 applications × 0.5 hr) at a cost of $4,343 (84 applications × $51.70//application).

TABLE 72: Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Simplified Self-Nomination Applications submitted (a)	84
Annual Hours Per Qualified Registry for Simplified Process (b)	0.5
Total Annual Hours for Simplified Self-nomination (c) = (a) * (b)	**42**
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$51.70
Total Annual Cost (**e**) = (a) * (d)	**$4,343**

In Table 73, the addition of this ICR for the CY 2024 performance period/2026 MIPS payment year will result in a change of +42 hours at a cost of $4,343 for the simplified qualified registry self-nomination process. We note that the increase in burden is due to separating the estimated burden for the simplified and full qualified registry self-nomination process.

TABLE 73: Change in Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS final rule (b) (See Table 72, row (c))	42
Difference (c) = (b) - (a)	**+42**
Total Currently Approved Annual Cost (d)	$0
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 72, row (e))	$4,343
Difference (f) = (e) - (d)	**+$4,343**

We did not receive any comments on our proposed requirements and burden estimates for the simplified qualified registry self-nomination process. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52642 through 52643) due to the availability of updated data.

(b) Full Qualified Registry Self-Nomination Process

Based on the number of applications we received during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 27 qualified registries will submit applications under the full self-nomination process. This is a decrease of 105 from the currently approved estimate of 132 for the qualified registry self-nomination process (87 FR 70140). We note we are not making any changes to our currently approved per response time estimate of 2 hours for the full qualified registry self-nomination process (87 FR 70139 through 70140).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on MIPS eligible clinicians.

In Table 74, we assume the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. We estimate the burden per response will be $206.80 (2 × 103.40/hr) for the full self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full qualified registry self-nomination process will be 54 hours (27 applications × 2 hr) at a cost of $5,584 (27 applications × $206.80/application).

TABLE 74: Estimated Burden for Qualified Registry Full Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Qualified Registry Full Self-Nomination Applications submitted (a)	27
Annual Hours Per Qualified Registry for Full Process (b)	2
Total Annual Hours for Full Self-Nomination (c) = (a) * (b)	**54**
Cost per Application at Labor Cost (computer systems analyst's labor rate of $103.40/hr) (d)	$206.80
Total Annual Cost (**e**) = (a) * (d)	**$5,584**

In Table 75, we use the currently approved burden as the baseline for calculating the net change in burden for the simplified qualified registry self-nomination process. We note that we discussed the estimated burden for the full qualified registry self-nomination process under ''maximum burden'' in Table 110 in the CY 2023 PFS final rule (87 FR 70140). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above results in a decrease of 210 hours and a decrease of $21,714 for the full qualified registry self-nomination process. We note the decrease in burden accounts for the changes due to separating the estimated burden based on the simplified and full qualified registry self-nomination process.

TABLE 75: Change in Estimated Burden for Full Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	264
Total Annual Time (hr) for Respondents in CY 2024 PFS final rule (b) (See Table 74, row (c))	54
Difference (c) = (b) - (a)	**-210**
Total Currently Approved Annual Cost (d)	$27,298
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 74, row (e))	$5,584
Difference (f) = (e) - (d)	**-$21,714**

We did not receive any comments on our proposed requirements and burden estimates for the full qualified registry self-nomination process. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52643 through 52644) due to the availability of updated data.

(4) Third Party Intermediary Plan Audits

The following changes associated with developing the plans and audits by QCDRs and qualified registries will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 through 65548), we finalized that beginning with the CY 2021 performance period/CY 2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS and CY 2023 PFS final rules for the QCDRs (86 FR 65574 and 87 FR 70141 respectively) and qualified registries (86 FR 65571 and 87 FR 70141 respectively) that would submit the results of targeted audits, we estimate the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume the staff involved in submitting the targeted audits will continue to be computer systems analysts or their

equivalent, who have an average labor rate of $103.40/hr.

Based on the number of data validation execution reports submitted for the CY 2022 performance period/2024 MIPS payment year, we estimate that 29 third party intermediaries will submit targeted audits for the CY 2024 performance period/2026 MIPS payment year (See Table 76). We estimate that the cost for a QCDR or a qualified registry to submit a targeted audit will range from $517 (5 hr × $103.40/hr) to $1,034 (10 hr × $103.40/hr). In aggregate, we estimate an annual burden ranging from 145 hours (29 responses × 5 hr/audit) and $14,993 (29 targeted audits × $517/audit) to 290 hours (29 responses × 10 hr/audit) and $29,986 (29 targeted audits × $1,034/audit) (see Table 77 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that did not submit performance data and therefore will need to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for additional details on policies for remedial action and termination of third party intermediaries.

In the CY 2023 PFS final rule, we estimated that it will take 3 hours for a QCDR or qualified registry to submit a participation plan (87 FR 70141). We found that we overestimated the time required to submit a participation plan and therefore, are revising our estimate that it would take 2 hours for a QCDR or qualified registry to submit a participation plan. We assume the staff involved in submitting a participation plan will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr.

As shown in Table 76, following additional review of the MIPS data submission reports, we estimate that 64 third party intermediaries will submit participation plans for the CY 2024 performance period/2026 MIPS payment year.

In Table 77, we estimate that the cost for a QCDR or a qualified registry to submit a participation plan is $206.80 (2 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans would be 128 hours (64 participation plans × 2 hr/plan) at a cost of $13,235 (64 participation plans × $206.80/plan) (see Table 77 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In the CY 2017 Quality Payment Program final rule, we established the process for corrective action plans (CAPs) (81 FR 77386 through 77389). As discussed in section IV.A.4.k.(6)(b) of this final rule, we are finalizing our proposal an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence. Additionally, we are finalizing to add at § 414.1400(e)(2)(v) that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years. We are not making any changes to our currently approved estimated burden due to these finalized policies because these changes provide additional rationale for remedial action policies and do not add any additional requirements for third party intermediaries.

Based on the increased number of QCDR and qualified registries that required remedial actions for the CY 2022 performance period/2024 MIPS payment year, we anticipate the same trend would continue for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimate 24 third party intermediaries will submit CAPs for the CY 2024 performance period/2026 MIPS payment year. This is an increase of 14 respondents from the currently approved estimate of ten (87 FR 70142). We are not changing our currently approved estimate of 3 hours for a QCDR or qualified registry to submit a CAP. We also assume the staff involved in submitting the CAP will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. As shown in Table 77, we estimate that the cost for a QCDR or a qualified registry to submit a CAP is $310.20 (3 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to CAPs will be 72 hours (24 CAPs × 3 hr/plan) at a cost of $7,445 (24 CAPs × $310.20/plan).

(d) Transition Plans

We established a policy at § 414.1400(a)(2)(F) which states a condition of approval for the third party intermediary is to agree that prior to discontinuing services to any MIPS eligible individual clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. In this final rule, we estimate that we will receive nine transition plans for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of one from the currently approved estimate of 10 (87 FR 70142). We continue to estimate it will take approximately 1 hour for a computer system analyst or their equivalent at a labor rate of $103.40/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. In aggregate, we estimate the impact associated with qualified registries completing transition plans is 9 hours (9 transition plans × 1 hr/plan) at a cost of $931 (9 transition plans × $103.40/hr). We refer readers to section VI.E.23.e.(2)(a) of this final rule where we discuss our impact analysis for the transition plans submitted by QCDRs and qualified registries.

As discussed in section IV.A.4.k.(6)(c) of this final rule, we are finalizing our proposal to add an additional requirement at § 414.1400(e)(1)(i)(F) for the QCDR or qualified registry under a corrective action plan to communicate the final resolution to CMS once the resolution is complete and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C). We believe the revision will ensure third party intermediaries complete the requirements within the communication plan and will not add any additional requirements for a third-party intermediary to submit a CAP.

As discussed in section IV.A.4.k.(6)(d) of this rule, we are finalizing our proposal to add a new provision at § 414.1400€(1)(ii)(B) that CMS may, beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary. We are also finalizing to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(a)(2)(ii)(A) and ending the policy after the CY 2025 MIPS reporting period/CY 2027 MIPS payment year.

As discussed in section IV.A.4.k.(6)(e) of this final rule, we are finalizing our proposal to clarify the previously established policy under § 414.1400(a)(2)(ii)(A) to state that our consideration can include past

compliance including remedial actions. We are also finalizing at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. We are also finalizing to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(vii) with minor changes in the text for clarity.

We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to finalizing the above policies and therefore, are not making any adjustments to the currently approved burden estimates for third party intermediary plan audits. Additionally, we refer readers to section VI.E.23.e.(2)(a) of this final rule where we outline the details in our impact analysis for these policies.

(e) Final Burden for Third Party Intermediary Plan Audits

In aggregate, as shown in Table 76, we assume that 126 third party intermediaries will submit plan audits (29 targeted audits, 64 participation plans, 24 CAPs, and 9 transition plans).

TABLE 76: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	29
# of Participation Plans (b)	64
# of Corrective Action Plans (CAPs) €	24
# of Transition Plans (d)	9
Total Respondents (e) = (a) + (b) + (c) + (d)	**126**

As shown in in Table 77, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. For the CY 2024 performance period/2026 MIPS payment year, in aggregate, the estimated annual burden for the submission of third party intermediary plan audits will range from 354 hours to 499 hours at a cost ranging from $36,604 (354 hr × $103.40/hr) and $51,597 (499 hr × $103.40/hr).

TABLE 77: Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 29 Targeted Audits (b)	**145**	**290**
# of Hours per Submission of Participation Plan (c)	2	2
Total Annual Hours for Submission of 64 Participation Plans (d)	**128**	**128**
# of Hours per Submission CAP (e)	3	3
Total Annual Hours for Submission of 24 CAPs (f)	**72**	**72**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 9 Transition Plans (h)	**9**	**9**
Total Annual Hours for Submission of Plan Audits (i) = (b) + (d) + (f) + (h)	**354**	**499**
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $103.40/hr) (j) = (a) * $103.40/hr	$517	$1,034
Cost Per Participation Plan (@ computer systems analyst's labor rate of $103.4€r) (k) = (c) * $103.40/hr	$206.80	$206.80
Cost per CAP (@ computer systems analyst's labor rate of $103.40/hr) (l) = (e) * $103.40/hr	$310.20	$310.20
Cost per Transition Plan @computer systems analyst's labor rate of $103.40/hr (m) = (g) * $103.40/hr	$103.40	$103.40
Total Annual Cost (n) = 29 * (j) + 64 * (k) + 24 * (l) + 9 * (m) (simplified) and 29 * (j) + 64 * (k) + 24 * (l) + 9 * (m) (full)	**$36,604**	**$51,597**

As shown in Table 78, for the CY 2024 performance period/2026 MIPS payment year, the change in the number of respondents for third party intermediary plan audits results in a change of −71 hours at a cost of −$7,341 under the simplified self-nomination process and -86 hours at a cost of −$8,892 under the full self-nomination process.

We note for the purposes of calculating estimated change in burden

in Tables 109 through 111 of this rule, we use only estimated burden for the plan audits submitted under the full self-nomination process.

TABLE 78: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
Total Currently Approved Annual Hours (a)	425	585
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (See Table 77, row (i))	354	499
Difference (c) = (b) - (a)	**-71**	**-86**
Total Currently Approved Annual Cost (d)	$43,945	$60,489
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 77, row (n))	$36,604	$51,597
Difference (f) = (e) - (d)	**-$7,341**	**-$8,892**

We did not receive any comments on our proposed requirements and burden estimates for the QCDRs and qualified registries submitting plan audits under the self-nomination process. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52644 through 52646) due to the availability of updated data.

(5) Survey Vendor Requirements

The following changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We noted that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey.

In the CY 2024 PFS proposed rule, we proposed to adjust the estimated number of currently approved vendors that will apply to participate as CAHPS for MIPS Survey vendors (88 FR 52646 through 52647). We estimated that we will receive approximately 10 survey vendor applications for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 5 survey vendor applications from our currently approved estimate of 15 vendors in the CY 2018 QPP final rule (82 FR 53908). As shown in Table 79, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 10 hours. This will result in an estimated annual burden of 100 hours (10 survey vendor applications × 10 hr/application) at a cost of $10,340 (10 applications × $1,034/application).

TABLE 79: Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Survey Vendor Applications (a)	10
# of Hours per Computer Systems Analyst (b)	10
Total Annual Hours (c) = (a) * (b)	**100**
Cost to Submit a Survey Vendor Application (computer systems analyst @ $103.40/hr) (d)	$1,034
Total Annual Cost (e) = (a) * (d)	**$10,340**

In Table 80, we illustrate the net change in estimated burden for survey vendor requirements using the currently approved burden in the CY 2018 Quality Payment Program final rule (82 FR 53908). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents participating as CAHPS for MIPS Survey vendors will result in a total annual adjustment of −50 hours (−5 responses × 10 hr/application) at a cost of −$5,170 (−5 × (10 hr × $103.40/hr)) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 80: Change in Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	150
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 79, row(b))	100
Difference (c) = (b) - (a)	**-50**
Total Currently Approved Annual Cost (d)	$15,510
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 79, row (e))	$10,340
Difference (f) = (e) - (d)	**-$5,170**

We did not receive any comments on our proposed requirements and burden estimates for the estimated burden on the requirements for the CAHPS Survey vendors.

d. ICRs Regarding Open Authorization (OAuth) Credentialing and Token Request Process

We did not propose any new or revised collection of information requirements or burden related to the OAuth credentialing and token request process for the CY 2024 performance period/2026 MIPS payment year. The requirements and burden for the OAuth credentialing and token request process are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the burden for the OAuth credentialing and token request process under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 through 77503 and 82 FR 53908 through 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, 86 FR 65576 through 65588, and 87 FR 70145 through 70154, respectively) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit data for the quality performance category under MIPS: those who submit data as MIPS eligible clinicians, and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP Performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2024 performance period/2026 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future for the CY 2024 performance period/2026 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2024 PFS proposed rule (88 FR 52648), we noted that we continued to use submissions data from the CY 2021 performance period/2023 MIPS payment year to estimate the number of respondents that will submit data for the CY 2024 performance period/2026 MIPS payment year. We note that in this final rule, we have received updated data and therefore, adjusted the estimated number of respondents that will submit data for the CY 2024 performance period/2026 MIPS payment year based on the submissions received for the CY 2022 performance period/2024 MIPS payment year. We refer readers to sections V.B.11.e.(4), V.B.11.e.(5), V.B.11.e.(6), V.B.11.e.7.(a)(i) and V.B.11.e.(7)(a)(iii) of this final rule for additional details.

We assume 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2021, CY 2022, and CY 2023 PFS final rules (85 FR 84972, 86 FR 65567 and 87 FR 70145), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.11.a.(4) of this final rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2024 performance period/2026 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2022 performance period/2024 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2022 performance period/2024 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this final rule because sections 1899(e) and

1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[511]

For the CY 2024 performance period/2026 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimated the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. Additionally, we captured the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking. In the CY 2019 PFS final rule, we finalized proposals to limit the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and to allow clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752).

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2022 performance period/2024 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 81 uses methods similar to those described above to estimate the number of MIPS eligible clinicians that will submit data as individual clinicians via each collection type in the CY 2024 performance period/2026 MIPS payment year. For the CY 2024 performance period/2026 MIPS payment year, we estimate that approximately 13,413 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 10,682 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 22,897 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2022 performance period/2024 MIPS payment year, these are adjustments of -1,323, -776, and 4,535 respondents from the currently approved estimates of 14,736, 11,458, and 18,362 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

TABLE 81: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a)	15,597	12,421	26,624	54,642
MVP Adjustment @ 14% (b) = (a)* 0.14	-2,184	-1,739	-3,727	-7,650
2024 MIPS Performance Period (excludes QPs and Adjusted for MVP) (c)= (a) – (b)	**13,413**	**10,682**	**22,897**	**46,992**
**Currently approved 2023 MIPS Performance Period (excludes QPs) (d)	14,736	11,458	18,362	44,556
Difference (**e) = (c) – (d**)	**-1,323**	**-776**	**4,535**	2,436

* We estimate 14 percent of clinicians will participate in MVP reporting as discussed in section V.11.e.(7) of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 81 are not mutually exclusive.

Table 82 provides our estimates for the number of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2024 performance periods/2026 MIPS payment year. We assume clinicians who submitted quality data as groups in the CY 2022 performance period/2024 MIPS payment year will continue to submit data for the quality performance category either as groups, or virtual groups for the same collection types for the 2024 performance period/2026 MIPS payment years. We used the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2022

[511] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

performance period/2024 MIPS payment year.

As shown in Table 82, for the CY 2024 performance period/2026 MIPS payment year, we estimate that 5,950 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 5,817 groups and virtual groups will submit for the eCQM collection type. These are adjustments of ×508 and 290 respondents from the currently approved estimates of 6,458, and 5,527 for the groups and virtual groups that will submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

TABLE 82: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a) prior to adjustments	0	6,918	6,764	13,682
Adjustment for MVPs (14%) (b) = (a) * 0.14	0	-968	-947	-1,915
2024 MIPS performance period (excludes QPs and) Adjusted for MVP). (c) = (a) – (b)	0	**5,950**	**5,817**	**11,**767
**Currently approved 2023 MIPS performance period (excludes QPs) (d)	0	6,458	5,527	11,985
Difference (e) = (c) - (d)	0	**-508**	**290**	-218

* We estimate 14 percent of clinicians will participate in MVP reporting as discussed in section V.B.11.e.7. of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621).

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their Electronic Health Record (EHR) implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimate the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group TINs could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 through 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2024 performance period/2026 MIPS payment year, we proposed a measure set of 200 quality measures (88 FR 52567 through 52568). As shown in Table 83, we are finalizing 198 quality measures for the CY 2024 performance period/2026 MIPS payment year. The new MIPS quality measures for inclusion in MIPS for the CY 2024 performance period/2026 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 83, as well as counts of new, removed, and substantively changed measures. There are no changes to the remaining measures not included in Appendix 1. We refer readers to Appendix 1: MIPS Quality Measures of this final rule for additional information.

TABLE 83: Summary of Quality Measure Inventory Finalized for the CY 2024 Performance Period

Collection Type	# Measures as New	# Measures for Removal*	# Measures with a Substantive Change*	# Measures for CY 2024*
Medicare Part B Claims	0	-3	10	27
MIPS CQMs Specifications	+11	-10	51	173
eCQM Specifications	0	-3	26	44
Survey – CSV	0	0	0	1
Administrative Claims	0	0	0	4
Total*	+11**	-11***	59	198

*A measure may be specified under multiple collection types but will only be counted once in the total.
**We are finalizing the proposal, with modification, to add 11 quality measures.
*** We are finalizing the proposal, with modification, to remove 11 MIPS quality measures and finalizing as proposed to partially remove 3 MIPS quality measures (removed from traditional MIPS, for use in MVPs.) NOTE: The 3 MIPS quality measures partially removed from traditional MIPS are not included in the total number of measures finalized for removal from MIPS starting with the CY 2024 performance period.

For the CY 2024 performance period/2026 MIPS payment year, we are finalizing 198 measures, which is the same as the currently approved estimate of 198 measures. Specifically, as discussed in section IV.A.4.f.(1)(e) of this rule, we are finalizing our proposal, with modification, to add 11 new MIPS quality measures. We are also finalizing our proposal, with modification, to remove 11 MIPS quality measures, and finalizing as proposed, to partially remove 3 MIPS quality measures (from traditional MIPS for use in MVPs) and make substantive updates to 59 MIPS quality measures. We do not anticipate our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures in traditional MIPS reporting or submit quality data for 4 measures in an MVP.

(3) Quality Payment Program Identity Management Application Process

We did not propose any new or revised collection of information requirements or burden related to the identity management application process for the CY 2024 performance period/2026 MIPS payment year. The identity management application process requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes for the identity management application process under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

In this rule, we did not propose any new or revised collection of information requirements or burden related to the submission of Medicare Part B claims data for the quality performance category. Our updated estimate for MVP participation due to policy changes to the MVP inventory as discussed in section IV.A.4.a. of this rule, impacts the number of clinicians submitting quality data for MIPS using the Medicare Part B Claims-based collection type. We refer readers to Table 87 of this section for the change in associated burden related to the submission of Medicare Part B claims data for the MVP quality performance category in the CY 2024 performance period/2026 MIPS payment year.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60004 through 60005, 84 FR 63124 through 63126, 85 FR 84975 through 84976, 86 FR 65582 through 65584, and 87 FR 70149 through 70151 respectively) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 81, we estimate that 13,413 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 1,323 from the currently approved estimate of 14,736 (87 FR 70150).

In Table 84, consistent with our currently approved per response time figures and using the updated wage rates in Table 62 of this final rule, we continue to estimate the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $15.51 (0.15 hr × $103.40) for a computer systems analyst to 7.2 hours at a cost of $744.48 (7.2 hr × $103.40/hr). The burden also accounts for the effort needed to become familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates and using the updated wage rates in Table 62 of this final rule, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours for a medical and health services manager at $123.06/hr, 1 hour for a physician at $274.44/hr, 1 hour for an LPN at $53.72/hr, 1 hour for a computer systems analyst at $103.40/hr, and 1 hour for a billing and posting clerk at $43.08/hr.

In Table 84, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In aggregate, the total annual time for the CY 2024 performance period/2026 MIPS payment year ranges

from 95,903 hours (7.15 hr × 13,413 respondents) to 190,465 hours (14.2 hr × 13,413 respondents). The total annual cost for the CY 2024 performance period/2026 MIPS payment year ranges from a minimum of $11,526,193 (13,413 respondents × $859.33/response) to a maximum of $21,303,868 (13,413 respondents × $1588.30/response).

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TABLE 84: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	13,413	13,413	13,413
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	**95,903**	**107,975**	**190,465**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (j)	$15.51	$108.57	$744.48
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr @ 3 hr) (k)	$369.18	$369.18	$369.18
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr @ 1 hr) (l)	$103.40	$103.40	$1'3.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr @1 hr) (m)	$53.72	$53.72	$53.72
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr @ 1 hr) (n)	$43.08	$43.08	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr @ 1 hr) (o)	$274.44	$274.44	$274.44
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$859.33	$952.39	$1,588.30
*Total Annual Cost (q) = (a) * (p)	**$11,526,193**	**$12,774,407**	**$21,303,868**

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In Table 85, we used the currently approved burden as the baseline to calculate the net burden for the quality data submissions from clinicians using the Medicare Part B Claims-based collection type. In aggregate, using our currently approved per response time estimates, the decrease in number of responses from 14,736 to 13,413 (−1,323) results in a total maximum adjustment of −18,786 hours (−1,323 responses × 14.2 hr/response) at a cost of −$2,101,321 (−1,323 responses × $1,588.30/response). For purposes of calculating total burden associated with this final rule as shown in Tables 109 through 111, only the maximum burden is used.

TABLE 85: Burden Adjustments for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	209,251
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (see Tab–e D-A23, row (i))	190,465
Difference (c) = (b) - (a)	**-18,786**
Total Currently Approved Annual Cost (d)	$23,405,189
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (see Tab–e D-A23, row (q)	$21,303,868
Difference (f) = (d) - (e)	**-$2,101,321**

We did not receive any comments on our proposed requirements and burden estimates for the quality performance category submission using the Medicare Part B Claims collection type. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52651 through 52653) due to the availability of updated data.

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 through 77505 and 82 FR 53912 through 53914, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60005 through 60006, 84 FR 63127 through 63128, 85 FR 84977 through 84979, 86 FR 65584 through 65586, and 87 FR 70151 through 70153, respectively) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 92 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2024 performance period/2026 MIPS payment year.

As noted in Tables 78 and 79, based on data from the CY 2022 performance period/2024 MIPS payment year, for the CY 2024 performance period/2026 MIPS payment year, we estimate that 16,632 clinicians (10,682 individuals and 5,950 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is a decrease of 1,284 clinicians from the currently approved estimate of 17,916 clinicians provided in the CY 2023 PFS final rule (87 FR 70152). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe the burden for an individual clinician or group to review measure specifications and submit quality data is a total of 9 hours at a cost of $1,039.54 per response. This consists of 3 hours at $103.40/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $123.06/hr for a medical and health services manager, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for a LPN, 1 hour at $43.08/hr for a billing clerk, and 1 hour at $274.44/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hr) at $103.40/hr for a computer systems analyst at a cost of $8.15 (0.083 hr × $103.40/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $1,039.54/response [(3 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr) + (0.083 hr × $103.40/hr)].

In Table 86, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 151,068 hours [9.083 hr/response × 16,632 responses] at a cost of $17,289,629 (16,632 responses × $1,039.54/response).

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TABLE 86: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	10,682
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	5,950
Total # of Respondents (c) = (a) + (b)	**16,632**
Hours Per Respondent to Report Quality Data (d)	3
# of Hours per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours for Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours for LPN to Review Measure Specifications (g)	1
# of Hours for Billing Clerk to Review Measure Specifications (h)	1
# of Hours for Physician to Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)*(k)	**151,068**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (m)	$310.20
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (n)	$246.12
Cost per Computer System's Analyst Review of Measure Specifications (@ computer systems analyst's labor rate of $103.40'hr) (o)	$103.40
Cost per LPN to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (p)	$53.72
Cost per Billing Clerk to Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (q)	$43.08
Cost for Physician to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (r)	$274.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $103.40/hr) (s)	$8.58
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$1,039.54
Total Annual Cost (u) = (c) * (t)	**$17,289,629**

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In Table 87, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden in the CY 2023 PFS final rule (87 FR 70151 through 70153). In aggregate, using the unchanged currently approved time per response estimate, the decrease of 1,284 respondents from 17,916 to 16,632 for the CY 2024 performance period/2026 MIPS payment year results in a decrease of 11,663 hours (−1,284 responses × 9.083 hr/response) at a cost of −$1,334,770 (−1,284 responses × $1,039.54/response).

TABLE 87: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	162,731
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (see Table 86, row (l))	151,068
Difference (c) = (b) - (a)	**-11,663**
Total Currently Approved Annual Cost (d)	$18,624,399
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (see Table 86, row (u))	$17,289,629
Difference (f) = (e) - (d)	**-$1,334,770**

We did not receive any comments on our proposed requirements and burden estimates for the quality performance category submission using the MIPS CQM and QCDR collection type. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52653 through 52654) due to the availability of updated data.

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77505 through 77506 and 82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130), CY 2021 PFS final rule (85 FR 84979 through 84980), the CY 2022 PFS final rule (86 FR 65586 through 65588), and the CY 2023 PFS final rule (87 FR 70153 through 70154) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2024 performance period/2026 MIPS payment year, we refer readers to Table 92.

Based on updated data from the CY 2022 performance period/2024 MIPS payment year data, we assume that 28,714 clinicians (22,897 individual clinicians and 5,817 groups and virtual groups) will submit quality data using the eCQM collection type for the CY 2024 performance period/2026 MIPS payment year. This is an increase of 4,825 clinicians from the currently approved estimate of 23,889 clinicians provided in the CY 2023 PFS final rule (87 FR 70153). We assume the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their certified EHR technology (CEHRT) and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $103.40/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $123.06/hr for a medical and health services manager, 1 hour at $274.44/hr for a physician, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for an LPN, and 1 hour at $43.08/hr for a billing clerk. Overall, we estimate a cost of $927.56/response [(2 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr)].

In Table 88, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 229,712 hours [8 hr × 28,714 responses] at a cost of $26,633,958 (28,714 responses × $927.56/response).

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TABLE 88: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	22,897
# of Groups submitting via EHR on behalf of individual clinicians (b)	5,817
Total # of Respondents (c)=(a)+(b)	**28,714**
Hours Per Respondent to Submit MIPS Quality Data File to (d)	2
# of Hours Per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours Per Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours Per LPN to Review Measure Specifications (g)	1
# of Hours Per Billing Clerk to Review Measure Specifications (h)	1
# of Hours Per Physician to Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	**229,712**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (l)	$206.80
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (m)	$246.12
Cost to Review Measure Specifications (@ computer system's analyst's labor rate of $103.40/hr) (n)	$103.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (o)	$53.72
Cost to Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (p)	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (q)	$274.44
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$927.56
Total Annual Cost (s) = (c) * (r)	**$26,633,958**

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In Table 89, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2023 PFS final rule (87 FR 70153 through 70154). In aggregate, using our currently approved time per response burden estimate, the increase of 4,825 respondents from 23,889 to 28,714 for the CY 2024 performance period/2026 MIPS payment year results in an increase of 38,600 hours (4,825 responses × 8 hr/response) at a cost of $4,475,477 (4,825 responses × $927.56/response).

TABLE 89: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	191,112
Total Annual Hours for respondents in CY 2024 PFS Final Rule (b) (see Table 88, row (k))	229,712
Difference (c) = (b) - (a)	**38,600**
Total Currently Approved Annual Cost (d)	$22,158,481
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (see Table 88, row (s))	$26,633,958
Difference (f) = (e) - (d)	**$4,475,477**

We did not receive any comments on our proposed requirements and burden estimates for the quality performance category submission using the eCQM collection type. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52655 through 52656) due to the availability of updated data.

(7) ICRs Regarding Burden for MVP Reporting

The following changes will be submitted to OMB for review under

control number 0938–1314 (CMS–10621).

(a) Burden for MVP Reporting Requirements

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 and CY 2023 PFS final rules for our previously finalized burden assumptions and requirements for submission data for the MVP performance category, and for the estimated number of clinicians participating as subgroups in the CY 2023 performance period/2025 MIPS payment year (86 FR 65590 through 65592 and 87 FR 70155).

As discussed in section IV.A.4.a of this final rule, we are finalizing our proposal to add five new MVPs to the MVP Inventory. Additionally, we are finalizing our proposal to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Therefore, MVP participants will have a total of 16 MVPs available for the CY 2024 performance period/2026 MIPS payment year. Due to the availability of new MVPs, we expect an increase in the projected number of MVP participants. For each newly proposed MVP, we calculated the average quality measure submission rate across the measures available in each MVP for the CY 2021 performance period/2023 MIPS payment year. The total of these average quality measure submissions for each MVP was equivalent to about 2 percent of total quality measure submissions in the CY 2021 performance period/2023 MIPS payment year. We assume there would not be any changes to MVP submissions due to the finalizing of our proposal discussed in section IV.A.4.b. of this final rule to consolidate the measures in the Promoting Wellness and Optimizing Chronic Disease Management MVPs into a Value in Primary Care MVP. That is, we assume clinicians who would have submitted the Optimizing Chronic Disease Management MVP, or the Promoting Wellness MVP would instead submit the Value in Primary Care MVP. Therefore, we estimate that 14 percent of the clinicians will participate in MVP reporting in the CY 2024 performance period/2026 MIPS payment year. This is an increase of 2 percentage points from the currently approved estimate of 12 percent in the CY 2023 PFS final rule (87 FR 70155). We refer readers to Appendix 3: MVP Inventory of this final rule for additional details on the MVPs available for the CY 2024 performance period/2026 MIPS payment year. We assume the changes to the existing MVPs and the addition of new MVPs will not impact the currently approved number of subgroups. We expect clinician participation in subgroups will be relatively low for the CY 2024 performance period/2026 MIPS payment year due the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we did not make any adjustments to our previously finalized estimate in the CY 2023 PFS final rule (87 FR 70155) that 20 subgroups will participate in MVP reporting.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2023 PFS final rule (87 FR 70155 through 70156) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

As previously discussed, we estimate that approximately 14 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2024 performance period/2026 MIPS payment year, we assume that the total number of individual clinicians, groups, subgroups and APM Entities that will complete the MVP registration process is 9,585. In Table 90, we estimate that it will take 2,396 hours (9,585 responses × 0.25 hr/response) at a cost of $247,772 (9,585 registrations × $25.85/registration) for individual clinicians, groups and APM Entities to register for MVP reporting in the CY 2024 performance period/2026 MIPS payment year.

TABLE 90: Estimated Burden for MVP Registration (Individuals, Groups, Subgroups, and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	9,585
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time for MVP Registration (c) = (a) * (b)	**2,396**
Estimated Cost Per Registration (e) = (d) * (b)	25.85
Estimated Total Annual Cost for MVP Registration (f) = (a) * (e)	**$247,772**

In Table 91, we illustrate the net change in burden for MVP registration using the currently approved burden in the CY 2023 PFS final rule (87 FR 70155 through 70156). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, the adjustment in the number of respondents expected to register for MVP reporting from 7,731 to 9,585 results in an increase of 1,854 responses. In aggregate, when combined with the currently approved per response time estimate, this will result in an increase of 463 hours (2,396 hours − 1,933 hours) at a cost of $47,926 ($247,772 − $199,846).

TABLE 91: Burden Adjustment for MVP Registration (Individuals, Groups, Subgroups, and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	1,933
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 90, row (c))	2,396
Difference (c) = (b) – (a)	**+463**
Total Currently Approved Annual Cost (d)	$199,846
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 90, row (e))	$247,772
Difference (f) = (e) - (d)	**+$47,926**

We did not receive any comments on our proposed requirements and burden estimates for the MVP registrations. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52657 through 52658) due to the availability of updated data.

(ii) Burden for Subgroup Registration

We did not propose any changes to our currently approved subgroup registration burden (86 FR 65590). We note that the subgroup policies discussed in section IV.A.4.d. of this final rule do not impact the currently approved burden for subgroup registration. We discuss in detail below, the policies and our reasons for not changing the currently approved burden for subgroup registration. The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes pertaining to subgroup registration under that control number.

As discussed in section IV.A.4.d.(2) of this final rule, we are finalizing our proposal to modify § 414.1365(e)(2)(ii) to read that, an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 MIPS performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B). We believe that the modification to the subgroup reweighting policy will not impact the currently approved burden for subgroup registration because it will not change any requirements related to subgroup registration.

As discussed in section IV.A.4.d.(3) of this final rule, we are also finalizing our proposal to modify the text at § 414.1365(e)(3) to read that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). Additionally, we are finalizing our proposal to add § 414.1365(e)(4)(i) to read that for subgroups, the affiliated group's complex patient bonus will be added to the final score. The revisions will not impact the currently approved burden for subgroup registration since these changes only modify the regulatory text relevant to subgroup scoring policies.

As discussed in section IV.A.4.d.(4) of this final rule, we are finalizing our proposal to modify § 414.1385(a)(1) to read that a MIPS eligible clinician, subgroup, or group (including their designated support staff), or a third-party intermediary as defined at § 414.1305, may submit a request for a targeted review. The change will not impact the currently approved burden for subgroup registration since the addition of subgroups to the targeted review language only modifies the regulatory text relevant to the targeted review process and does not change the subgroup registration requirements. We finalized in the CY 2017 Quality Payment Program final rule that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77546). We note that information collection requirements, such as targeted reviews, that are imposed after an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, we are not making any adjustments to the currently approved subgroup registration burden because of the proposal to add subgroups to the targeted review regulation text.

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we previously finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). As discussed in section V.B.11.e. of this rule, we did not propose new requirements to submit data for the quality performance category of MVPs. Therefore, we are not making any changes to our currently approved per response time estimates for submitting the MVP quality performance category data.

As described in section V.B.11.e.(7)(a) of this final rule, we estimate that 14 percent of the clinicians who participated in MIPS for the CY 2022 performance period/2024 MIPS payment year will submit data for the quality performance category of MVP in the CY 2024 performance period/2026 MIPS payment year. We also estimate there will be 20 subgroup reporters in the CY 2024 performance period/2026 MIPS payment year. In Table 92, we estimate that 4,674 clinicians and 10 subgroups will submit data using eCQMs collection type at $614.45/response (see line q for eCQMs); 2,707 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type at $683.73/response (see line q for CQM and QCDRs); and 2,184 clinicians and 0 subgroups will submit data for the MVP quality performance category using the Medicare Part B claims collection type at $1,055.70/response (see line q for claims). For the CY 2024 performance period/2026 MIPS payment year, using our currently approved per response time estimates

for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 24,825 hours [5.3 hr × 4,684 (4,674 +10) responses] at a cost of $2,878,084 (4,684 responses × $614.45/response) for the eCQM collection type, 16,220 hours [5.97 hr × 2,717 (2,707 +10)] at a cost of $1,857,694 (2,717 responses × $683.73/responses) for the MIPS CQM and QCDR collection type, and 20,617 hours (9.44 hr × 2,184 clinician responses) at a cost of $2,305,649 (2,184 responses × $1,055.70/response) for the Medicare Part B claims collection type.

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TABLE 92: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	4,674	2,707	2,184
# of Subgroup reporters (b)	10	10	0
Total MVP participants(c) = (a) + (b)	4,684	2,717	2,184
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**24,825**	**16,220**	**20,617**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (k)	$137.52	$206.80	$496.32
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (l)	$163.67	$163.67	$246.12
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (m)	$68.24	$68.24	$68.24
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (n)	$35.46	$35.46	$35.46
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr) (o)	$28.43	$28.43	$28.43
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (p)	$181.13	$181.13	$181.13
Total Annual Cost Per Submission (q) = (k) + (l) + (m) + (n) + (o) + (p)	$614.45	$683.73	$1,055.70
Total Cost (r) = (c) * (q)	**$2,878,084**	**$1,857,694**	**$2,305,649**

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Table 93 illustrates the changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and claims collection types in the CY 2024 performance period/2026 MIPS payment year. We note we used the currently approved burden in the CY 2023 PFS final rule (87 FR 70157 through 70159) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the increase in 1,854 respondents who will submit data for the MVP quality performance category will result in an increase of 7,505 hours and $870,048 for the eCQM collection type, an increase of 1,576 hours and $180,499 for the CQM and QCDR collection type, and an increase of 1,643 hours and $183,687 for the claims collection type.

TABLE 93: Burden Adjustments for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	17,320	14,644	18,974
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 92, row (k))	24,825	16,220	20,617
Difference (c) = (b) - (a)	**7,505**	**1,576**	**1,643**
Total Currently Approved Annual Cost (d)	$2,008,036	$1,677,195	$2,121,962
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 92, row (r))	$2,878,084	$1,857,694	$2,305,649
Difference (f) = (e) - (d)	**$870,048**	**$180,499**	**$183,687**

We did not receive any comments on our proposed requirements and burden estimates for the MVP quality performance category submission. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52658 through 52660) due to the availability of updated data.

(8) Beneficiary Responses to CAHPS for MIPS Survey

The following changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We noted that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to the CY 2021 Quality Payment Program final rule (85 FR 84982 through 84983) for our previously finalized estimated burden associated with beneficiary responses to the CAHPS for MIPS Survey.

As discussed in section IV.A.4.f.(1)(c)(ii)(A) of this final rule, we are finalizing our proposal to require Spanish language administration of the CAHPS for MIPS Survey. Specifically, we are finalizing our proposal to require organizations to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. For requirements and burden, we estimate an average administration time of 13.1 minutes (or 0.2183 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.7 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for the CY 2022 performance period/2024 MIPS payment year, we are not updating our burden estimates to include the time associated with the Spanish version at this time.

In the CY 2024 PFS proposed rule (88 FR 52660), we proposed to adjust the currently approved estimated number of beneficiaries that will respond to the CAHPS for MIPS survey. For the CY 2024 performance period/2026 MIPS payment year, we estimated that 100 groups will elect to report on the CAHPS for MIPS survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the CY 2022 performance period/2024 MIPS payment year, we estimated that an average of 255 beneficiaries will respond per group for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimated that the CAHPS for MIPS survey will be administered to approximately 25,500 beneficiaries for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 4,452 beneficiary respondents from our currently approved estimate of 29,952 beneficiary respondents in the CY 2021 PFS final rule (85 FR 84982). As shown in Table 94, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time to administer the survey is 0.2183 hours. This will result in an estimated annual burden of 5,567 hours at a cost of $165,750.

TABLE 94: Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Groups Practices Administering CAHPS for MIPS Survey (a)	100
# of Beneficiaries Per Group Responding to Survey (b)	255
# of Total Beneficiaries Reporting (c)=(a)*(b)	25,500
# of Hours Per Beneficiary Respondent (d)	0.2183
Total Annual Hours (e) = (c) * (d)	**5,567**
Cost for Beneficiary to Respond to CAHPS for MIPS Survey @ labor rate of $29.76/hr (f) = (d) *$29.76/hr	$6.50
Total Annual Cost (g) = (e) * (f)	**$165,750**

In Table 95, we illustrate the net change in estimated burden for beneficiary response requirements using the currently approved burden in the CY 2021 PFS final rule (85 FR 84982 through 84983). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents submitting responses for the CAHPS for MIPS survey results in a total annual adjustment of −972 hours at a cost of −$28,938 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 95: Change in Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	6,539
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 94, row (e))	5,567
Difference (c) = (b) - (a)	**-972**
Total Currently Approved Annual Cost (d)	$194,688
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 94, row (g))	$165,750
Difference (f) = (e) - (d)	**-$28,938**

We did not receive any comments on our proposed requirements and burden estimates for the beneficiaries responding to the CAHPS for MIPS Survey.

(9) Group Registration for CAHPS for MIPS Survey

The following changes will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We noted that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to CY 2019 PFS final rule (83 FR 60009 through 60010) for the previously approved requirements and burden for group registration for the CAHPS for MIPS Survey.

In the CY 2024 PFS proposed rule (88 FR 52661), we proposed to adjust the estimated number of groups registering for the CAHPS for MIPS Survey that were previously approved in the CY 2019 PFS final rule (83 FR 60009 through 60010) based on updated data from the CY 2022 performance period/2024 MIPS payment year. We estimated that 266 groups will register for the CAHPS for MIPS Survey for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 16 group registrations from our currently approved estimate of 282 groups in the CY 2019 PFS final rule (83 FR 60010). In Table 96, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 0.75 hours. This will result in an estimated annual burden of 200 hours (266 groups × 0.75 hr/registration) at a cost of $20,628 (266 registrations × $77.55/registration) for a computer systems analyst).

TABLE 96: Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	Burden Estimate
# of Groups Registering for the CAHPS for MIPS Survey (a)	266
# of Hours Per Computer Systems Analyst (b)	0.75
Total Annual Hours (c) = (a) * (b)	**200**
Cost to Register a Group for the CAHPS for MIPS Survey (@ computer systems analyst @ $103.40/hr) (d) = (b) *$103.40/hr	$77.55
Total Annual Cost (e) = (c) * (d)	**$20,628**

In Table 97, we illustrate the net change in estimated burden for groups registering for the CAHPS for MIPS Survey using the currently approved burden in the CY 2019 PFS final rule (83 FR 60009 through 60010). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents registering for the CAHPS for MIPS Survey from 282 to 266 results in a total annual adjustment of −12 hours (−16 responses × 0.75 hr/nomination) at a cost of −$1,241 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 97: Change in Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	212
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 96, row (c))	200
Difference (c) = (b) - (a)	**-12**
Total Currently Approved Annual Cost (d)	$21,869
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 96, row (i))	$20,628
Difference (f) = (e) - (d)	**-$1,241**

We did not receive any comments on our proposed requirements and burden estimates for the groups registering for the CAHPS for MIPS Survey.

f. ICRs Regarding the Call for MIPS Quality Measures

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

In this rule, we did not propose any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, based on the actual number of quality measure submissions received for CMS consideration during the 2023 Annual Call for Quality Measures, we adjusted our burden estimates for the CY 2024 performance period/2026 MIPS payment year.

In the CY 2024 PFS proposed rule (88 FR 52662), we estimated that we will receive 31 quality measure submissions during the 2023 Annual Call for Quality Measures, an increase of 2 from the currently approved number of quality measure submissions for consideration (87 FR 70159 through 70160). We did not propose any changes to the 5.5 hour (2.4 hr for practice administrator + 3.1 hr for clinician) per response time estimate for quality measure submissions.

In Table 98, we estimate an annual burden of 171 hours (31 measure submissions × 5.5 hr/measure) at a cost of $35,529 (31 measure submissions × $1,146.11/submission for the CY 2024 performance period/2026 MIPS payment year.

TABLE 98: Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	31
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**171**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $123.06/hr) * 2.4 hr = (g)	$295.34
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $274.44/hr) * 3.1 hr = (h)	$850.77
Total Annual Cost Per Submitted Measure (i) = (g) + (h)	$1,146.11
***Total Annual Cost (j)=(a)*(i)**	**$35,529**

In Table 99, we illustrate the net change in estimated burden for the call for quality measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70159 through 70160). In aggregate, the estimated increase in the number of quality measure submissions will result in an adjustment of +11 hours (+2 measure submissions × 5.5 hr/measure submission) at a cost of $2,292 (+2 measure submissions × $1,146.11/measure submission) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 99: Burden Adjustments for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	160
Total Annual Hours for Respondents in CY 2024 PFS Final Rule (b) (See Table 98, row (f))	171
Difference (c) = (b) - (a)	**+11**
Total Currently Approved Annual Cost for Respondents (d)	$33,237
Total Annual Cost for Respondents in CY 2024 PFS Final Rule (e) (See Table 98, row (j))	$35,529
Difference (f) = (e) - (d)	**+$2,292**

We did not receive any comments on our proposed requirements and burden estimates for the call for quality measures.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians, groups, subgroups, and APM Entities can submit Promoting Interoperability performance category data through direct log in and upload or log in and attest submission types. We note that the log in and attest submission type is only available for the Promoting Interoperability performance category and is not available for the quality performance category. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, we anticipated that MIPS eligible individual clinicians, groups, subgroups, and APM Entities will use the same data submission type for both the quality and Promoting Interoperability performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. We note that this analysis assesses burden by performance category and submission type and emphasizes that MIPS is a consolidated program. We analyzed data submitted by MIPS eligible clinicians, groups, subgroups and APM Entities, and assesses clinician performance based on all the four MIPS performance categories, as applicable.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The following changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60011 through 60012, 84 FR 63134 through 63135, 85 FR 84984 through 84985, 86 FR 65596 through 65598, and 87 FR 70160 through 70162, respectively) for our previously finalized requirements for, and our analysis of the information collection and reporting burden associated with, reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians may submit an application requesting reweighting to zero percent for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or other type of exception (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Table 100 summarizes our analysis of the estimated burden, including for MIPS eligible clinicians to apply for reweighting of the Promoting Interoperability performance category and other performance categories to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i).

Respondents (MIPS eligible individual clinicians, groups, or APM Entities) who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances (for example, PHE for COVID–19, vendor issues, etc.) will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

As discussed in section IV.A.4.f.(4)(f) of this final rule, we are finalizing our proposal to continue the existing policy of CMS automatically reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year and making the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4*)(*iii*). In our analysis of the information collection and reporting burden, we did not adjust our estimated number of respondents submitting reweighting applications due to this proposal because these changes only modify the regulatory text and do not change the existing reweighting policy for these clinician types participating in MIPS in the CY 2024 performance period/2026 MIPS payment year. To further clarify, these clinician types are automatically reweighted for the Promoting Interoperability performance category and do not need to submit a reweighting application, and therefore do not impact our information collection and reporting burden analysis.

Based on the number of reweighting applications received at the time of the publication of this rule for the CY 2022 performance period/2024 MIPS payment year, we adjusted our burden

estimates relevant to this ICR. In this final rule, we estimate that we will receive a total of 29,227 applications to request reweighting for any or all the four MIPS performance categories for the CY 2024 performance period/2026 MIPS payment year. Out of the 29,227, we estimate that 2,706 respondents will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C). We estimate that the remaining 26,510 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance as provided in § 414.1380(c)(2)(i). Additionally, we estimated 11 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2024 performance period/2026 MIPS payment year. This adjustment results in an increase of 23,788 respondents compared to our currently approved estimate of 5,439 respondents (87 FR 70161). This increase is based on the actual number of reweighting applications submitted for the CY 2022 performance period/2024 MIPS payment year. We note this estimate reflects the significant increase in the number of submitted applications due to extending the deadline, as a result of the ongoing PHE for COVID–19 at the time, for submitting the reweighting applications for the CY 2022 performance period/2024 MIPS payment year to March 3rd, 2023.

Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70160 through 70162), we continued to estimate it will take 0.25 hours for a computer system analyst to complete and submit the reweighting application. In Table 100, we estimate an annual burden of 7,307 hours (29,227 applications × 0.25 hr/application) at a cost of $755,518 (29,227 applications × $25.85/application).

TABLE 100: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	29,216
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	11
Total Applications Submitted (c)	**29,227**
Annual Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (c) * (d)	**7,307**
Cost to Submit a Reweighting Application @ computer systems analyst's labor rate of $103.40/hr (f) = (d) *$103.40/hr	$25.85
Total Annual Cost (g) = (e) * (f)	**$755,518**

In Table 101, we illustrate the net change in estimated burden for submission of reweighting applications for Promoting Interoperability and other performance categories using the currently approved burden in the CY 2023 PFS final rule (87 FR 70160 through 70162). The adjustment in the estimated number of respondents, from 5,439 to 29,227 respondents, results in an increase of 23,788 respondents. In aggregate, using our currently approved per response time estimate, as shown in Table 101, the increase in 23,788 respondents results in an increase of 5,947 hours (+23,788 responses × 0.25 hr/response) and $614,920 (+5,947 hr × $103.40/hr) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 101: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	1,360
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (See Table 100, row (c))	7,307
Difference (c) = (b) - (a)	**+5,947**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$140,598
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 100, row (e))	$755,518
Difference (f) = (e) - (d)	**+$614,920**

We did not receive any comments on our proposed requirements and burden estimates for the submission of reweighting applications for Promoting Interoperability and other performance categories.

(3) Submitting Promoting Interoperability Data

The following changes relevant to the submission of Promoting Interoperability data requirements and burden will be submitted for approval under OMB under control number 0938–1314 (CMS–10621). We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52664 through 52665) due to the availability of updated data from the CY 2022 performance period/2024 MIPS payment year.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, and 82 FR 53919 through 53920, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60013 through 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, 86 FR 65598 through 65600, and 87 FR 70162 through 70164, respectively) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

As discussed in section IV.A.4.f.(4)(b) of this final rule, we are finalizing our proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year and are revising the regulation text at § 414.1320 to reflect this change. We assume MIPS eligible clinicians and groups that currently submit data for the Promoting Interoperability performance category will utilize the CEHRT for an entire calendar year performance period and therefore, the increase in the length of the performance period for the Promoting Interoperability performance category from 90 to 180 days will not create additional burden for MIPS eligible clinicians and groups that will submit data for the Promoting Interoperability performance category. We note that this is consistent with the discussion of burden for the above policy in the FY 2022 IPPS final rule (86 FR 45515).

As discussed in section IV.A.4.f.(4)(d)(i) of this final rule, we are finalizing our proposed changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective. Specifically, we are modifying the second exclusion for the Query of PDMP measure as proposed so that it reads as follows: Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period. The changes will not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since the revision is meant to revise the previously finalized second exclusion in the CY 2018 Quality Payment Program final rule (82 FR 53679). Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

As discussed in section IV.A.4.f.(4)(d)(ii) of this final rule, we are finalizing to revise the e-Prescribing measure description in Table 51 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically using CEHRT'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.'' These revisions will not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since these changes provide technical updates to the e-prescribing measure. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

As discussed in section IV.A.4.f.(4)(d)(iii) of this final rule, we are finalizing our proposal to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year and subsequent years, to require MIPS eligible clinicians conduct, and therefore attest ''yes'' to having completed an annual self-assessment of the CEHRT using the High Priority Practices SAFER Guide. Additionally, we are finalizing our proposal to amend the regulatory text *at* § 414.1375(b)(2)(ii)(C) to clearly specify that a MIPS eligible clinician must submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs; this regulatory provision will only be applicable for the 2024 MIPS payment year through the 2025 MIPS payment year. We noted we have captured the estimated burden for reporting this measure in the CY 2022 PFS final rule (86 FR 65599) and the revision will not affect the data collection and submission requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

As shown in Table 102, based on updated data from the CY 2022 performance period/2024 MIPS payment year, we are adjusting our currently approved estimated burden for the submission of data in Promoting Interoperability performance category (87 FR 70162 through 70164). We estimate that a total number of 25,990 respondents, consisting of 19,292 individual MIPS eligible clinicians, 6,678 groups and virtual groups, and 20 subgroups will submit data for the Promoting Interoperability performance category in the CY 2024 performance period/2026 MIPS payment year. For MIPS eligible clinicians participating in an APM, we assume that each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants.

TABLE 102: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data

Burden and Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability in CY 2024 performance period (a)	19,292
Number of groups to submit Promoting Interoperability in CY 2024 performance period (b)	6,678
# of Subgroups to submit Promoting Interoperability in MVPs during the CY 2024 performance period (c)	20
Total Respondents in CY 2024 performance period (d) = (a) + (b) + (c)	**25,990**
Currently Approved Respondents (2023 PFS Final Rule) (e)	30,107
Difference (f) = (d) – (e)	**-4,117**

As shown in Table 103, we are not making any changes to the currently approved estimated time of 2.70 hours per response. Therefore, we estimate that it will result in a total burden of 70,173 hours (25,990 respondents × 2.70 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $7,989,083 (81,289 hrs × $98.28/hr)) to submit data for the Promoting Interoperability performance category in the CY 2024 performance period/2026 MIPS payment year.

TABLE 103: Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	19,292
Number of groups to submit Promoting Interoperability (b)	6,678
Number of subgroups to submit Promoting Interoperability (c)	20
Total Respondents (d) = (a) + (b) + (c)	**25,990**
Annual Hours Per Respondent (e)	2.70
Total Annual Hours (f) = (d) * (e)	**70,173**
Cost per Respondent to submit Promoting Interoperability data @ Computer System Analyst's Labor Rate of $103.40/hr (g) = (e) * $103.40/hr	$279.18
Total Annual Cost (h) = (d) * (e)	**$7,255,888**

As shown in Table 104, we illustrate the change in burden for clinicians to submit data in the Promoting Interoperability performance category for the CY 2024 performance period/2026 MIPS payment year. In aggregate, we estimate that the decrease in the number of respondents from 30,107 to 25,990 will result in a decrease of 11,116 hours (−4,117 respondents × 2.70 hrs/response) at a cost of −$1,149,384 (−4,117 respondents × $279.18/response).

TABLE 104: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Description	Burden Estimate
Total Currently Approved Annual Hours (a)	81,289
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (see Table 103, row (f))	70,173
Difference (c) = (b) - (a)	**-11,116**
Total Currently Approved Annual Cost (d)	$8,405,272
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (see Table 103, row (h))	$7,255,888
Difference (f) = (e) - (d)	**-$1,149,384**

We did not receive any comments on our proposed requirements and burden estimates for the data submission in the Promoting Interoperability performance category. We note that we adjusted the burden estimates from the CY 2024 PFS proposed rule (88 FR 52664 through 52665) due to the availability of updated data from the CY 2022 performance period/2024 MIPS payment year.

h. ICRs Regarding the Nomination of Promoting Interoperability Measures

The following changes associated with the information collection related to the nomination of Promoting Interoperability measures will be submitted to OMB for review to remove the information collection relevant to the nomination of Promoting Interoperability measures under control number 0938–1314 (CMS 10621). This rule does create any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability performance category measures. Due to a consistent decline in the number of submissions received for the Promoting Interoperability performance category measures, we estimated to receive fewer than 10 responses for this ICR. Therefore, we proposed to remove the ICR for nomination of Promoting Interoperability performance category measures.

As shown in Table 105, we estimated an annual burden of zero hours at a cost of $0 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 105: Estimated Burden for Call for Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
# of Organizations Nominating New Promoting Interoperability Measures (a)	0
# of Hours Per Medical and health services manager to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) [x] (d)	**0**
Cost to Identify and Submit Measure (@ medical and health services manager's labor rate of $123.06/hr.) (f) = (b) [x] $123.06/hr	$36.92
Cost to Identify Improvement Measure (@ physician's labor rate of $274.44/hr.) (g) = (c) [x] $274.44/hr	$54.89
Total Annual Cost Per Respondent (h) = (f) + (g)	$91.81
Total Annual Cost (i) = (a) [x] (h)	**$0**

In Table 106, we illustrated the net change in estimated burden for nomination of Promoting Interoperability measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70163). The removal of the ICR for nomination of Promoting Interoperability measures results in a decrease of 5 hours (−10 responses × 0.5 hr/response) and a decrease of $918 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 106: Change in Estimated Burden for Nomination of Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	5
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (See Table 105, row (c))	0
Difference (c) = (b) - (a)	**-5**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$918
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 105, row (e))	0
Difference (f) = (e) - (d)	**-$918**

We did not receive any comments on our proposal to remove the ICR for the nomination of Promoting Interoperability measures.

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The following requirements and burden will be submitted for approval under OMB control number 0938–1222 (CMS–10450).

As discussed in section IV.A.4.f.(3)(b)(ii) of this final rule, we are finalizing our proposed changes to the improvement activities inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities. We do not believe the changes will impact our currently approved time for interested parties to submit information because MIPS eligible clinicians are still required to submit the same number of activities and the estimated per response time for each activity is uniform. Therefore, we are not adjusting our currently approved burden for improvement activities submission as a result of this proposal.

As shown in Table 107, we are adjusting the currently approved burden estimates (87 FR 70164 through 70165) due to availability of updated data from the CY 2022 performance period/2024 MIPS payment year. We estimate that a total of 50,269 respondents consisting of 37,939 individual clinicians, 12,330 groups and 20 subgroups will submit improvement activities during the CY 2024 performance period/2026 MIPS payment year. This adjustment represents an increase of 6,153 respondents from the currently approved estimate of 44,136 respondents in the CY 2023 PFS final rule (87 FR 70164 through 70165). As discussed in section V.B.11.e.(2) of this final rule, we did not include in our estimates clinicians who participate in an APM Entity and are determined to be QPs for the CY 2024 performance period/2026 MIPS payment year as we assume they will not be required to submit improvement activities data.

TABLE 107: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2024 performance period (a)	37,939
# of Groups to submit improvement activities on behalf of clinicians during the CY 2024 performance period (b)	12,330
# of Subgroups to submit improvement activities in MVPs during the CY 2023 performance period (c)	20
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data during the CY 2024 performance period (d) = (a) + (b) + (c)	**50,289**
*Total # of Currently Approved Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data (CY 2023 PFS Final Rule) (e)	44,136
Difference (f) = (d) - (e)	**+6,153**

As shown in Table 108, we continue to estimate that the time required per response per individual or group is 5 minutes or 0.083 hours for a computer system analyst at a labor rate of $103.40/hr to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. Therefore, we estimate an annual burden of 4,174 hours (50,289 respondents × 0.083 hr/response) at a cost of $431,480 (50,289 respondents × $8.58/response)) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 108: Estimated Burden for Improvement Activities Data Submission

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2024 performance period (a)	50,289
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) * (b)	**4,174**
Cost per Respondent to submit improvement activities data @ Computer System Analyst's Labor Rate of $103.40/hr (d) = (b) * $103.40/hr	$8.58
Total Annual Cost (e) = (a) * (d)	**$431,480**

As shown in Table 109, using our unchanged currently approved per respondent burden estimate, the increase in the number of respondents results in an increase of 511 hours (+6,153 respondents × 0.083 hr/respondent) at a cost of $52,793 (+6,153 respondents × $8.58/response) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 109: Change in Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	3,663
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (See Table 108, row (c))	4,174
Difference (c) = (b) - (a)	**+511**
Total Currently Approved Annual Cost (d)	$378,687
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 108, row (e))	$431,480
Difference (f) = (e) - (d)	**+$52,793**

We did not receive any comments on our proposed requirements and burden estimates for the submission of improvement activities. We note that we updated the burden estimates from the CY 2024 PFS proposed rule (87 FR 52666) due to the availability of updated data.

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The changes associated with data submission will be submitted to OMB for review under control number 0938–1314 (CMS 10621).

In the CY 2024 PFS proposed rule (88 FR 52666 through 52667), based on the actual number of respondents that submitted improvement activity nominations, we proposed to adjust the estimated number of improvement activity nominations that were previously approved in the CY 2022 PFS final rule (86 FR 65603 through 65605). We estimate that we will receive approximately 15 improvement activity nominations for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 16 improvement activity nominations from our currently approved estimate of 31 nominations in the CY 2022 PFS final rule (86 FR 65605). In Table 110, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 4.4 hours. This will result in an estimated annual burden of 66 hours (15 nominations × 4.4 hr/nomination) at a cost of $11,755 (15 × [(2.8 hr × $123.06/hr for a medical and health services manager) + (1.6 hr × $274.44/hr for a physician)]).

TABLE 110: Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	Burden Estimate
# of Nominations of New IAs (a)	15
# of Hours Per Medical and Health Services Manager (b)	2.8
# of Hours Per Physician (c)	1.6
Annual Hours Per Respondent (d)= (b) + (c)	4.4
Total Annual Hours (e) = (a) * (d)	**66**
Cost to Nominate an IA (@ medical and health services manager's labor rate of $123.06/hr) (f) = (b) x $123.06/hr	$344.57
Cost to Nominate an IA (@ physician's labor rate of $274.44/hr) (g) = (c) x $274.44/hr	$439.10
Total Annual Cost Per Respondent (h) = (f) + (g)	$783.67
Total Annual Cost (i) = (a) * (h)	**$11,755**

In Table 111, we illustrate the net change in estimated burden for nomination of improvement activities using the currently approved burden in the CY 2022 PFS final rule (86 FR 65605). In aggregate, using our currently approved per response time estimate, the proposed decrease in the number of respondents submitting improvement activity nominations results in a total annual adjustment of −70 hours (−16 responses × 4.4 hr/nomination) at a cost of −$12,539 (−16 × [(2.8 hr × $123.06/hr) + (1.6 hr × $274.44/hr)]) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 111: Change in Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	136
Total Annual Hours for Respondents in CY 2024 PFS final rule (b) (See Table 110, row (d))	66
Difference (c) = (b) - (a)	**-70**
Total Currently Approved Annual Cost (d)	$24,294
Total Annual Cost for Respondents in CY 2024 PFS final rule (e) (See Table 110, row (i))	$11,755
Difference (f) = (e) - (d)	**-$12,539**

We did not receive any comments on our proposed requirements and burden estimates for the nomination of improvement activities.

k. Nomination of MVPs

We did not propose any new or revised collection of information requirements or burden related to the nomination of MVPs for the CY 2024 performance period/2026 MIPS payment year. The requirements and burden for nomination of MVPs are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the nomination of MVPs under that control number.

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not making any changes under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

We did not propose any new or revised collection of information requirements or burden related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician in the CY 2024 performance period/2026 MIPS payment year. The requirements and burden for Partial QP Elections are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to Partial QP Elections under that control number.

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

We did not propose any new or revised collection of information requirements related to Other Payer Advanced APM determinations for the CY 2024 performance period/2026 MIPS payment year.

(1) Payer-Initiated Process (§ 414.1445)

We did not propose any new or revised collection of information requirements related to the Payer-Initiated Process for the CY 2024 performance period/2026 MIPS payment year. The requirements and

burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Payer-Initiated process under that control number.

(2) Eligible Clinician-Initiated Process (§ 414.1445)

We did not propose any new or revised collection of information requirements or burden related to the Eligible Clinician-Initiated Process for the CY 2024 performance period/2026 MIPS payment year. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the Eligible Clinician-Initiated Process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

We did not propose any new or revised collection of information requirements or burden related to the Submission of Data for QP Determinations under the All-Payer Combination Option for the CY 2024 performance period/2026 MIPS payment year. The requirements and burden for the All-Payer Combination option are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

We did not propose any new or revised collection of information requirements or burden related to the election by voluntary participants to opt-out of public reporting on Compare Tools for the CY 2024 performance period/2026 MIPS payment year. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

p. Summary of Annual Quality Payment Program Burden Estimates

Table 112 summarizes this rule's total burden estimates for the Quality Payment Program for the CY 2024 performance period/2026 MIPS payment year.

In the CY 2023 PFS final rule, the total estimated burden for the CY 2024 performance period/2026 MIPS payment year (see Table 112, row a) was 710,644 hours at a cost of $75,687,130 (87 FR 70169). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs outlined in this rule compared to the CY 2023 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year is 710,964 hours at a cost of $79,563,761 (see Table 112, row b). These represent an increase of 320 hours and an increase of $3,876,631. To understand the burden implications of the policies in this rule, we provided an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year. The estimated burden of 728,359 hours at a cost of $81,799,657 (see Table 112, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and represents an increase of 17,395 hours and $2,235,896 (see Table 112, row d). Our total burden estimate for the CY 2024 performance period/2026 MIPS payment year is 724,212 hours and $81,332,556 (see Table 112, row e), which represents an increase of 13,248 hours and $1,758,795 from the CY 2023 PFS final rule estimate with updated wage rates and ICRs (see Table 112, row f). The difference of −4,147 hours (13,248 hours − 17,395 hours) and −$477,101 ($1,758,795 − $2,235,896) (see Table 112, row g) between this estimate and the total burden shown in Table 112 is the decrease in burden associated with impacts of the policies for the CY 2024 performance period/2026 MIPS payment year.

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TABLE 112: Summary of Burden Estimates and Requirements from the CY 2024 PFS Final Rule

CY 2024 Performance Period/2026 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2023 PFS Final Rule (a)	710,644	$75,687,130
CY 2023 PFS Final Rule w/ updated wage rates and ICRs (b)	710,964	$79,563,761
CY 2023 PFS Final Rule w/ updated data and assumptions (c)	728,359	$81,799,657
Change in burden due to updated data and assumptions (d) = (c) – (b)	**17,395**	**$2,235,896**
CY 2024 PFS Final Rule Total Burden (e)	724,212	$81,322,556
Total change in burden (as shown in Table 104) (f) = (e) – (b)	13,248	$1,758,795
Change in burden associated with policies (g) = (f) – (d)	**-4,147**	**-$477,101**

TABLE 113: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314) and CMS-10450 (OMB 0938-1222)

Requirement	Currently Approved Responses	CMS-1784-Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR simplified self-nomination (see Tables 65 and 66)	0	44	+44	0	418	+418
§ 414.1400 QCDR full self-nomination (see Tables 67 and 68)	63	12	-51	636	138	-498
§ 414.1400 Registry simplified self-nomination (see Tables 69 and 70)	0	84	+84	0	42	+42
§ 414.1400 Registry full self-nomination (see 71 and 72)	132	27	-105	264	54	-210
§ 414.1400 Third Party Intermediary Plan Audits (see Tables 74 and 75)	127	126	-1	585	499	-86
§ 414.1400 Survey Vendor Requirements (see Tables 76 and 77)	15	10	-5	150	100	-50
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see	14,736	13,413	-1,323	209,251	190,465	-18,786

Requirement	Currently Approved Responses	CMS-1784-Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-Total Time (Hours)	Change in Total Time (Hours)
Tables 81 and 82)						
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see 83 and 84)	17,916	16,632	-1,284	162,731	151,068	-11,663
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Tables 85 and 86)	23,889	28,714	+4,825	191,112	229,712	+38,600
§414.1365 MVP Registration (see Tables 87 and 88)	7,731	9,585	+1,854	1,933	2,396	+463
MVP Quality Submission (see Tables 89 and 90)	7,731	9,585	+1,854	50,938	61,662	+10,724
§§ 414.1325 and 414.1335 Beneficiary Responses for CAHPS for MIPS Survey (see Tables 91 and 92)	29,952	25,500	-4,452	6,539	5,567	-972
Group Registration for CAHPS for MIPS Survey (see Tables 93 and 94)	282	266	-16	212	200	-12
Call for Quality Measures (see Tables 95 and 96)	29	31	+2	160	171	+11
§ 414.1380(c)(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Tables 97 and 98)	5,439	29,227	+23,788	1,360	7,307	+5,947
§ 414.1375. Data Submission for Promoting Interoperability Performance Category (see Tables 100 and 101)	30,107	25,990	-4,117	81,289	70,173	-11,116
Call for Promoting Interoperability Measures (see Tables 102 and 103)	10	0	-10	5	0	-5
§ 414.1360 (Improvement Activities Performance Category Data Submission) (see 106 and 107)	44,136	50,289	+6,153	3,663	4,174	+511
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see Tables 107 and 108)	31	15	-16	136	66	-70
TOTAL	182,326	209,550	+27,224	710,964	724,212	+13,248

Table 114 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to policies in the CY 2024 PFS rule and those related to adjustments in burden continued from the CY 2023 PFS final rule policies that reflect updated data and revised methods.

TABLE 114: Reasons for Change in Burden Compared to the Currently Approved CY 2023 Information Collection Burden

ICR Title	Changes in burden due to CY 2024 rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
QCDR Simplified Self-Nomination and other Requirements (See Table 69)	None	Addition of a new ICR.
QCDR Full Self-Nomination and other Requirements (See Table 71)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Qualified Registry Simplified Self-Nomination and other Requirements (See Table 73)	None	Addition of a new ICR.
Qualified Registry Full Self-Nomination and other Requirements (See Table 75)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Third Party Intermediary Plan Audits (see Table 78)	None	Decrease in number of respondents and hours due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Survey Vendor Requirements (see Table 80)	None	Decrease in number of respondents due to updated assumptions.
Quality Performance Category: Medicare Part B Claims Collection Type (see Table 85)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type.	Decrease in the number of respondents due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Quality Performance Category: QCDR/ MIPS CQM Collection Type (see Table 87)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type.	Decrease in the number of respondents due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Quality Performance Category: eCQM Collection Type (see Table 89)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type.	Increase in the number of respondents due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
MVP Registration (see Table	Increase in number of	Increase in the number of respondents due

ICR Title	Changes in burden due to CY 2024 rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
91)	respondents due to finalized addition of 5 new MVPs.	to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
MVP Quality Submission (see Table 93)	Increase in number of respondents due to finalized addition of 5 new MVPs.	Increase in the number of respondents due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Beneficiary Responses for CAHPS for MIPS Survey (see Table 95)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Group Registration for CAHPS for MIPS Survey (see Table 97)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Call for Quality Measures (see Table 99)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Promoting Interoperability Performance Category: Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 101)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year.
Data Submission for the Promoting Interoperability Performance Category (see Table 104)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Call for Promoting Interoperability Measures (see Table 106)	None	Removal of ICR.
Data Submission for the Improvement Activities Performance Category (see Table 109)		
Improvement Activities Performance Category: Nomination of Improvement Activities (see Table 111)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year

C. Summary of Annual Burden Estimates for Changes

TABLE 115: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 414.940 (Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts)	0938-1435 (CMS-10835	22 in the initial year; 2 in subsequent years	22 in the initial year, 2 in subsequent years	5	110 in the initial year, 10 in subsequent years	41.74	4,591 in the initial year; 418 in subsequent years
§ 414.94(c)(2) (AUC Program Provider-Led Entity reapplication for qualification)	0938-1288 (CMS-10570)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)
§ 491.9(b) RHC and FQHC Patient care policies	0938-0344 (CMS-R-38)	8,286	8,286	0.50	4,143	Varies	$817,631.92
§§ 600.125(a)(1), 600.140(b)(4) through (6), 600.145(a), 600.145(f)(2), and 600.170(a)(2) Basic Health Program (BHP) Provisions	0938-1218 (CMS-10510)	2	varies	varies	356	varies	30,322
§§414.1325 and 414.1335 Quality Payment Program: CAHPS Survey	0938-1222 (CMS-10450)	25,500	(4,452)	Varies	(1,034)	Varies	(35,349)
§§ 414.1318, 414.1325 and 414.1335, 414.1360, 414.1365, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 Quality Payment Program	0938-1314 (CMS-10621)	92,604	+4,859	Varies	+14,282	Varies	+1,794,144
TOTAL		126,404	8,705	Varies	15,636	Varies	2,138,457

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VI. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we are finalizing payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 (CAA, 2021); sections 301, 302, 303, 304, and 305 under the Consolidated Appropriations Act, 2022 (CAA, 2022); sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018, sections 4113, 4114, and 4121 under the Consolidated Appropriations Act of 2023 (CAA, 2023), section 90004 of the Infrastructure Investment and Jobs Act, section 6 of the Sustaining Excellence in Medicaid Act of 2019, and sections 11101, 11402, 11403, 11407 under the Inflation Reduction Act (IRA). Our policies in this rule specifically address: changes to the PFS; other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program; updates to the Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); changes to the regulations associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System; and changes to release Medicare Advantage risk adjustment data early for use with Care Compare websites. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Extension of Certain Medicare Telehealth Flexibilities, Under Section 1834(m) of the Act, as Amended by the CAA, 2023

Section II.D.1.e. of this final rule implements section 4113, of the CAA, 2023, which extended through CY 2024 several temporary flexibilities for Medicare telehealth services adopted during the PHE for COVID–19. Specifically, section 4113 extended the temporary inapplicability of geographic and location restrictions, extended the temporary expansion of practitioner types who can be paid for Medicare telehealth services, delayed the in-person visit requirements for mental health services furnished via telehealth, and extended audio-only flexibilities for certain telehealth services. This provision is necessary to fulfill the

statutory requirement to implement this extension through December 31, 2024.

b. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this final rule, we discuss regulations text changes to implement provisions of the Inflation Reduction Act of 2022 that affect payment amounts or patient out-of-pocket costs for certain drugs and biologicals payable under Part B. Two provisions affect payment amounts for biosimilar biological products. Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. Section 11403 makes changes to the payment limit for certain biosimilar products with an ASP that is not more than the ASP of the reference biological for a period of 5 years. Two other provisions make statutory changes to patient out-of-pocket costs for certain drugs payable under Medicare Part B. Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. Section 11407 makes statutory changes to waive the deductible for insulin that is furnished through a covered item of durable medical equipment (DME) and establishes a $35 cap on cost sharing for a month's supply of insulin furnished through a covered item of DME, both beginning July 1, 2023.

In section III.A.3. of this final rule, we discuss policies to implement section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA) which requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. These provisions are necessary to fulfill the statutory requirement to implement this policy effective January 1, 2023 and reduce unnecessary Medicare spending for discarded drug.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, we implement sections 4113, 4121, and 4124 of the CAA, 2023. Section 4113 of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by RHCs and FQHCs for the limited period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024. Section 4113 also delays the in-person requirements under Medicare for mental health visits furnished by RHCs and FQHCs via telecommunications technology until January 1, 2025.

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding marriage and family therapists (MFT) and mental health counselors (MHC) as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. Section 4121 allows MFTs and MHCs to bill directly and be paid as an RHC and FQHC practitioner under the RHC AIR an FQHC PPS.

Section 4124 of the CAA, 2023 establishes an Intensive Outpatient benefit in RHCs and FQHCs. Final policies related to implementation of IOP for RHCs and FQHCs are outlined in the CY 2024 OPPS final rule.

d. Clinical Laboratory Fee Schedule (CLFS)—Revisions Consistent With Recent Statutory Changes

In section III.D. of this final rule, we discuss the conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 4114 of the CAA, 2023. For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), the CAA, 2023 delayed the next data reporting period by one year. Instead of taking place from January 1, 2023 through March 31, 2023, data reporting will now take place from January 1, 2024 through March 31, 2024, based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle (2027, 2030, etc.). Additionally, the CAA, 2023 amended the statutory provisions for the phase-in of payment reductions resulting from private payor rate implementation to specify that the applicable percent in CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. The CAA, 2023 further amended the statutory phase-in provisions to provide that for CYs 2024 through 2026, the payment amount for a CDLT may not be reduced by more than 15 percent as compared to the payment amount for that test established in the preceding year.

e. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

In section III.E. of this final rule, we are finalizing the proposed revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). These provisions are necessary to fulfill the statutory requirement to implement these changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) effective January 1, 2024.

f. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In the CY 2024 PFS proposed rule (88 FR 52531 through 52536), we proposed changes to the electronic prescribing for controlled substances (EPCS) requirement specified in section 2003 of the SUPPORT Act (referred to as the CMS EPCS Program). The provisions finalized in section III.M. of this final rule specify the basis for the evaluation of compliance by describing how prescriptions are calculated, remove the same entity exception while conditioning the electronic prescribing requirement as subject to the exemption in § 423.160(a)(3)(iii), identify non-compliance actions for subsequent measurement years, and update other CMS EPCS Program exceptions. Previously finalized policies did not include actions for non-compliance after the 2024 measurement year, and we needed to identify actions for non-compliance in subsequent measurement years.

g. Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System

Section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. In this final rule, we are finalizing our proposal only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

Section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include

use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. In this final rule, we are finalizing our proposed revisions to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aimed to reduce burden on respondents, improve data quality, or both.

h. Quality Payment Program

This final rule is also necessary to make changes to the Quality Payment Program to move the program forward to focus more on measurement efforts, refine how clinicians will be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for traditional MIPS is seen as siloed across the performance categories. These policy proposals are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories, and make changes to scoring that will provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

Section III.A.3. of this final rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug, finalizes the dates we will issue the initial refund report and subsequent annual reports to manufacturers, the method of calculation of the refund amount when there are multiple manufacturers of a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

b. RHCs and FQHCs

In section III.B. of this final rule, we finalized the policy to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2024 for RHCs and FQHCs. We also finalized the policy change the required level of supervision for behavioral health services furnished ''incident to'' a physician or non-physician practitioner's services at RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023.

In section III.B.4. of this final rule, we finalized the policy to include Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), and Principal Illness Navigation (PIN) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. We also finalized the revision of the calculation for G0511 to include the weighted average of these services using the CY 2021 PFS non-facility utilization. These provisions are necessary in that we evaluate coding policies in this rule and their applicability to RHCs and FQHCs.

Also, in section III.B.4. of this final rule, we clarified the supervision requirement for obtaining consent for CCM services and virtual communication services furnished in RHCs and FQHCs.

c. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As outlined in section III.F. of this final rule, we finalized the policy to allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met. We believe this modification is needed because extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE, and evidence has shown that Medicare beneficiaries from historically underserved populations are more likely to be offered and use audio-only telemedicine services than audio-video services.[512] Therefore, minimizing disruptions to care for audio-only periodic assessments may further promote health equity and minimize disparities in access to care.

d. Medicare Shared Savings Program

In section III.G. of this final rule, we are finalizing modifications to the Shared Savings Program to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties. The changes to the Shared Savings Program include the following: modifications to the quality performance standard and reporting requirements under the APP that would continue to move ACOs toward digital measurement of quality and to align with the Quality Payment Program; modifications to the step-wise beneficiary assignment methodology to add a new third step and related changes to how we identify the assignable beneficiary population; updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines; refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to (1) cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth, (2) apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year, (3) further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high cost beneficiaries, and (4) specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; refine newly established AIP policies; make updates to other programmatic areas including the

[512] *https://pubmed.ncbi.nlm.nih.gov/33471458/.*

program's eligibility requirements; and make timely technical changes to the regulations for clarity and consistency.

e. Medicare Part B Payment for Preventive Vaccine Administration Services

Section III.H. of this final rule outlines the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit, specifically the in-home additional payment for Part B vaccine administration. Section III.H. of this final rule also codifies other amendments to the regulation text for Part B preventive vaccine administration. These provisions are necessary to provide stable payment for preventive vaccine administration and to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

f. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

In section III.J. of this final rule, we are finalizing our proposal to pause efforts to implement the AUC program for reevaluation and to rescind and reserve for future use the current AUC program regulations at § 414.94. These provisions are necessary because we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization.

g. Medicare and Medicaid Provider Enrollment

This final rule also includes several regulatory enhancements to our Medicare and Medicaid provider enrollment policies that we proposed. These provisions focus on, but are not limited to: (1) expanding the bases for denying or revoking a provider's or supplier's Medicare enrollment; (2) revising the effective dates of certain Medicare revocations; and (3) revising certain policies regarding Medicaid terminations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes. We believe that fulfilling these objectives will assist in protecting the Trust Funds and Medicare beneficiaries.

h. Expand Diabetes Screening and Diabetes Definitions

In section III.L. of this final rule, we are finalizing our proposal to (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT). Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2, and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[513] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[514] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the US.[515] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

i. Basic Health Program Provisions

Section 1331 of the ACA requires the Secretary to establish a BHP, and section 1331(c)(4) of the ACA specifically provides that a State shall coordinate the administration of, and provision of benefits under the BHP with other State programs. Additionally, section 1331(f) of the ACA requires the Secretary to review each State's BHP on an annual basis. These regulations build from previous BHP regulations to provide for options for BHP implementation and operations as well as oversight of the BHP program, beginning with program year 2024.

j. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

As outlined in section III.S. of this final rule, we are finalizing our proposal to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We proposed that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention plan. The AWV also provides an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV can be found on the CMS website at (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html*).

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

[513] CDC website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html.*

[514] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

[515] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021.*

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this final rule describe significant alternatives we considered, if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2023 with payment rates for CY 2024 using CY 2022 Medicare utilization. The payment impacts described in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because

practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2024, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, the CAA, 2023 provided a one-year 2.50 percent increase in PFS payment amounts for services furnished in CY 2023, and a one-year 1.25 percent increase in PFS payment amounts for services furnished during CY 2024, and required that the supplementary percentage increases shall not be taken into account in determining PFS payment rates for subsequent years.

To calculate the CY 2024 PFS conversion factor (CF), we took the CY 2023 conversion factor without the one-year 2.50 percent payment increase provided by the CAA, 2023 for CY 2023 and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs and the 1.25 percent PFS payment increase provided by the CAA, 2023 for CY 2024. We estimate the CY 2024 PFS CF to be 32.7442 which reflects the −2.18 percent budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the 1.25 percent payment increase for services furnished in CY 2024, as provided in the CAA, 2023. We estimate the CY 2024 anesthesia CF to be 20.4349, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 116: Calculation of the CY 2024 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.20 percent (0.9780)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7375**

TABLE 117: Calculation of the CY 2024 Anesthesia Conversion Factor

CY 2023 National Average Anesthesia Conversion Factor		21.1249
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		20.6097
CY 2024 RVU Budget Neutrality Adjustment	-2.18 percent (0.9782)	
CY 2024 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.11 percent (1.0011)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**20.4349**

Table 118 shows the payment impact of the policies in this final rule on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 118 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 118.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2022 utilization and CY 2023 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 118: CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
ALLERGY/IMMUNOLOGY	$217	0%	-1%	0%	-1%
ANESTHESIOLOGY	$1,650	-2%	-1%	0%	-2%
AUDIOLOGIST	$69	-1%	-1%	0%	-2%
CARDIAC SURGERY	$175	-1%	-1%	0%	-2%
CARDIOLOGY	$6,015	0%	0%	0%	0%
CHIROPRACTIC	$649	-1%	-1%	0%	-2%
CLINICAL PSYCHOLOGIST	$717	1%	0%	0%	2%
CLINICAL SOCIAL WORKER	$801	2%	0%	0%	2%
COLON AND RECTAL SURGERY	$147	-1%	-1%	0%	-2%
CRITICAL CARE	$333	-1%	0%	0%	-2%
DERMATOLOGY	$3,717	0%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$833	0%	-1%	0%	-2%
EMERGENCY MEDICINE	$2,473	-2%	-1%	0%	-2%
ENDOCRINOLOGY	$509	1%	1%	0%	3%
FAMILY PRACTICE	$5,538	2%	2%	0%	3%
GASTROENTEROLOGY	$1,476	0%	0%	0%	0%
GENERAL PRACTICE	$368	1%	1%	0%	2%
GENERAL SURGERY	$1,625	-1%	-1%	0%	-1%
GERIATRICS	$184	0%	1%	0%	1%
HAND SURGERY	$252	-1%	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	$1,595	1%	0%	0%	2%
INDEPENDENT LABORATORY	$551	-1%	-1%	0%	-1%
INFECTIOUS DISEASE	$576	-1%	0%	0%	-1%
INTERNAL MEDICINE	$9,683	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$853	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$458	-1%	-3%	0%	-4%
MULTISPECIALTY CLINIC/OTHER PHYS	$147	0%	0%	0%	0%
NEPHROLOGY	$1,813	-1%	0%	0%	-1%
NEUROLOGY	$1,330	0%	0%	0%	1%
NEUROSURGERY	$699	-1%	0%	0%	-1%
NUCLEAR MEDICINE	$51	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	$1,081	-2%	0%	0%	-2%
NURSE PRACTITIONER	$6,297	1%	1%	0%	2%
OBSTETRICS/GYNECOLOGY	$560	0%	1%	0%	1%
OPHTHALMOLOGY	$4,647	0%	0%	0%	-1%
OPTOMETRY	$1,299	-1%	-1%	0%	-2%
ORAL/MAXILLOFACIAL SURGERY	$63	-1%	-1%	0%	-2%
ORTHOPEDIC SURGERY	$3,369	-1%	0%	0%	-1%
OTHER	$56	0%	0%	0%	0%
OTOLARYNGOLOGY	$1,115	0%	0%	0%	0%
PATHOLOGY	$1,142	-1%	-1%	0%	-2%
PEDIATRICS	$56	0%	0%	0%	1%
PHYSICAL MEDICINE	$1,093	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	$5,281	-1%	-2%	0%	-3%
PHYSICIAN ASSISTANT	$3,377	1%	1%	0%	2%
PLASTIC SURGERY	$303	-1%	-1%	0%	-1%
PODIATRY	$1,910	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$76	0%	0%	0%	-1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
PSYCHIATRY	$907	1%	1%	0%	2%
PULMONARY DISEASE	$1,295	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,556	0%	-2%	0%	-2%
RADIOLOGY	$4,536	-1%	-2%	0%	-3%
RHEUMATOLOGY	$510	1%	1%	0%	2%
THORACIC SURGERY	$293	-1%	-1%	0%	-2%
UROLOGY	$1,630	0%	0%	0%	1%
VASCULAR SURGERY	$1,011	-1%	-3%	0%	-3%
TOTAL	$88,967	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

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In recent years, we have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in last year's final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We provided an additional impact table for this rulemaking cycle that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 119.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2022 utilization and CY 2023 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges.

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TABLE 119: CY 2024 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$217	-1%
	Non-Facility	$210	-1%
	Facility	$8	2%
ANESTHESIOLOGY	*TOTAL*	$1,650	-2%
	Non-Facility	$316	-2%
	Facility	$1,335	-2%
AUDIOLOGIST	*TOTAL*	$69	-2%
	Non-Facility	$67	-2%
	Facility	$3	-2%
CARDIAC SURGERY	*TOTAL*	$175	-2%
	Non-Facility	$34	-2%
	Facility	$141	-2%
CARDIOLOGY	*TOTAL*	$6,015	0%
	Non-Facility	$3,724	1%
	Facility	$2,292	-1%
CHIROPRACTIC	*TOTAL*	$649	-2%
	Non-Facility	$647	-2%
	Facility	$1	-2%
CLINICAL PSYCHOLOGIST	*TOTAL*	$717	2%
	Non-Facility	$572	2%
	Facility	$145	1%
CLINICAL SOCIAL WORKER	*TOTAL*	$801	2%
	Non-Facility	$651	2%
	Facility	$150	2%
COLON AND RECTAL SURGERY	*TOTAL*	$147	-2%
	Non-Facility	$54	-2%
	Facility	$93	-2%
CRITICAL CARE	*TOTAL*	$333	-2%
	Non-Facility	$51	2%
	Facility	$282	-2%
DERMATOLOGY	*TOTAL*	$3,717	-1%
	Non-Facility	$3,579	-1%
	Facility	$138	0%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$833	-2%
	Non-Facility	$832	-2%
	Facility	$2	-3%
EMERGENCY MEDICINE	*TOTAL*	$2,473	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$195	-1%
	Facility	$2,278	-2%
ENDOCRINOLOGY	*TOTAL*	$509	3%
	Non-Facility	$408	3%
	Facility	$101	1%
FAMILY PRACTICE	*TOTAL*	$5,538	3%
	Non-Facility	$4,399	4%
	Facility	$1,139	0%
GASTROENTEROLOGY	*TOTAL*	$1,476	0%
	Non-Facility	$548	2%
	Facility	$928	-1%
GENERAL PRACTICE	*TOTAL*	$368	2%
	Non-Facility	$290	3%
	Facility	$77	-1%
GENERAL SURGERY	*TOTAL*	$1,625	-1%
	Non-Facility	$470	-1%
	Facility	$1,155	-2%
GERIATRICS	*TOTAL*	$184	1%
	Non-Facility	$109	2%
	Facility	$75	0%
HAND SURGERY	*TOTAL*	$252	-1%
	Non-Facility	$134	0%
	Facility	$118	-1%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,595	2%
	Non-Facility	$1,039	1%
	Facility	$556	2%
INDEPENDENT LABORATORY	*TOTAL*	$551	-1%
	Non-Facility	$538	-1%
	Facility	$13	-3%
INFECTIOUS DISEASE	*TOTAL*	$576	-1%
	Non-Facility	$84	2%
	Facility	$492	-2%
INTERNAL MEDICINE	*TOTAL*	$9,683	1%
	Non-Facility	$4,732	3%
	Facility	$4,951	-1%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$853	0%
	Non-Facility	$669	1%
	Facility	$184	-2%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$458	-4%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$292	-5%
	Facility	$167	-3%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$147	0%
	Non-Facility	$73	1%
	Facility	$74	-1%
NEPHROLOGY	*TOTAL*	$1,813	-1%
	Non-Facility	$1,074	0%
	Facility	$739	-2%
NEUROLOGY	*TOTAL*	$1,330	1%
	Non-Facility	$849	2%
	Facility	$480	-1%
NEUROSURGERY	*TOTAL*	$699	-1%
	Non-Facility	$120	0%
	Facility	$579	-2%
NUCLEAR MEDICINE	*TOTAL*	$51	-3%
	Non-Facility	$26	-2%
	Facility	$26	-3%
NURSE ANES / ANES ASST	*TOTAL*	$1,081	-2%
	Non-Facility	$24	-2%
	Facility	$1,057	-2%
NURSE PRACTITIONER	*TOTAL*	$6,297	2%
	Non-Facility	$4,060	3%
	Facility	$2,237	1%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$560	1%
	Non-Facility	$382	2%
	Facility	$177	0%
OPHTHALMOLOGY	*TOTAL*	$4,647	-1%
	Non-Facility	$3,278	0%
	Facility	$1,369	-1%
OPTOMETRY	*TOTAL*	$1,299	-2%
	Non-Facility	$1,234	-2%
	Facility	$65	-1%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$63	-2%
	Non-Facility	$52	-2%
	Facility	$11	-2%
ORTHOPEDIC SURGERY	*TOTAL*	$3,369	-1%
	Non-Facility	$1,483	0%
	Facility	$1,885	-1%
OTHER	*TOTAL*	$56	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$44	0%
	Facility	$12	-1%
OTOLARYNGOLOGY	*TOTAL*	$1,115	0%
	Non-Facility	$884	1%
	Facility	$230	-1%
PATHOLOGY	*TOTAL*	$1,142	-2%
	Non-Facility	$593	-1%
	Facility	$550	-3%
PEDIATRICS	*TOTAL*	$56	1%
	Non-Facility	$34	2%
	Facility	$22	-1%
PHYSICAL MEDICINE	*TOTAL*	$1,093	-1%
	Non-Facility	$537	1%
	Facility	$556	-2%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$5,281	-3%
	Non-Facility	$5,281	-3%
	Facility	$	0%
PHYSICIAN ASSISTANT	*TOTAL*	$3,377	2%
	Non-Facility	$2,266	3%
	Facility	$1,111	0%
PLASTIC SURGERY	*TOTAL*	$303	-1%
	Non-Facility	$134	-1%
	Facility	$169	-2%
PODIATRY	*TOTAL*	$1,910	0%
	Non-Facility	$1,700	0%
	Facility	$210	0%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$76	-1%
	Non-Facility	$73	-1%
	Facility	$3	-2%
PSYCHIATRY	*TOTAL*	$907	2%
	Non-Facility	$501	4%
	Facility	$406	0%
PULMONARY DISEASE	*TOTAL*	$1,295	0%
	Non-Facility	$534	3%
	Facility	$761	-2%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,556	-2%
	Non-Facility	$1,078	-2%
	Facility	$478	-2%
RADIOLOGY	*TOTAL*	$4,536	-3%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$1,986	-3%
	Facility	$2,550	-3%
RHEUMATOLOGY	*TOTAL*	$510	2%
	Non-Facility	$458	2%
	Facility	$52	3%
THORACIC SURGERY	*TOTAL*	$293	-2%
	Non-Facility	$58	-5%
	Facility	$236	-2%
UROLOGY	*TOTAL*	$1,630	1%
	Non-Facility	$1,155	1%
	Facility	$476	0%
VASCULAR SURGERY	*TOTAL*	$1,011	-3%
	Non-Facility	$725	-4%
	Facility	$286	-2%
TOTAL	***TOTAL***	$88,967	0%
	Non-Facility	$55,336	1%
	Facility	$33,631	-1%

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2. CY 2024 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including family practice, endocrinology, nurse practitioner, physician assistant, clinical social worker, psychiatry, clinical psychologist, and general practice, reflect increases relative to other specialties. These increases can largely be attributed to our implementation of the separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. Approximately 90 percent of the budget neutrality adjustment is attributable to the O/O E/M visit inherent complexity add-on code, with all other proposed valuation changes making up the other 10 percent. The services furnished by these specialties include relatively more E/M services, behavioral health care, or clinical labor for their practice expense costs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates.

The estimated impacts for several specialties, including anesthesiology, interventional radiology, radiology, nuclear medicine, vascular and thoracic surgery, physical/occupational therapy, anesthesiology, and audiology, reflect decreases in payments relative to payment to other specialties, largely resulting from the redistributive effects of the implementation of separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. The services furnished by these specialties were negatively affected by the redistributive effects of increases in work RVUs for other codes, and/or rely primarily on supply/equipment items for their practice expense costs and, therefore, were affected negatively by the updated Year 3 clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized supply and equipment pricing updates. The estimated impacts also reflect decreases due to the continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 118), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 118 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a

specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed above, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2022 utilization data, Total RVUs change between −1 percent and 1 percent for more than 15 percent of practitioners, representing approximately 26 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as gastroenterology, exhibit little variation in changes in total RVUs per practitioner. Table 118 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates an overall change of 0 percent for this specialty, and the practitioner-level distribution shows that 89 percent of these practitioners will experience a change in Total RVUs between −2 percent and 2 percent. The specific service mix within a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 118 indicates a 1 percent increase in RVUs for the internal medicine specialty as a whole; however, 49 percent of internal medicine specialty practitioners—representing over 41 percent of Total RVUs for the specialty—will experience a 1 percent or more decrease in Total RVUs. Meanwhile, 40 percent of internal medicine specialty practitioners will experience 2 percent or more increases in Total RVUs, and these practitioners account for 40 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

The specialty impacts displayed in Table 118 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from finalized policies within BN (such as the updated proposals associated with the complexity add-on code G2211 in CY 2024 or the clinical labor pricing update that began in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to BN adjustment, and therefore, have a neutral impact across all specialties. The 2.50 and 1.25 percent payment supplements for CY 2023 and CY 2024, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 118.

b. Impact

Column F of Table 118 displays the estimated CY 2024 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2024 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and nonfacility rates are shown. For an explanation of facility and nonfacility PE, we referred readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

3. Health Equity

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[516] As part of our efforts to gain insight into how the PFS policies could affect health equity, we considered adding elements to our impact analysis detailing how policies impact particular patient populations. Patient populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes, people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59395 through 59401), we included a table that details providers in terms of the beneficiaries they serve, as well as differences in estimated average payments per case and changes in estimated average payments per case relative to other providers. Because we do not have data for all characteristics that may identify disadvantaged or underserved patient populations, we use several proxies to capture these characteristics, including elements from claims data and Medicare enrollment data. The characteristics included in the table in the IPPS/LTCH PPS final rule, described in further detail below, include race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low-income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD–10–CM Z code indicating a ''social determinant of health'' (SDOH), presence of a behavioral health diagnosis code, receiving end-stage renal disease (ESRD) Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85.

a. Race and Ethnicity

The first health equity-relevant grouping is race/ethnicity. To assign the race/ethnicity variables, we utilized the Medicare Bayesian Improved Surname Geocoding (MBISG) data in conjunction with the claims data. The method used to develop the MBISG data involves estimating a set of six racial and ethnic probabilities (White, Black, Hispanic, American Indian or Alaska Native, Asian or Pacific Islander, and multiracial) from the surname and address of beneficiaries by using previous self-reported data from a national survey of Medicare beneficiaries, post-stratified to CMS enrollment files. The CMS Office of Minority Health uses the MBISG method in its reports analyzing Medicare Advantage plan performance on Healthcare Effectiveness Data and Information Set (HEDIS) measures, and is being considered by CMS for use in other CMS programs. In the 2024 IPPS/LTCH proposed rule (88 FR 27261 through 27266), we estimated the percentage of discharges for each specified racial/ethnic category for each hospital by taking the sum of the probabilities for that category for that hospital and dividing by the hospital's total number of discharges.

[516] Available at *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

b. Income

The two main proxies for income available in the Medicare claims and enrollment data are dual eligibility for Medicare and Medicaid and Medicare LIS status. Dual-enrollment status is a powerful predictor of poor outcomes on some quality and resource use measures even after accounting for additional social and functional risk factors.[517] Medicare LIS enrollment refers to a beneficiary's enrollment in the low-income subsidy program for the Part D prescription drug benefit. This program covers all or part of the Part D premium for qualifying Medicare beneficiaries and gives them access to reduced copays for Part D drugs. (We note that beginning on January 1, 2024, eligibility for the full low-income subsidy will be expanded to include individuals currently eligible for the partial low-income subsidy.) Because Medicaid eligibility rules and benefits vary by State/territory, Medicare LIS enrollment identifies beneficiaries who are likely to have low income but may not be eligible for Medicaid. Not all beneficiaries who qualify for the duals or LIS programs actually enroll. Due to differences in the dual eligibility and LIS qualification criteria and less than complete participation in these programs, sometimes beneficiaries were flagged as dual but not LIS or vice versa. Hence this analysis also used a ''dual or LIS'' flag as a third proxy for low income. The dual and LIS flags were constructed based on enrollment/eligibility status in the CMS Chronic Conditions Data Warehouse (CCW) during the month of the hospital discharge.

c. Social Determinants of Health (SDOH)

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[518] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. ICD–10–CM contains Z-codes that describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. The presence of ICD–10–CM Z-codes in the range Z55–Z65 identifies beneficiaries with these SDOH characteristics. The SDOH flag used for this analysis was turned on if one of these Z-codes was recorded on the claim for the physician service itself (that is, the beneficiary's prior claims were not examined for additional Z-codes). Analysis of Z-codes in Medicare claims data from 2019 suggests that Z-codes are used inconsistently across provider types and population groups, and are generally underreported.[519] Therefore, we believe Z-codes may not reflect the actual rates of SDOH.

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses but often experience difficulty accessing care.[520] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[521] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[522] We used the presence of one or more ICD–10–CM codes in the range of F01- F99 to identify beneficiaries with a behavioral health diagnosis.

e. Disability

Individuals under age 65 who are determined eligible for social security disability benefits may also be eligible for Medicare coverage.[523] Individuals may qualify for social security disability benefits on the basis of a medically determinable physical or mental impairment(s) that has lasted or is expected to last for a continuous period of at least 12 months or is expected to result in death [524]. Disabled beneficiaries often have complex healthcare needs and difficulty accessing care. Compared to people without disabilities, people with disabilities generally have less access to health care, have more depression and anxiety, engage more often in risky health behaviors such as smoking, and are less physically active.[525] Beneficiaries were classified as disabled for the purposes of this analysis if their original reason for qualifying for Medicare was disability; this information was obtained from Medicare's CCW enrollment data. We noted that this is likely an underestimation of disability, because it does not account for beneficiaries who became disabled after becoming entitled to Medicare.

f. End-Stage Renal Disease (ESRD)

Beneficiaries with ESRD have high healthcare needs and high medical spending, and often experience comorbid conditions and poor mental health. Beneficiaries with ESRD also experience significant disparities, such as a limited life expectancy.[526] Beneficiaries were classified as ESRD for the purposes of this analysis if they were receiving Medicare ESRD coverage during the month of the discharge; this information was obtained from the CCW enrollment data.

g. Geography

Beneficiaries in some geographic areas—particularly rural areas or areas with concentrated poverty—often have difficulty accessing care.[527] [528] For this analysis, beneficiaries were classified on two dimensions: from a rural area and from an area with an area deprivation index (ADI) greater than or equal to 85.

Rural status is defined for this analysis using the primary Rural-Urban Commuting Area (RUCA) codes 4–10 (including micropolitan, small town, and rural areas) corresponding to each beneficiary's zip code. RUCA codes are defined at the census tract level based on measures of population density, urbanization, and daily commuting. The ADI is obtained from a publicly

[517] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[518] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[519] Maksut JL, Hodge C, Van CD, Razmi, A, & Khau MT. Utilization of Z Codes for Social Determinants of Health among Medicare Fee-For-Service Beneficiaries, 2019. Office of Minority Health (OMH) Data Highlight No. 24. Centers for Medicare and Medicaid Services (CMS), Baltimore, MD, 2021. Available at *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[520] Viron M, Zioto K, Schweitzer J, Levine G. Behavioral Health Homes: an opportunity to address healthcare inequities in people with serious mental illness. Asian J Psychiatr. 2014 Aug;10:10–6. doi: 10.1016/j.ajp.2014.03.009.

[521] Cully, J.A., Breland, J.Y., Robertson, S. et al. Behavioral health coaching for rural veterans with diabetes and depression: a patient randomized effectiveness implementation trial. BMC Health Serv Res 14, 191 (2014). *https://doi.org/10.1186/1472-6963-14-191.*

[522] *https://www.cms.gov/cms-behavioral-health-strategy.*

[523] Medicare eligibility on the basis of disability is discussed in 42 CFR 406.12.

[524] *https://www.ssa.gov/disability/professionals/bluebook/general-info.htm.*

[525] *https://www.cdc.gov/ncbddd/human development/health-equity.html#ref.*

[526] Smart NA, Titus TT. Outcomes of early versus late nephrology referral in chronic kidney disease: a systematic review. Am J Med. 2011 Nov;124(11):1073–80.e2. doi: 10.1016/j.amjmed.2011.04.026. PMID: 22017785.

[527] National Healthcare Quality and Disparities Report chartbook on rural health care. Rockville, MD: Agency for Healthcare Research and Quality; October 2017. AHRQ Pub. No. 17(18)–0001–2–EF available at *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/qdr-ruralhealthchartbook-update.pdf.*

[528] Muluk, S, Sabik, L, Chen, Q, Jacobs, B, Sun, Z, Drake, C. Disparities in geographic access to medical oncologists. *Health Serv Res.* 2022; 57(5): 1035–1044. doi:10.1111/1475–6773.13991.

available dataset designed to capture socioeconomic disadvantage at the neighborhood level.[529] It utilizes data on income, education, employment, housing quality, and 13 other factors from the American Community Survey (ACS) and combines them into a single raw score, which is then used to rank neighborhoods (defined at various levels), with higher scores reflecting greater deprivation. The version of the ADI used for this analysis is at the Census Block Group level and the ADI corresponds to the Census Block Group's percentile nationally. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[530] [531] [532] [533] [534] The MedPAR discharge data was linked to the ADI data available in the CCW. Beneficiaries with no recorded ADI were treated as being from an urban area and as having an ADI less than 85.

In examining how we might expand our PFS impact analysis, we considered what framework might accurately provide insight into the relationship between PFS policies and health equity. Rather than examining changes in estimated average payments, we believe that illuminating the baseline is a necessary first step toward advancing our goal of measuring the impact of PFS policies on health equity. Table 121 displays the share of utilization for each of the health-equity relevant characteristics listed above. First, we list the share of enrollees with each characteristic. Next, we list the share of utilization by beneficiaries (that is, enrollees with at least one claim for a physician service in CY 2022) with each characteristic by provider specialty. The information contained in Table 121 is provided solely to demonstrate beneficiary utilization of services by provider specialty impact across a number of health equity dimensions and does not form the basis or rationale for the finalized policies.

In consideration of the differences between IPPS/LTCH and the PFS discussed below, we solicited comment from interested parties about how we might structure a PFS impact analysis that addresses these and other considerations to examine how changes in the PFS will impact beneficiaries of particular groups. We also solicited comment about how such a framework will allow us to consider developing policies that enhance health equity under our existing statutory authority. We welcomed suggestions about alternative measures of health equity in our impact analysis, in particular with regard to the ADI as a proxy for disparities related to geographic variation. Finally, we sought feedback about additional categories beyond those described previously that should be considered in our analysis, along with potential data sources.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the inclusion of Table 121. One commenter suggested an alternative index of vulnerability in place of the ADI, citing concerns about the accuracy of the ADI. This commenter also requested clarification about how CMS may use the information in Table 121.

Response: We appreciate commenters support for our inclusion of the data in Table 121. With respect to the comment regarding an alternative vulnerability index, we may consider this in future rulemaking.

Comment: A commenter stated that the rule ''contemplates variable payments for factors such as race/ethnicity . . .'' and ''it's clear that CMS means to use the data to produce a payment based on billing or outcomes''.

Response: We believe the commenter misunderstood the purpose of including Table 121. We did not contemplate variable payments for factors such as race/ethnicity. As stated in the proposed rule, ''the information contained in Table 107 is provided solely to demonstrate beneficiary utilization by provider specialty impact across several health equity dimensions. This does not form the basis or rationale for the proposed policies in the proposed rule.'' As stated in the proposed rule, the purpose of including this data was to seek comment on how we might structure a PFS impact analysis that addresses these considerations and how we might develop policies that enhance health equity under our existing statutory authority.

Comment: A commenter requested clarification about the MBISG, specifically how it addresses mixed-race couples and individuals who are not appropriately placed in any racial category.

Response: The purpose of our use of the MBISG method is to augment CMS administrative measures of race and ethnicity (that is, enrollment data) to more accurately assign individuals into racial and ethnic categories for purposes of displaying utilization data across specialty. While no imputation method is 100 percent accurate, it is an improvement over administrative data and we believe it is sufficient for the purpose for which it is being used—to gain a general understanding of beneficiary utilization across specialty.

Nature of a service. In the table that details providers in terms of the beneficiaries they serve in the IPPS/LTCH PPS final rule, the unit of measurement we used was a hospital discharge. A discharge includes all resources involved in the hospital's caring for a beneficiary during the hospital stay. There is no parallel construct under the PFS. While the resources involved in furnishing a given discharge can and do vary under the IPPS, a discharge consists of a somewhat predictable set of resources that occur across a number of cost centers. On the other hand, a service unit under the PFS can range from very discrete services, such as a single pulse oximetry measurement (CPT code 94760) with total RVUs of 0.07 to complex services that include several visits during a global period, such as a liver transplant (CPT code 47135) with total RVUs of 160.44. As an illustration, based on the MS–DRGs reported in the claims data, the standard deviation of the mean IPPS relative weight is of

[529] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[530] 7 U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-inMedicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[531] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: *10.7326/M13–2946 (December 2, 2014), available at https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[532] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[533] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, *2021), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[534] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

similar magnitude to the mean. In contrast, based on the PFS services reported in the claims data, the standard deviation of the mean PFS RVU service is vastly larger than the mean.

TABLE 120: Differences in Claim-level Relative Weights between IPPS and PFS

	IPPS Relative Weight[535] on claim	PFS RVU on claim
Mean	1.95	2.62
Standard Deviation	1.72	1,241

In addition, under the PFS, some services furnished during a single encounter are billed in multiple units. These services could range from allergy testing (CPT codes 95004 through 95078) to anesthesia services (CPT codes 00100 through 01860). The average total RVUs for services billed in multiple units are not comparable to services billed in a single unit per encounter.

Number of practitioners serving a beneficiary and associated spending. Under the IPPS, most beneficiaries who had one or more IPPS claims during fiscal year 2022 were served by 1 or 2 providers, which accounts for most of the spending under the IPPS. The share of beneficiaries served by a given number of providers is consistent with the share of spending incurred for these discharges. Less than 10 percent of beneficiaries were served by 5 or more providers. Under the PFS, during CY 2022, most beneficiaries with one or more PFS claims saw 5 or more practitioners. In contrast to the pattern under the IPPS, PFS spending for beneficiaries who saw 10 or more practitioners accounted for a disproportionate share of total spending. Under the IPPS, examining providers in terms of beneficiary characteristics reflects the care of most beneficiaries with one or more discharges under the IPPS. Under the PFS, the same framework would be mostly describing the 40 percent of beneficiaries with one or more PFS services who account for close to 80 percent of total spending.

Utilization of services by beneficiary characteristic. As shown in Table 121, the specialty-level services utilized by beneficiaries with particular characteristics varies widely. Beneficiaries with the characteristics in Table 121 do not access services consistent with the share of enrollees with that characteristic. As a result, comparing across deciles, for example, of practitioners serving beneficiaries of one race, would often be comparing very different service mixes. How discrete a service is, the setting it is furnished in, and the associated inputs may result in services that have very different baseline allowed charges.

A significant body of literature has examined the reasons for differential access to physician services by beneficiary characteristics. Some of the explanations of the differential utilization of services include:

- Patient preferences and willingness to undergo procedures, such as due to decreased belief in treatment efficacy and concerns about surgical risks.[536] [537] [538] [539]
- Geographic location: specialists and sub-specialists are sometimes clustered in urban areas due to higher demand for services.[540]
- Differences in referral patterns [541] from primary care physicians and following hospitalizations.
- Differences in providers who can speak the language of beneficiaries with Limited English Proficiency.[542]

The information contained in Table 121 is provided solely to demonstrate beneficiary utilization by provider specialty impact across a number of health equity dimensions. This does not form the basis or rationale for the policies in this final rule.

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[535] The IPPS relative weights are not fully comparable to PFS RVUs because IPPS payments may include outliers. Even considering outliers, however, the standard deviation on IPPS payments is only slightly higher relative to the mean($17,104+/−$21,825).

[536] Ibrahim SA, Siminoff LA, Burant CJ, et al. Differences in expectations of outcome mediate African American/white patient differences in ''willingness'' to consider joint replacement. *Arthritis Rheum.* 2002;46:2429–2435.

[537] Vina ER, Cloonan YK, Ibrahim SA, et al. Race, sex, and total knee replacement consideration: role of social support. *Arthritis Care Res (Hoboken)* 2013;65:1103–1111.

[538] Allen KD, Golightly YM, Callahan LF, et al. Race and sex differences in willingness to undergo total joint replacement: the Johnston County Osteoarthritis Project. *Arthritis Care Res (Hoboken)* 2014;66:1193–1202.

[539] Hausmann LR, Mor M, Hanusa BH, et al. The effect of patient race on total joint replacement recommendations and utilization in the orthopedic setting. *J Gen Intern Med.* 2010;25:982–988.

[540] Cyr, M.E., Etchin, A.G., Guthrie, B.J. et al. Access to specialty healthcare in urban versus rural US populations: a systematic literature review. BMC Health Serv Res 19, 974 (2019). *https://doi.org/10.1186/s12913-019-4815-5*.

[541] Landon BE, Onnela J, Meneades L, O'Malley AJ, Keating NL. Assessment of Racial Disparities in Primary Care Physician Specialty Referrals. JAMA Netw Open. 2021;4(1):e2029238. doi:10.1001/jamanetworkopen.2020.29238.

[542] Berdahl TA, Kirby JB. Patient-Provider Communication Disparities by Limited English Proficiency (LEP): Trends from the US Medical Expenditure Panel Survey, 2006–2015. J Gen Intern Med. 2019 Aug;34(8):1434–1440. doi: 10.1007/s11606–018–4757–3. Epub 2018 Dec 3. PMID: 30511285; PMCID: PMC6667581.

TABLE 121: Beneficiary Service Utilization by Payment Impact Specialty Across Demographic and Equity Characteristics, CY 2022

	All	White	Black	Hispanic	AAPI[543]	AIAN[544]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
All Enrollees	28,285,281	79.8 %	7.4 %	5.8 %	3.2 %	0.5 %	0.9 %	31.5 %	0.9 %	7.7 %	17.7 %	16.6 %	18.0 %	22.6 %	18.6 %
	Total Services	% Services													
All Users	2,504,984,961	81.8 %	7.2 %	5.1 %	2.4 %	0.4 %	0.0 %	3.7 %	1.9 %	6.7 %	18.8 %	17.7 %	19.0 %	16.3 %	23.7 %
ALLERGY/IMMUNOLOGY	20,089,081	84.0 %	5.5 %	4.1 %	2.5 %	0.1 %	0.0 %	0.5 %	0.3 %	4.4 %	8.6 %	7.8 %	8.6 %	11.7 %	16.3 %
ANESTHESIOLOGY	9,563,100	82.9 %	6.4 %	5.4 %	2.1 %	0.5 %	0.0 %	6.2 %	1.2 %	6.9 %	19.5 %	17.7 %	19.6 %	16.8 %	30.7 %
CARDIAC SURGERY	457,226	82.7 %	5.9 %	5.8 %	2.1 %	0.5 %	0.0 %	2.1 %	4.3 %	8.0 %	16.6 %	15.5 %	16.8 %	22.7 %	16.7 %
CARDIOLOGY	71,347,515	81.5 %	7.2 %	5.3 %	2.8 %	0.3 %	0.0 %	1.8 %	2.4 %	7.3 %	15.8 %	14.6 %	15.9 %	17.4 %	16.4 %
COLON AND RECTAL SURGERY	724,904	83.7 %	5.6 %	4.7 %	2.5 %	0.2 %	0.0 %	0.7 %	1.3 %	5.7 %	13.6 %	12.6 %	13.8 %	12.8 %	19.9 %
CRITICAL CARE	1,867,947	76.1 %	10.3 %	6.9 %	3.4 %	0.4 %	0.1 %	5.3 %	5.2 %	7.4 %	28.8 %	27.6 %	29.2 %	13.0 %	27.1 %
DERMATOLOGY	49,298,654	93.2 %	0.9 %	1.6 %	0.7 %	0.1 %	0.0 %	0.6 %	0.5 %	3.7 %	4.2 %	3.8 %	4.3 %	15.4 %	7.4 %
EMERGENCY MEDICINE	21,952,901	78.7 %	9.6 %	6.0 %	2.4 %	0.6 %	0.2 %	5.3 %	3.1 %	7.8 %	25.1 %	23.8 %	25.4 %	17.3 %	24.8 %
ENDOCRINOLOGY	13,439,562	82.9 %	5.2 %	4.2 %	3.7 %	0.2 %	0.0 %	1.1 %	1.4 %	4.2 %	11.2 %	10.2 %	11.3 %	9.1 %	16.4 %

	All	White	Black	Hispanic	AAPI[543]	AIAN[544]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
FAMILY PRACTICE	99,140,616	84.0 %	5.8 %	4.3 %	2.3 %	0.5 %	0.2 %	11.6 %	0.9 %	8.0 %	16.3 %	15.1 %	16.5 %	22.0 %	19.4 %
GASTROENTEROLOGY	25,248,189	84.4 %	5.7 %	4.0 %	2.0 %	0.2 %	0.0 %	0.6 %	1.1 %	5.3 %	11.2 %	10.4 %	11.3 %	12.9 %	17.9 %
GENERAL PRACTICE	5,342,814	73.9 %	8.4 %	9.8 %	3.9 %	0.5 %	0.1 %	12.5 %	1.3 %	7.2 %	28.6 %	27.6 %	28.8 %	16.5 %	23.2 %
GENERAL SURGERY	9,166,757	80.9 %	8.2 %	5.8 %	1.9 %	0.5 %	0.0 %	3.7 %	5.2 %	8.8 %	23.0 %	21.9 %	23.3 %	21.9 %	28.9 %
GERIATRICS	1,625,353	76.7 %	9.3 %	5.8 %	5.1 %	0.4 %	0.6 %	30.1 %	1.6 %	5.1 %	30.8 %	30.2 %	31.3 %	9.1 %	17.2 %
HAND SURGERY	3,013,821	87.6 %	3.7 %	3.0 %	1.7 %	0.2 %	0.0 %	0.1 %	0.5 %	3.8 %	7.4 %	6.7 %	7.5 %	11.4 %	13.2 %
HEMATOLOGY/ONCOLOGY	458,304,885	81.4 %	8.1 %	4.8 %	2.4 %	0.3 %	0.0 %	1.0 %	1.2 %	7.4 %	13.9 %	12.9 %	14.0 %	14.5 %	18.2 %
INFECTIOUS DISEASE	48,318,745	86.6 %	4.9 %	4.2 %	1.1 %	0.2 %	0.0 %	0.4 %	3.3 %	6.7 %	12.8 %	11.4 %	12.9 %	5.4 %	24.5 %
INTERNAL MEDICINE	142,667,884	80.0 %	8.2 %	5.2 %	3.3 %	0.4 %	0.1 %	10.0 %	2.4 %	6.6 %	19.9 %	18.9 %	20.1 %	15.1 %	21.0 %
INTERVENTIONAL PAIN MGMT	15,783,928	83.7 %	6.3 %	5.4 %	1.7 %	0.4 %	0.0 %	3.7 %	0.6 %	7.2 %	18.3 %	16.5 %	18.4 %	15.3 %	32.5 %
INTERVENTIONAL RADIOLOGY	6,371,060	75.5 %	10.3 %	7.1 %	3.6 %	0.3 %	0.0 %	0.6 %	11.3 %	7.0 %	21.3 %	20.1 %	21.5 %	14.6 %	20.5 %
MULTISPECIALTY CLINIC/OTHER PHYS	1,874,372	81.5 %	6.6 %	4.6 %	3.2 %	0.7 %	0.2 %	6.7 %	1.9 %	5.9 %	19.3 %	18.3 %	19.4 %	15.8 %	20.7 %
NEPHROLOGY	15,193,786	61.7 %	19.2 %	10.8 %	4.7 %	0.8 %	0.0 %	1.5 %	35.1 %	10.2 %	31.4 %	29.3 %	31.8 %	14.4 %	26.1 %

	All	White	Black	Hispanic	AAPI[543]	AIAN[544]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
NEUROLOGY	49,770,374	83.8 %	5.6 %	5.0 %	2.0 %	0.3 %	0.0 %	4.2 %	0.7 %	5.3 %	20.4 %	19.2 %	20.6 %	12.9 %	40.7 %
NEUROSURGERY	2,430,012	83.7 %	6.3 %	4.3 %	2.0 %	0.4 %	0.0 %	1.0 %	0.9 %	8.1 %	17.0 %	15.8 %	17.2 %	20.6 %	25.8 %
NUCLEAR MEDICINE	1,840,191	82.2 %	6.1 %	5.4 %	2.6 %	0.1 %	0.0 %	0.6 %	1.0 %	6.0 %	14.6 %	13.7 %	14.7 %	9.0 %	15.4 %
OBSTETRICS/GYNECOLOGY	11,867,340	81.2 %	8.6 %	4.6 %	2.2 %	0.5 %	0.0 %	1.1 %	0.6 %	6.8 %	14.2 %	13.4 %	14.3 %	15.7 %	18.3 %
OPHTHALMOLOGY	55,861,861	83.3 %	5.2 %	4.7 %	3.5 %	0.3 %	0.0 %	0.1 %	1.4 %	5.6 %	10.9 %	10.0 %	11.0 %	17.4 %	9.8 %
ORTHOPEDIC SURGERY	48,700,496	85.2 %	5.4 %	4.0 %	2.1 %	0.3 %	0.0 %	0.3 %	0.5 %	6.0 %	9.7 %	8.7 %	9.7 %	17.4 %	13.8 %
OTOLARYNGOLOGY	13,168,571	84.1 %	5.8 %	4.2 %	2.4 %	0.2 %	0.0 %	0.8 %	0.5 %	5.7 %	11.8 %	10.9 %	11.8 %	16.9 %	16.0 %
PATHOLOGY	22,251,357	83.3 %	6.1 %	4.3 %	2.4 %	0.3 %	0.0 %	0.5 %	2.1 %	6.2 %	13.2 %	12.2 %	13.3 %	18.1 %	15.6 %
PEDIATRICS	2,097,101	78.4 %	7.1 %	8.9 %	1.4 %	0.3 %	0.1 %	3.9 %	1.9 %	9.4 %	19.3 %	18.2 %	19.4 %	12.4 %	29.8 %
PHYSICAL MEDICINE	24,542,987	80.2 %	8.2 %	4.9 %	3.0 %	0.3 %	0.0 %	3.8 %	1.2 %	5.6 %	26.4 %	25.3 %	26.7 %	13.7 %	34.7 %
PLASTIC SURGERY	1,800,630	84.2 %	6.4 %	4.6 %	1.4 %	0.4 %	0.0 %	2.0 %	1.6 %	5.4 %	17.9 %	17.0 %	18.0 %	16.2 %	20.0 %
PSYCHIATRY	9,308,283	75.7 %	10.6 %	6.7 %	2.5 %	0.5 %	1.0 %	94.6 %	0.7 %	7.6 %	51.8 %	50.0 %	52.2 %	12.7 %	58.7 %
PULMONARY DISEASE	13,466,574	81.7 %	7.8 %	5.0 %	2.3 %	0.3 %	0.1 %	5.0 %	2.4 %	7.3 %	19.3 %	18.1 %	19.5 %	17.2 %	23.2 %

	All	White	Black	Hispanic	AAPI[543]	AIAN[544]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	12,793,376	83.3 %	6.4 %	4.7 %	2.0 %	0.4 %	0.0 %	0.9 %	0.9 %	7.1 %	11.5 %	10.5 %	11.6 %	20.1 %	13.4 %
RADIOLOGY	181,430,147	81.4 %	6.7 %	5.3 %	2.8 %	0.3 %	0.0 %	0.4 %	1.4 %	5.3 %	15.0 %	14.0 %	15.1 %	14.3 %	17.6 %
RHEUMATOLOGY	166,143,825	85.0 %	5.4 %	4.7 %	1.9 %	0.2 %	0.0 %	0.4 %	0.4 %	5.7 %	6.5 %	5.5 %	6.6 %	12.9 %	21.3 %
THORACIC SURGERY	729,721	80.8 %	8.5 %	5.1 %	2.2 %	0.4 %	0.0 %	2.5 %	4.3 %	8.0 %	18.7 %	17.5 %	19.0 %	19.9 %	19.2 %
UROLOGY	54,057,785	83.2 %	7.4 %	3.9 %	1.5 %	0.2 %	0.0 %	0.4 %	0.7 %	5.4 %	8.3 %	7.6 %	8.4 %	14.0 %	15.9 %
VASCULAR SURGERY	5,409,525	74.5 %	12.9 %	7.0 %	2.3 %	0.3 %	0.0 %	1.2 %	16.2 %	8.0 %	23.2 %	21.6 %	23.4 %	15.1 %	22.1 %
AUDIOLOGIST	2,055,569	85.3 %	4.3 %	3.9 %	2.6 %	0.3 %	0.1 %	0.2 %	0.6 %	4.5 %	12.1 %	11.5 %	12.2 %	15.4 %	12.4 %
CHIROPRACTOR	17,158,259	91.2 %	2.0 %	2.1 %	1.2 %	0.3 %	0.0 %	0.0 %	0.3 %	5.9 %	7.5 %	6.7 %	7.6 %	27.2 %	12.5 %
CLINICAL PSYCHOLOGIST	6,463,428	83.1 %	6.4 %	4.8 %	1.8 %	0.3 %	1.0 %	88.4 %	0.9 %	4.3 %	32.2 %	31.2 %	32.5 %	10.7 %	36.2 %
CLINICAL SOCIAL WORKER	6,599,714	82.9 %	8.3 %	3.9 %	1.0 %	0.4 %	1.6 %	99.6 %	0.8 %	6.7 %	43.9 %	42.5 %	44.3 %	14.7 %	49.2 %
DIAGNOSTIC TESTING FACILITY	23,489,346	83.1 %	6.2 %	4.5 %	2.8 %	0.2 %	0.0 %	0.3 %	0.6 %	5.4 %	12.3 %	11.1 %	12.4 %	14.0 %	16.3 %
INDEPENDENT LABORATORY	31,744,057	78.1 %	12.5 %	5.6 %	1.6 %	0.2 %	0.0 %	2.4 %	1.6 %	9.7 %	39.8 %	39.3 %	40.3 %	14.7 %	26.4 %
NURSE ANES / ANES ASST	543,164	86.1 %	4.3 %	4.8 %	1.3 %	0.7 %	0.0 %	14.2 %	1.6 %	8.3 %	16.9 %	15.6 %	17.1 %	31.4 %	23.8 %

[543] American Asian and Pacific Islander.

[544] American Indian and Alaskan Native.

	All	White	Black	Hispanic	AAPI[543]	AIAN[544]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
NURSE PRACTITIONER	128,768,200	84.8 %	7.2 %	3.7 %	1.4 %	0.4 %	0.1 %	10.6 %	1.9 %	8.5 %	21.1 %	20.2 %	21.5 %	22.1 %	25.7 %
OPTOMETRY	19,912,703	87.0 %	5.1 %	2.8 %	1.6 %	0.5 %	0.0 %	0.1 %	0.6 %	8.8 %	11.7 %	10.8 %	11.8 %	33.8 %	12.1 %
ORAL/MAXILLOFACIAL SURGERY	296,908	79.2 %	4.5 %	6.0 %	6.0 %	0.1 %	0.0 %	1.2 %	0.5 %	3.6 %	20.8 %	19.9 %	20.9 %	10.6 %	20.4 %
PHYSICAL/OCCUPATIONAL THERAPY	159,690,345	85.1 %	4.7 %	3.8 %	2.7 %	0.2 %	0.0 %	2.3 %	0.5 %	3.7 %	10.8 %	10.2 %	10.9 %	13.5 %	13.0 %
PHYSICIAN ASSISTANT	65,080,844	86.5 %	5.1 %	3.5 %	1.4 %	0.5 %	0.1 %	4.3 %	1.1 %	6.0 %	13.7 %	12.8 %	13.9 %	20.2 %	18.6 %
PODIATRY	27,252,983	80.8 %	8.7 %	5.5 %	2.1 %	0.4 %	0.0 %	0.4 %	2.3 %	6.4 %	23.9 %	23.0 %	24.2 %	14.9 %	20.9 %
PORTABLE X-RAY SUPPLIER	3,380,767	79.2 %	10.4 %	6.5 %	2.2 %	0.3 %	0.2 %	0.2 %	2.1 %	9.9 %	59.1 %	59.3 %	60.0 %	17.2 %	28.5 %
OTHER	311,487,534	74.2 %	10.1 %	8.6 %	3.2 %	1.0 %	0.0 %	2.1 %	3.8 %	8.2 %	44.9 %	42.9 %	45.2 %	20.7 %	52.9 %
D6	2,597,888	47.5 %	21.5 %	10.2 %	0.1 %	0.0 %	0.0 %	0.0 %	15.5 %	17.0 %	65.5 %	64.6 %	65.5 %	12.1 %	67.8 %

BILLING CODE 4120–01–C

D. Impact of Changes Related to Telehealth Services

In this final rule, we finalized implementation of the provisions of the CAA, 2023 that amended section 1834(m) of the Act to extend the application of certain Medicare telehealth flexibilities through December 31, 2024, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S.; continuing the expanded scope of telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists; extending payment for telehealth services furnished by FQHCs and RHCs; and delaying the requirement that there be an in-person visit with the physician or practitioner within 6 months before an initial mental health telehealth service.

In this final rule, we finalized a refined process for considering requests received for adding services to the Medicare Telehealth Services List, which will include a decision on whether the services should be included on the list on a permanent or provisional basis. Because the underlying criteria for adding services to the Medicare Telehealth Services List are not changing, we do not expect this to impact the utilization of Medicare Telehealth services beginning in CY 2024 but we will continue to monitor the utilization of these services. We are finalizing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) are paid at the non-facility PFS rate. Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate. As we are currently paying for the majority of services that will be billed with POS 10 at the PFS non-facility rate under the PHE-specific policy of basing payment on the place of service (and POS code) had the service been furnished in person, we believe that these services furnished via telehealth will largely continue to be paid as they are currently. Therefore, we believe the impact of this proposal will be roughly neutral even if utilization remains at current levels for these services. We anticipate that these provisions will result in continued utilization of Medicare telehealth services during CY 2024 at levels comparable to observed utilization of these services during the PHE for COVID–19.

E. Other Provisions of the Regulation

1. Impact of Provisions for Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In section II.K.2. of this final rule, we are finalizing to allow Medicare Parts A and B payment for dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment of cancer. We are also finalizing to allow Medicare Parts A and B payment for dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these. However, we do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of these therapies. Although, we acknowledge that the observed utilization of these services might have been low because of the size of the population of patients whose treatment would include such dental services and also because the dental services have been viewed as subject to the payment preclusion under section 1862(a)(12).

Based on an analysis of 2018–2022 incurred claims experience, we estimated that there are potentially 155,000 additional beneficiaries who might receive dental services for which Medicare payment could be made, relative to the current number of beneficiaries that received dental services. These are beneficiaries who would receive any of the treatments identified in our finalized policies for CY 2024 (that is, chemotherapy/CAR T-cell therapy/bone-modifying agent therapies used in the treatment of cancer and treatments for head and neck cancer) who would likely require dental services, and could utilize dental services for which services Medicare could pay in CY 2024. The estimated average cost for these additional dental services is about $525 per person on an allowed charge basis and roughly $420 per person on a Medicare payment basis. This assumption is based on an analysis of 2019 incurred claims, but we believe results using more recent data would not be likely to change, due to the limited claims involving these services. Based on this same analysis, the effective rate of coverage was less than 0.2 percent. We do acknowledge that the actual take-up rate of services could be higher due to the proposed additional examples of medical services to which dental services are inextricably linked, which may raise awareness that payment is available. Therefore, we prepared impact estimates under the utilization assumptions of 0.2 percent and between 1–3 percent. We then applied these utilization ratios to estimate projected payments for dental exams and treatments in connection with cancer therapies. We found that the estimated yearly impact beginning in CY 2024 to be roughly $130,000 per year with a 0.2 percent utilization assumption, and roughly $650,000 to 2 million per year for the utilization assumptions of 1–3 percent. Therefore, we do not anticipate a significant payment impact for these provisions. It is important to note that there is a certain amount of uncertainty in these take-up rate assumptions, but they are consistent with the current utilization of dental services, including the expansion provided for in the CY 2023 PFS final rule. Additionally, since the cost impact of this proposal is negligible, it is not necessary to adjust the budget neutrality factor for the conversation factor.

2. Impact of Proposal To Implement Separate Payment for the Office/Outpatient (O/O) E/M Visit Inherent Complexity Add-On Code (HCPCS G2211)

In recent years, the AMA's CPT Editorial Committee has largely restructured the E/M visit code sets to acknowledge changes in medical practice. The AMA RUC has reviewed and provided recommendations for the revised E/M visit code sets in the context of the generally recognized need to better recognize resources involved in furnishing different types of services within the broader PFS. While we adopted the RUC-recommended values for the O/O E/M visit code family in the CY 2021 final rule, recognizing that those values generally reflect the resources involved in furnishing those services, we did not believe those valuations appropriately reflected the resource costs involved in furnishing primary and other similarly longitudinal medical care for a serious or complex condition in office settings. To address this concern, effective beginning in CY 2021, we finalized an add-on code to

separately pay for visit complexity inherent to O/O E/M visits for primary care and other medical care services that are part of ongoing care related to a patient's single, serious, or complex condition in the office setting (the O/O E/M visit inherent complexity add-on). After we finalized the CY 2021 payment changes for O/O E/M visits, in the CAA of 2021, Congress imposed a statutory moratorium on Medicare payment for the O/O E/M visit inherent complexity add-on code until January 1, 2024.

We proposed to implement payment for the O/O E/M visit inherent complexity add-on, HCPCS code G2211, with significant refinements to target improved payment for primary and other similar longitudinal care for serious or complex conditions. Specifically, we proposed that the O/O E/M visit complexity add-on code cannot be billed with visits reported using Modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. (Previously, in the CY 2021 final rule, we stated we would not expect such billing; but as there was no explicit prohibition, these visits were included in the budget neutrality adjustment (85 FR 84572)). We also proposed to set PFS rates with a refined, more specific utilization assumption that better recognizes likely uptake of the code, differential use among specialties, and new and established patient visits, among other changes. These refined assumptions were developed, considering perspectives and information from interested parties. The resulting estimate reflects that the O/O E/M visit inherent complexity add-on code would likely be reported with approximately 38 percent of all O/O E/M visits for CY 2024. As discussed previously and shown below, we estimated the specific portion of the total budget neutrality adjustment attributable to the proposal to make payment for the O/O E/M inherent complexity add-on code to be approximately 2.00 percent compared to an attributable budget neutrality adjustment of 3.20 percent as calculated in CY 2021 rulemaking.

3. Advancing Access to Behavioral Health

a. Impact of Proposed Payment for Marriage and Family Therapist (MFT) Services and Mental Health Counselor (MHC) Services

As outlined in section II.J. of this final rule, section 4121 of CAA, 2023 added section 1861(s)(2)(II) to establish a new Medicare benefit category for MFT services and MHC services furnished and billed by MFTs and MHCs, respectively. MFT and MHC services are defined in section 1861(lll)(2) and 1861(lll)(4), respectively, as services for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital). An MFT or MHC is defined as an individual who possesses a master's or doctor's degree, is licensed or certified by the State in which they furnish services, who has performed at least 2 years of clinical supervised experience, and meets other requirements as the Secretary determines appropriate. Section 1833(a)(1)(FF) of the statute requires that MFT and MHC services be paid at 75 percent of the amount determined for payment of a clinical psychologist. MFT and MHC services are excluded from consolidated billing requirements under the skilled nursing facility prospective payment system. Services furnished by an MFT and MHC are covered when furnished in a rural health clinic and federally qualified health center. In addition, the hospice interdisciplinary team is required to include one social worker, MFT or MHC. Expenditures associated with payment for services furnished by MFTs and MHCs in CY 2024 will be incorporated into budget neutrality for PFS ratesetting in future years.

4. Drugs and Biological Products Paid Under Medicare Part B

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023 final rule, we finalized several policies to implement the provision, including: reporting requirements for the JW and JZ modifiers; the date upon which we will begin to edit claims for appropriate use of the JW and JZ modifiers, October 1, 2023; the definition of ''refundable single-dose container or single-use package drug''; the manner in which refund amounts will be calculated; the annual basis we will send reports to manufacturers; the dispute resolution process; and enforcement provisions. In section III.A.3. of this final rule, we finalize the date of the initial report to manufacturers, the dates for subsequent reports, the method of calculation of the refund amount when there are multiple manufacturers of a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

As we discussed in the CY 2024 PFS proposed rule (88 FR 52699 through 52704), we analyzed JW modifier data from 2021 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[545] Similar to our regulatory impact analysis in the CY 2023 PFS final rule (87 FR 70187 through 70188), we used the 2021 JW modifier data to estimate refund amounts as described in section 1847A(h)(3) of the Act. First, we subtracted the percent units discarded by 10 percent (the applicable percentage for most refundable drugs), except for five drugs for which we are finalizing higher applicable percentages in this final rule (for example, J9262, J0775, J0223, J3300, and J9269). Then, we multiplied that percentage by the CY 2021 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. We note that this analysis remains appropriate for this final rule because we are finalizing the increased applicable percentages for the two categorical unique circumstances and the associated five billing and payment codes as proposed. In addition, the JW modifier data from 2021 is still the most recent data available for estimating how our final policies impact Medicare Part B expenditures.

Overall in the 2021 calendar year, Medicare paid nearly $1.56 billion for discarded amounts of drugs from a single-dose container or single-use package paid under Part B. In that year, there were 51 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 11 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are multiple source drug codes; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in

[545] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling; and 3 are products referred to as skin substitutes, which were removed because we anticipate making changes to coding and payment policies regarding those products in future rulemaking. After these exclusions, there were 31 billing and payment codes that met the definition of refundable single-dose container or single-use package drug and have discarded units above the relevant finalized applicable percentage. Of these, three have discarded units that would fall below increased applicable percentages finalized in this final rule.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage), except for drugs with higher applicable percentages finalized in the CY 2023 final rule or as finalized in this final rule. Then, we multiplied the appropriate percentage by the CY 2021 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there will be approximately $83.1 million in refunds due from manufacturers for the calendar year of 2021 ($20.8 million each calendar quarter). See Table 122.

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TABLE 122: Estimated Refund Amounts Based on CY 2021 JW Modifier Data[546]

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
Q9965	$2,276,001.01	67.41%	Y; Radiopharm or imaging agent	10%			
J7342	$4,559.95	53.26%	N	10%	43.26%	$1,972.63	$493.16
J9281	$26,703,749.86	37.60%	N	35%	2.60%	$694,297.50	$173,574.37
J9262	$220,987.21	30.98%	N	26% (finalized)	4.98%	$11,005.16	$2,751.29
J9043	$146,745,385.39	29.11%	N	10%	19.11%	$28,043,043.15	$7,010,760.79
J9041	$380,429,509.43	27.00%	Y; multiple source	10%			
J9351	$475,677.64	26.37%	Y; multiple source	10%			
Q9961	$19,366.66	26.28%	Y; Radiopharm or imaging agent	10%			
J0894	$17,872,985.28	24.16%	Y; multiple source	10%			
J9044	$4,616,507.83	21.91%	N; see new single source codes J9046, J9048, J9049	10%	11.91%	$549,826.08	$137,456.52
J9025	$37,997,710.06	21.83%	Y; multiple source	10%			
J9017	$1,733,222.58	21.25%	Y; multiple source	10%			
J1448	$1,739,523.98	20.85%	N	10%	10.85%	$188,738.35	$47,184.59
J0775	$68,490,974.85	20.83%	N	45% (finalized)			
J9065	$451,404.96	20.26%	Y; multiple source	10%			
J9223	$90,785,710.74	20.25%	N	10%	10.25%	$9,305,535.35	$2,326,383.84
J0565	$3,928,811.98	19.53%	N	10%	9.53%	$374,415.78	$93,603.95

[546] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9178	$9,922.54	18.95%	Y; multiple source	10%			
J9229	$17,911,595.08	18.21%	N	10%	8.21%	$1,470,541.96	$367,635.49
J0223	$10,731,531.69	17.00%	N	26% (finalized)			
Q9966	$2,230,516.82	16.89%	Y; Radiopharm or imaging agent	10%			
J1640	$8,405,837.59	15.52%	Y; filtered	10%			
J9153	$5,526,153.53	15.00%	N	10%	5.00%	$276,307.68	$69,076.92
J2425	$124,548.01	14.07%	N	10%	4.07%	$5,069.10	$1,267.28
J9027	$62,602.70	13.98%	Y; multiple source	10%			
J9264	$347,464,875.59	13.86%	N	10%	3.86%	$13,412,144.20	$3,353,036.05
J2796	$257,348,654.37	13.60%	N	10%	3.60%	$9,264,551.56	$2,316,137.89
Q9956	$737,908.86	13.03%	Y; Radiopharm or imaging agent	10%			
J0515	$16,911.88	12.88%	Y; multiple source	10%			
J2562	$18,752,340.26	12.81%	N	10%	2.81%	$526,940.76	$131,735.19
J9179	$43,581,966.38	12.71%	N	10%	2.71%	$1,181,071.29	$295,267.82
J9307	$22,805,063.36	12.65%	N	10%	2.65%	$604,334.18	$151,083.54
J9037	$33,082,159.80	12.10%	N	10%	2.10%	$694,725.36	$173,681.34
J3396	$2,537,428.32	11.93%	N	10%	1.93%	$48,972.37	$12,243.09
J9042	$169,482,924.33	11.89%	N	10%	1.89%	$3,203,227.27	$800,806.82
J9319	$6,572,808.69	11.78%	Y; multiple source	10%			
Q9950	$516,142.11	11.77%	Y; Radiopharm or imaging agent	10%			
J0485	$76,861,131.89	11.61%	N	10%	1.61%	$1,237,464.22	$309,366.06
J9205	$59,413,621.44	11.55%	N	10%	1.55%	$920,911.13	$230,227.78

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9228	$417,946,062.94	11.40%	N	10%	1.40%	$5,851,244.88	$1,462,811.22
J3241	$306,975,463.35	11.32%	N	10%	1.32%	$4,052,076.12	$1,013,019.03
J2997	$66,254,826.34	11.31%	N	10%	1.31%	$867,938.23	$216,984.56
J3300	$8,964,090.01	10.97%	N	90% finalized			
J0122	$144,528.76	10.84%	N	10%	0.84%	$1,214.04	$303.51
J3101	$12,921,647.56	10.67%	N	10%	0.67%	$86,575.04	$21,643.76
J9315	$23,154,637.13	10.33%	Y; multiple source	10%			
J9269	$7,755,186.19	10.15%	N	26% finalized			
J9352	$9,225,195.63	10.10%	N	10%	0.10%	$9,225.20	$2,306.30
Q4121	$6,484,123.19	17.85%	Y; skin substitute (proposed)	10%	7.85%		
Q4106	$1,511,046.28	16.64%	Y; skin substitute (proposed)	10%	6.64%		
Q4101	$2,176,035.02	14.58%	Y; skin substitute (proposed)	10%	4.58%		
					TOTAL	$82,883,368.59	$20,720,842.15

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There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved, this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also noted that this estimate is based on CY 2021 data for discarded drug amounts, which, for reasons discussed in the CY 2023 PFS final rule (87 FR 69716), we believe to be an underestimate due to the frequent omission of the JW modifier. Once we begin to edit claims for both the JW and JZ modifiers, reported discarded drug amounts will likely increase. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file [547] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

We received one public comment on this economic impact analysis. The following is a summary of the comment and our response.

Comment: One commenter stated that our economic impact analysis on the discarded drug refund provision reflects incomplete and inaccurate data because use of the JW modifier was not uniformly enforced during the year from which the data was collected. The commenter requested that we take efforts to verify the accuracy of the analysis.

Response: As noted previously in this final rule, we understand our analysis to have several limitations, including that we believe our refund estimates to understate actual discarded amounts for refundable drugs due to low compliance with the JW modifier requirement that went into effect on January 1, 2017. The discarded drug data that has been reported with the JW modifier data since 2013 is the best data available and is what we used for this analysis. We expect this data and our impact analyses to become more accurate after the implementation of claims edits for appropriate JW and JZ modifier use on October 2, 2023.

a. Impacts Related to the Issuance of the Initial Report

In section III.A.3.b. of this final rule, we finalized the policy to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. Accordingly, as outlined in section III.B.3.c. of this final rule, we finalized the policy to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute.

Delaying the receipt of the rebate, that is in 2025 instead of 2024, only represents a cost to the extent the SMI trust fund receives less interest revenue. Only a portion of SMI trust fund revenue ends up invested in the bond portfolio. Based on current SMI trust fund operation patterns a delay in rebate collection as described in the rule would represent a cost less than $2 million dollars in any given year and therefore would be negligible to SMI trust fund operations.

b. Impacts Related to the Application for Consideration

As outlined in section V.B.1. of this final rule, the information collection requirements, we estimated the annual burden per applicant to be 5 hours. If we anticipate no more than 22 applications in the initial year applications are available, the total annual drafting and submitting burden would be 110 hours (22 applications per year × 5 hrs per applicant). We estimate an annual cost of this burden to be $4,591.40 ($41.74/hr × 110 hr). For subsequent years, we estimate a total annual burden related to drafting and submission of 10 hours (2 applications × 5 hr per respondent/applicant) at an annual cost of $418 (41.74/hr × 10 hr).

5. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.4. of this final rule, we finalized the policy to include Remote Patient Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) services, Community Health Integration (CHI) and Principal Illness Navigation (PIN) services, in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Due to the growing number of services in the code, we revised the calculation for G0511 to include the weighted average of these services based on utilization under the PFS as this may provide a more complete and accurate payment amount.

In terms of estimated impacts to the Medicare program, expanding use of General Care Management HCPCS code G0511 to include RPM, RTM, CHI, and PIN may result in an increase in spending. Prior updates to G0511 have resulted in negligible increases.

6. RHC and FQHC CfC Changes: Permitting MFTs and MHCs To Furnish Services

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding MFTs and MHCs as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. We proposed regulation text changes to permit MFT and MHCs to provide services furnished at RHCs and FQHCs. These changes will include MFTs and MHCs as members of the staff who may be the owner or an employee of the clinic or center, or furnish services under contract to the clinic or center. Along with other permitted physicians and nonphysician practitioners, MFT and MHCs may be available to furnish patient care services at all times the clinic or center operates.

At § 491.9(b)(3) RHCs and FQHCs must have patient care policies that include: (1) a description of the services the clinic or center furnishes directly or through agreement or arrangement; (2) guidelines for medical management of health problems; and (3) rules for storage, handling, and administration of drugs and biologicals. Additionally, § 491.9(b)(4) states that the RHC and FQHC patient policies must regularly be reviewed at least once every 2 years by a group of professional personnel that includes one or more physicians, one or more physician assistants (PAs) or nurse practitioners (NPs), and at least one person who is not a member of the clinic or center staff. If an RHC or FQHC provides services furnished by an MHC or MFT they must update their patient

[547] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

care policies with a description of the services they will provide.

The most recently published collection of information for RHCs and FQHCs (OMB control number 0938–0334), estimates that an annual review of the patient care policies may take approximately 2 hours. Therefore, we assume, it would take each medical professional (at least one physician and at least one PA or NP) 1 hour to review all policies and procedures, annually. Based on the prior analysis, we estimated it will take 30 minutes to add the description of MFT and MHC services. We also assume that only half of the RHCs and half of the FQHCs will have this burden applied to them, for a total burden estimate of $817,631.92. We noted that there would be variations in how many clinics or centers employ or contract with an MFT and MHC based on their ability to expand their services. We also recognized that some RHCs and FQHCs may already provide these services as some States provide reimbursement under the Medicaid program; however, we do not know the exact number of clinics or centers that already have these practitioners on staff and will not incur the burden.

While this final rule does have a 1-time burden, there is evidence to suggest there are long-term financial savings in integrating mental health in medical care. Effectively integrating mental and medical care can save upwards of $52 billion annually due to the existing Medicare mental health coverage gap.[548] Though this total encompasses all facility types, expanding access to MFT and MHC services in RHCs and FQHCs will have individual and societal cost savings. Older adults with mental health conditions have poorer health outcomes, higher hospitalization rates, and emergency room visits.[549] While there is an increasing need for mental health services, one barrier to effective treatment is access to mental health services.[550] Ensuring access to mental health care in rural communities is challenging as there are fewer mental health providers per capita in nonmetropolitan counties.[551] This coincides with HRSA's second quarter of the fiscal year 2023 designated health professional shortage area (HPSA) quarterly summary, which breaks down the number of HPSAs by primary medical care, dental, and mental health HPSAs based on four categories (rural, non-rural, partial rural, and unknown); and as population HPSAs, geographic HPSAs, or Facility HPSAs. The report does not provide accumulative HPSAs by the four categories.[552] Approximately 65 percent of federally designated health professional shortage areas are located in rural areas, and about 30 percent are located in non-rural areas.[553] The shortage of professionals in rural areas is severe, and the shortage of qualified professionals in combination with geographic limitations only exacerbates the mental health crisis in older adults.[554] While there are disparities in the availability of the behavioral workforce between rural and nonrural areas, counselors are integral to providing care in rural areas.[555]

7. Clinical Laboratory Fee Schedule

In section III.D. of this final rule, we outline statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 4114 of the CAA, 2023, we finalized certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are updating certain definitions and revising § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. The CAA, 2023 delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2024 through March 31, 2024. Subsequently, the next private payor rate-based CLFS update for these tests will be effective January 1, 2025, instead of January 1, 2024. In addition, we are making conforming changes to our requirements for the phase-in of payment reductions to reflect the CAA, 2023 amendments. Specifically, we are revising § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as outlined in section III.D. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the CAA, 2023 amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories and calculating the updated CLFS rates.

Regarding the conforming changes to our requirements for the phase-in of payment reductions, we note that for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2024.

[548] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0003.*

[549] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0005.*

[550] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[551] *https://psycnet.apa.org/record/2018-25164-007.*

[552] *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[553] *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.*

[554] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[555] *chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2016/09/RHRC_DB160_Larson.pdf.*

8. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

As outlined in section III.E. of this final rule, we are finalizing the proposed revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) which permit other specific types of practitioners to supervise these services effective January 1, 2024. The amendments add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). Accordingly, we are finalizing additions and revisions to the PR and CR/ICR regulations to reflect these statutory amendments.

To assess the potential impact from expanding the types of practitioners that may supervise PR/CR/ICR we searched the literature for articles that evaluated the utilization rates of PR, CR and ICR to determine the historical utilization trends of these services as well as known barriers to utilization. Based on historical utilization trends as well as barriers to utilization discussed in the literature, we do not expect the changes to make a significant impact on the Medicare program.

Nishi et al. (2016) investigated the number of Medicare beneficiaries with COPD who received PR from January 1, 2003, to December 31, 2012. Their results included both individuals who had experienced hospitalizations for COPD and those who were outpatients only. The number of unique patients with COPD who initially participated in PR during the study period was 2.6 percent in 2003 (before conditions of coverage at § 410.47 were established) and 2.88 percent in 2012 (after conditions of coverage at § 410.47 were established).[556] In 2019, *Spitzer, et al.* published an article based on Medicare claims data from 2012, finding that 2.7 percent of eligible Medicare beneficiaries received PR within 12 months of hospitalization with COPD.[557] Using claims data from fee-for-service Medicare beneficiaries hospitalized for COPD in 2014, *Lindenauer et al.* (2020) reported that only 3 percent initiated PR within 1 year of their hospital discharge.[558] Taken together, this data informs us that utilization of PR in the Medicare population is very low.

Million Hearts® 2027, a national initiative co-led by the Centers for Disease Control and Prevention (CDC) and CMS to prevent 1 million preventable cardiovascular disease (CVD) events in the next 5 years,[559] includes a goal of increasing use of CR and states that CR participation rates remain low, ranging from 19 percent to 34 percent.[560] Fleg and colleagues (2020) report that less than 25 percent ''of eligible patients participate in CR'' with a smaller proportion completing 36 sessions as recommended.[561] In their 2022 article, Varghese and colleagues state that less than 30 percent of eligible patients participate in CR in the United States.[562] *Husaini and colleagues* (2022) analyzed a sample of Medicare fee-for-service claims between 2012 and 2016 and reported that within 1 year of a qualifying event, 16 percent of patients completed one or more CR session and 0.1 percent of patients completed one or more ICR sessions. They observed an increase of combined CR and ICR utilization from 14 percent (patients with qualifying events in 2012) to 18 percent (patients with qualifying events in 2015).[563] Taken together, this data informs us that utilization of CR and ICR is low, although not as low as PR.

Underutilization of PR, CR and ICR has been attributed to numerous factors as described by *Fleg et al.* ''including a lack of referral or strong recommendation from a physician and inadequate follow-up or facilitation of enrollment after referral. Financial issues such as limited or absent health insurance coverage and the inability to afford copayments, even when insured, also limit CR/PR participation as do conflicting work and home responsibilities and distance and transportation difficulties. Social and cultural factors, including the lack of gender and racial diversity among CR/PR staff, language and cultural barriers, and lack of program availability and access are additional challenges . . . Many eligible patients are also commonly perceived as too frail . . .'' [564] *Husaini et al.* (2022) reinforce the impact of similar factors in CR underuse. They cite ''lower reimbursements relative to cost and variability in access'', physician ''skepticism over benefit and a primary emphasis on cardiac medications and procedures'', and patient ''reluctance or inability to commit 3–6 hr/wk for 8–12 wk to CR, logistical (transportation, work, etc) or financial impediments, a preference for exercise/rehabilitation at home, fear of failure, and physical limitations.'' [565]

While the expansion of supervision requirements to include nonphysician practitioners could offer greater flexibility for PR and CR programs to operate, the barriers to utilization as described by *Fleg and colleagues* (2020) and *Husiani and colleagues* (2022) are widespread and complex and low participation in PR, CR and ICR has remained steady for many years. We do not believe the expansion of supervising practitioners is likely to address these barriers. Therefore, we do not anticipate any significant increase in utilization of PR, CR and ICR services and subsequent impact to the Medicare program or interested parties.

[556] Nishi SP, Zhang W, Kuo YF, Sharma G. Pulmonary Rehabilitation Utilization in Older Adults With Chronic Obstructive Pulmonary Disease, 2003 to 2012. J Cardiopulm Rehabil Prev. 2016;36(5):375–382. doi:10.1097/HCR.0000000000000194.

[557] Spitzer KA, Stefan MS, Priya A, et al. Participation in pulmonary rehabilitation after hospitalization for chronic obstructive pulmonary disease among Medicare beneficiaries. *Ann Am Thorac Soc.* 2019;16:99–106.DOI: 10.1513/AnnalsATS.201805–332OC. PMID: 30417670; PMCID: PMC6344454.

[558] Lindenauer PK, Stefan MS, Pekow PS, et al. Association Between Initiation of Pulmonary Rehabilitation After Hospitalization for COPD and 1-Year Survival Among Medicare Beneficiaries. *JAMA.* 2020;323(18):1813–1823. doi:10.1001/jama.2020.4437.

[559] *https://millionhearts.hhs.gov/about-million-hearts/index.html.*

[560] *https://millionhearts.hhs.gov/about-million-hearts/optimizing-care/cardiac-rehabilitation.html.*

[561] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[562] Varghese MS, Beatty AL, Song Y, et al., Cardiac Rehabilitation and the COVID–19 Pandemic: Persistent. Declines in Cardiac Rehabilitation Participation and Access Among US Medicare Beneficiaries. Circ Cardiovasc Qual Outcomes. 2022;15:e009618. DOI: 10.1161/CIRCOUTCOMES.122.009618.

[563] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

[564] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[565] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

9. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As outlined in section III.F. of this final rule, we are allowing periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met.

We believe the Part B cost impact of this flexibility for the use of telecommunications will be minimal because we do not expect that these flexibilities will increase the frequency with which medically necessary assessments are furnished.

10. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2023, 10.9 million Medicare beneficiaries receive care from a health care provider in one of the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country. The modifications to Shared Savings Program policies we are finalizing with this final rule advance Medicare's overall value-based care strategy of growth, alignment, and equity, with many provisions overlapping these categories. Many of the policies in this final rule are incremental refinements to the broader changes finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968). Those changes were designed to reverse recent trends where program participation had plateaued, higher spending populations were increasingly underrepresented in the program since the change to regionally adjusted benchmarks, and access to ACOs appeared inequitable as evidenced by data indicating underserved populations were less likely to be assigned to a Shared Savings Program ACO, and to encourage growth of ACOs in underserved communities.

The changes to the Shared Savings Program regulations finalized with the CY 2023 PFS final rule were designed to increase program participation for new ACOs through the AIP option intended to promote health equity and provide ACOs greater choice in the pace of progression to performance-based risk; sustain program participation by reducing the effect of ACO performance on benchmark updates and benchmark rebasing; mitigate the bias in regional expenditure calculations that benefits ACOs electing prospective assignment; strengthen incentives for ACOs serving high-risk and high dual populations; improve the risk adjustment methodology to better account for medically complex, high-cost beneficiaries while continuing to guard against coding initiatives; increase opportunities for low revenue ACOs in the BASIC track to share in savings by allowing ACOs that do not meet the minimum savings rate (MSR) requirement to share in savings at a lower rate; encourage ACOs to transition more quickly to all-payer quality measure reporting; update the ACO beneficiary assignment methodology; and reduce administrative burden on ACOs. The changes to Shared Savings Program policies in this final rule include modifications designed to further these goals in concert with implementation of certain changes finalized in the CY 2023 PFS final rule, which are applicable for agreement periods beginning on January 1, 2024, and in subsequent years.

On average, updated benchmarks would marginally increase as a result of the modifications to the calculation of the regional component of the blended update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (PY) by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b. of this final rule). This change is expected to increase the regional update factor amount in certain cases where an ACO may operate in a regional service area with rapid change in the average prospective HCC risk score for the FFS assignable beneficiary population. The current methodology for calculating the regional update factor risk adjusts county-level FFS expenditures in an ACO's regional service area by Medicare enrollment type by dividing average county-level FFS expenditures for assignable beneficiaries in the county by the average prospective HCC risk score for both the performance year and BY3. The expenditure growth between BY3 and the performance year calculated using risk-adjusted regional expenditures could therefore be reduced by large increases in average prospective HCC risk scores in the ACO's regional service area that would only be partly offset by the increase in prospective HCC risk score growth for the ACO's assigned beneficiary population due to the cap on ACO assigned beneficiary prospective HCC risk score growth when updating the benchmark between BY3 and the performance year. The adjustment we are adopting in this final rule, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, will effectively strengthen the regional portion of the three-way blended update factor and help to limit losses ACOs may face when operating in regional service areas with high risk score growth and a beneficiary population that becomes more medically complex between BY3 and the performance year, increasing incentives for ACOs to form or continue participation in such areas. By utilizing a market share adjusted cap to account for ACO market share in the ACO's regional service area, the adjustment will still retain a disincentive against coding intensity for ACOs that may have a high market share in their region and consequently have greater influence on regional service area risk score changes. We expect this feature of the methodology will help dissuade such ACOs from attempting to artificially increase their benchmark by selectively serving lower risk beneficiaries and increasing the intensity of diagnoses submitted for those beneficiaries.

Analyses outlined in section III.G.4.b.(2) of this final rule, surrounding Tables 38 and 39, provide the basis for estimating the impact for the cap on regional service area risk score growth. Analysis of average prospective HCC risk score changes at the Hospital Referral Region (HRR) level over an extended 2007 to 2021 historical period consistently indicated that risk score changes would be highly unlikely to exceed the cap in the first two years of an ACO's agreement period but will increase somewhat as the 5-year agreement period progresses. The analysis also notably showed that average prospective HCC risk score variation increased markedly in 2020 and 2021 with the COVID–19 PHE.[566] The 11 percent of ACOs simulated to be impacted by the adjustment in PY 2021 (a mix of ACOs with 2-year and 3-year gaps between their respective BY3 and the simulated PY 2021) is therefore anticipated to overstate variation expected in agreement periods that start on January 1, 2024 or later.

Based on the simulation in the context of the longer-run HRR data, we project that starting in 2024 the adjustment will impact less than 1 percent of ACOs in PY1 of an agreement

[566] Public use data on Medicare Geographic Variation—by Hospital Referral Region, used for this analysis, is available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-geographic-comparisons/medicare-geographic-variation-by-hospital-referral-region.*

period, between 5 to 7 percent of ACOs by PY3, and up to 10 to 15 percent of ACOs by PY5. The adjustment for ACOs that are simulated to be impacted is relatively small, increasing updated benchmarks by about 0.2 percent up to 0.4 percent on average by PY5, but with the potential for up to a net adjustment of about 1.5 percent in extreme scenarios. The estimated cost from additional shared savings payments resulting from these adjustments totals $370 million over 10 years as shown in Table 123.

TABLE 123: Projected Impact of Using Adjustment Factor to Apply Risk Score Cap to Regional Portion of Blended Update Factor Calculation ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	10	20	40	70	50	20	40	40	70	**370**
Estimate Range:											
Low Estimate	0	0	10	20	40	40	20	20	30	40	**220**
High Estimate	10	20	30	60	90	80	40	50	60	100	**540**

A material, albeit uncertain impact, is also estimated for the (a) use of a rolling 3-year historical period instead of contemporary performance to calculate the 40th percentile of the MIPS Quality performance category scores starting in PY 2024 and (b) use of the higher of the ACO's health equity adjusted quality performance score or the 40th percentile MIPS Quality performance category score across all MIPS Quality performance scores if a measure that is used to calculate the MIPS Quality performance category score is excluded or does not have a benchmark. It is likely that MIPS Quality performance will improve at least marginally over time and therefore the historical performance could produce a target that effectively is lower than the contemporary 40th percentile stipulated at baseline. The effective reduction in the threshold when using the historical MIPS scores, combined with the 'higher of' approach when a measure is excluded or lacking a benchmark, are assumed to effectively reduce the quality target by 0 to 5 percentage points (mode 1.5 percentage points), which would produce an estimated $110 million in additional shared savings payments over 10 years, as shown in the Table 124.

TABLE 124: Projected Combined Impact of Quality Provisions to (a) Use Rolling 3-Year Historical Period to Calculate the 40th Percentile of the MIPS Quality Performance Category Scores and (b) Use the 'Higher Of Value' When Measures are Suppressed ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	10	10	10	10	10	10	10	20	20	**110**
Estimate Range:											
Low Estimate	0	0	0	0	0	0	0	0	0	0	**0**
High Estimate	0	30	30	30	40	40	30	40	40	40	**320**

The impact of the policies to mitigate the impact of the negative regional adjustment on the benchmark is also estimated to be material. In the CY 2023 PFS final rule, CMS finalized changes applicable for agreement periods beginning on January 1, 2024, and in subsequent years, that would reduce the cap on negative regional adjustments from 5 percent to 1.5 percent and provide an offset factor to gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases, or both. Removing the regional adjustment entirely, when the ACO's regional adjustment amount (expressed as a single per capita value) is negative, will incrementally increase benchmarks for higher spending ACOs (increasing shared savings payments) but will also improve the incentive for higher spending ACOs to join the Shared Savings Program and drive down unnecessary spending. For a high cost estimate we conservatively assume no new participation is generated in response to this change and estimate the higher benchmarks would generate about $1.8 billion in additional shared savings payments partly offset by about $1.6 billion in reduced spending in response to improved incentives. For a mean estimate we additionally assume 10 percent growth in participation from new high spending ACOs leading to about $490 million net savings over 10 years.[567] For a low cost estimate we instead assume 20 percent growth in

[567] Elimination of overall negative regional adjustments would likely generate participation growth from ACOs that would have faced significant negative adjustments despite the changes from the CY 2023 PFS final rule to reduce the impact of the negative regional adjustment, but also from other prospective high spending ACOs that may have difficulty estimating the relief they will ultimately receive from the offsets applicable to agreement periods beginning on January 1, 2024, and in subsequent years. Eliminating the overall negative regional adjustment entirely will materially improve the business case for participation from ACOs in the former category and may at least optically improve the business case for ACOs in the latter category without actually incurring cost to the program by increasing their benchmarks.

participation from high spending ACOs leading to about $1.2 billion in net savings over 10 years. Table 125 shows these estimates over the 2024–2033 window.

TABLE 125: Projected Impact of Provision to Mitigate the Impact of Negative Regional Adjustment on Benchmarks ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	30	10	-20	-70	-110	-100	-70	-90	-70	**-490**
Estimate Range:											
Low Estimate	-10	-10	-40	-80	-130	-200	-200	-180	-200	-170	**-1,220**
High Estimate	10	60	50	30	0	-20	0	30	20	30	**210**

Use of the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period for agreement periods beginning January 1, 2024, and in subsequent years, is anticipated to remove a potential bias that may otherwise reduce benchmarks particularly for ACOs with beneficiaries exhibiting higher average renormalized risk scores at baseline. An increase in average shared savings payments to ACOs that would have participated regardless of this modification is expected to ultimately be more than offset by additional savings from increased participation from ACOs serving high risk beneficiaries that would have otherwise dropped out or avoided entering the Shared Savings Program under the current approach to calculating prospective HCC risk scores. Net savings are expected to be greater at the end of the 10-year scoring window because residual savings from added participation would grow, whereas benchmarks would not be as impacted in the later part of the scoring window because there is lower likelihood that later agreement periods would have been impacted by changes in the CMS HCC risk adjustment methodology. Table 126 shows these estimates over the 2024–2033 window.

TABLE 126: Projected Impact of Using a Uniform Approach to Calculate Risk Scores in the Shared Savings Program Benchmark Calculations ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	20	60	100	140	-70	-130	-180	-160	-110	**-320**
Estimate Range:											
Low Estimate	10	-10	10	30	50	-120	-200	-270	-280	-260	**-1,040**
High Estimate	20	80	130	190	240	70	10	-50	-40	-20	**630**

An overall net impact is difficult to quantify for the changes in section III.G.3.a. of this final rule, to incorporate use of a new third step in the step-wise beneficiary assignment methodology and the changes to how we identify the assignable beneficiary population. These changes are not currently estimated to have a net impact on program spending in either direction. Impacts on benchmark calculations for individual ACOs would likely be mixed and of relatively limited magnitude. The changes could allow some ACOs to increase efficiency by utilizing more non-physician practitioners in delivering primary care by reducing the risk of their beneficiaries being assigned to other ACOs. On the other hand, these changes could marginally increase shared savings payments to ACOs for efficiencies that currently accrue entirely to the program as spillover effects on beneficiaries unable to be assigned. The overall impact is currently anticipated to be roughly neutral. We will continue to analyze data on the impact of these changes on existing ACOs and will monitor effects of these policies in the future.

The remaining changes to the Shared Savings Program regulations are not estimated to have an impact on program spending at the aggregate level. These changes include modifying the definition of primary care services for purposes of determining beneficiary assignment, recalculating the prior savings adjustment for changes in the amount of savings earned by an ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or changes in the amount of savings or losses for a benchmark year as a result of the issuance of a revised initial determination of financial performance, expanding quality reporting options to include Medicare CQMs, requiring reporting of the MIPS Promoting Interoperability performance category for all ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, QPs, or Partial QPs, unless otherwise excluded, and using beneficiary counts instead of person years in health equity adjustment calculations, as well as changes to further refine AIP policies, revise program eligibility requirements, and make technical changes.

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and new policies adopted in section III.G. of this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: the modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b. of this final rule and the refinements to AIP policies as described in section III.G.5. of this final rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations will be affected by the addition of a new third step of the beneficiary assignment methodology and the revisions to the definition of assignable beneficiary described in section III.G.3. of this final rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided risk models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for ACOs under two-sided risk models); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. When considered together, these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the ability for ACOs to sustain effective participation in regions with changing populations and increasing the overall proportion of Medicare beneficiaries assigned to ACOs, and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule we estimated that the projected impact of the payment methodology that incorporates all finalized changes from that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the changes adopted in this final rule is estimated to be $330 million lower net spending over the 10- year window for all new policies combined, including the cap on an ACO's regional service area risk score growth, the addition of a new third step to the beneficiary assignment methodology, and the revised approach to identify the assignable beneficiary population. Therefore, we believe the relatively minor changes to program spending arising from the policies adopted in this final rule will not change our assessment that the payment methodology adopted in the CY 2023 PFS final rule satisfies the requirement under section 1899(i)(3)(B) of the Act.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

11. Medicare Part B Payment for At-Home Preventive Vaccine Administration Services

In section III.H. of this final rule, we finalized the policy to maintain the additional payment when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances, and to extend this payment to the administration of a pneumococcal, hepatitis B or influenza vaccines.

We estimate the impact of maintaining the additional payment for in-home COVID–19 vaccine administrations and to expand the policy to the administration of all Part B preventive vaccines. For this estimate, we analyzed CY 2021–2022 utilization of HCPCS code M0201 for the providers and suppliers that billed it, along with their utilization of the relevant preventive vaccine administration codes. During this period, the in-home additional payment was billed about 200,000 times by roughly 1,500 different providers and suppliers. For those providers or suppliers who administered COVID–19 vaccine in the home in 2021–2022, HCPCS code M0201 was billed about 2 percent of the time they administered any COVID–19 vaccination. Total Medicare payments for this service in 2021 and 2022 were $4 million and $3 million, respectively.

While we expect that in-home administrations of COVID vaccines will continue into CY 2024, we note that the overall utilization of the COVID–19 vaccine was significantly lower in 2022 than in 2021, and future utilization is unknown. Further, if we apply the prevalence of the utilization of HCPCS code M0201 for in-home administration of the COVID–19 vaccine to the utilization of the other three Part B preventive vaccinations, it will result in higher spending of roughly $1–2 million. Therefore, the overall estimated impact of this final policy is increased spending of less than $5 million in 2024. We note that our analysis assumed that there will be no additional providers or suppliers who will decide to begin providing these vaccines at home for CY2024, given that COVID–19 PHE ended on May 11, 2023.

12. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

a. Effects on Beneficiaries

We proposed to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) Extend the flexibilities allowed during the PHE for the COVID–19 1135 waiver event by 4 years (or until December 31, 2027), (2) update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments, (3) remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition, and (4) remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We anticipate that these changes will have a positive impact on beneficiaries' access to MDPP services by increasing the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers and, more importantly, increasing beneficiary access to the Set

of MDPP services by allowing them continued access to MDPP through a live in-person or virtual classroom (or a combination of both modalities). The changes will also remove barriers specific to attending these classes solely in-person, which may include a lack of MDPP suppliers in certain communities and challenges related to beneficiary logistics concerning course attendance.

These modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date, feedback from Medicare Advantage plans and existing MDPP suppliers, and feedback from beneficiary focus groups. The changes are also in response to comments from interested parties made through public comments in response to prior rulemaking.

During the initial rulemaking for the MDPP expanded model, we sought to ensure that MDPP will be delivered in-person, in a classroom-based setting, and within an established period of service to maintain consistency with the original DPP model test. At the time, priority was placed on establishing a structured expanded model that, when delivered within the confines of the rule, will create the least risk of fraud, waste, and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes.

However, circumstances such as the PHE for COVID–19 led us to make changes to the MDPP expanded model through implementation of an Emergency Policy for MDPP that allows for temporary flexibilities while prioritizing availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by such section 1135 waiver events. For example, in the CY 2021 PFS, we finalized the regulations in the March 31st COVID–19 IFC to amend the MDPP expanded model to revise certain MDPP policies during the COVID–19 PHE as well as any future 1135 waiver events where such 1135 waiver event may cause a disruption to in-person MDPP service delivery. These flexibilities allowed beneficiaries to either continue to have access to MDPP through participation in virtual sessions, pause an in-person MDPP class and resume with the most recent attendance session of record, or restart MDPP from the beginning in accordance with the March 31st COVID–19 IFC (85 FR 19230).

When establishing these flexibilities, we could not predict that the COVID–19 PHE would continue for over 3 years. Although beneficiary participation decreased significantly during the initial year of the COVID–19 PHE, MDPP participation has slowly increased since 2021. As this additional modality of delivery has helped improve supplier access to beneficiaries, removing the PHE flexibilities and suppliers' ability to deliver MDPP virtually after 3 years will not only be disruptive to suppliers, it may in-fact be detrimental to the operations of the MDPP expanded model.

During the COVID–19 PHE, we permitted virtual delivery of the Set of MDPP services by MDPP suppliers who were recognized by the CDC with Diabetes Prevention Recognition Program (DPRP) in-person delivery mode, but did not permit suppliers who were only recognized by the CDC with either online or distance learning delivery modes. Although we finalized in the CY 2021 PFS that suppliers had to be prepared to return to in-person delivery when the PHE ended, the PHE lasted for over 39 months. Therefore, returning to a solely in-person, pre-PHE delivery model may not be as simple for some suppliers.

Post-PHE, many beneficiaries and suppliers have reported the desire to continue utilizing virtual delivery of MDPP for a wide range of reasons. Maintaining suppliers' ability to offer both synchronous virtual (distance learning) and in-person MDPP may increase beneficiary uptake of these services. It is important to note that permitting virtual delivery of MDPP throughout the PHE has not resulted in a spike in MDPP utilization. A reason for a lack of beneficiary participation may be tied to the fact that suppliers still had to maintain the ability to deliver in-person services (rent or own physical space), while some suppliers were unfortunately unable to pivot to virtual delivery during the COVID–19 PHE for a variety of reasons.

Current data depict that the most impactful MDPP results correspond to attending MDPP sessions virtually or through utilizing a hybrid approach (attending classes both virtually and in-person). Interim MDPP evaluation data illustrated that average participant weight loss is 5.1 percent since the expanded model launched on April 1, 2018, surpassing the expanded model's weight loss goal of 5 percent. In addition, the interim evaluation data show that, 53 percent of MDPP participants attained the 5 percent weight-loss goal, and 24.6 percent attained the 9 percent weight-loss goal.[568] Aligning with the Diabetes Prevention Program (DPP) model test[569] and studies on the National DPP,[570] [571] MDPP participants who attended more sessions lost more weight. For example, among beneficiaries who attended at least 9 sessions, 64 percent met the 5 percent weight loss goal and 30 percent met the 9 percent weight loss goal. For MDPP participants impacted by the COVID–19 PHE, evaluation data confirm significantly increased weight loss accompanied with a higher number of sessions attended by participants completing the expanded model in 2021, with these participants attending primarily virtual sessions or a mixture of virtual and in-person sessions.

To date, there have been no preliminary indications that the synchronous virtual delivery of MDPP has limited supplier instruction or beneficiary success, as defined by achievement of the 5 percent weight loss goal. However, it is too early to determine the impact of synchronous virtual delivery of MDPP on other outcomes such as cost-savings or incidence of diabetes. MDPP has been fundamentally limited by low beneficiary participation and corresponding small sample sizes. We believe that an increase in supplier uptake, which may be accomplished through our proposal to maintain more options of MDPP delivery modalities, will result in an increase in beneficiary enrollment. This will be critical to conducting robust programmatic evaluations, including a potential future certification of the synchronous virtual delivery of MDPP.

To assist with our ability to improve monitoring and evaluation of the synchronous virtual delivery of MDPP, we have proposed a new HCPCS G-code specific to distance learning. Additionally, extending the flexibilities allowed during the PHE for COVID–19 by 4 years will improve MDPP eligible organizations' MDPP service delivery opportunities due to the use of multiple modalities.

b. Effects on the Market

While we acknowledge that additional changes will likely be

[568] MDPP 2nd Annual Evaluation Report.

[569] RTI International. *Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring: THIRD ANNUAL REPORT*. March 2017. *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf*.

[570] Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393–403. doi:10.1056/NEJMoa012512.

[571] Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *Lancet Diabetes Endocrinol.* 2015;3(11):866–875. doi:10.1016/S2213–8587(15)00291–0.

necessary to improve beneficiary access to MDPP, we anticipate that the enhancements proposed in this rule are likely to result in an increase of MDPP suppliers and increased beneficiary access to the Set of MDPP services. We anticipate that this will assist in contributing to a reduction of the incidence of diabetes among eligible Medicare beneficiaries, and in particular, those residing in underserved communities. Currently, there are approximately 786 in-person organizations nationally that are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 25 percent of eligible in-person organizations are participating in MDPP, and only one-third of MDPP suppliers have submitted MDPP-related claims. Through updating the payment structure to one that is similar to those of existing CMS Medicare Preventive Services such as the Intensive Behavioral Counseling for Obesity, the MDPP claims submission process may be more intuitive for existing Medicare suppliers. In addition, we anticipate that simplifying the MDPP payment structure will address some of the complexities related to the process for submitting claims, while encouraging more suppliers to submit claims for MDPP due to a reduced set of codes.

Since MDPP was established through the CY 2017 PFS, we have consistently heard from interested parties that we should include virtual delivery of MDPP as part of the expanded model test, which would increase beneficiary access to the Set of MDPP services while providing flexibility of where both a beneficiary may take the course and from where a supplier may deliver the course. Although we did not allow for a fully virtual delivery of MDPP until the COVID–19 PHE, we did allow a limited number of virtual make-up sessions, which could be delivered either synchronously or asynchronously. The rationale for allowing a limited number of virtual make-up sessions was due to the fact that the data used to certify MDPP were based upon in-person delivery, thereby fully virtual delivery was arguably outside the scope of certification.

The COVID–19 PHE led CMS to establish MDPP flexibilities that allowed fully virtual delivery of the Set of MDPP services by suppliers. We established several emergency flexibilities within the IFC–1 that removed the limit on the number of virtual makeup sessions, and in the CY 2021 PFS, we finalized the MDPP flexibilities from the IFC–1 while establishing the MDPP Emergency Policy that allowed for virtual delivery of MDPP, including virtual weight collection. However, the CY 2021 PFS stated that MDPP suppliers must retain the capacity to deliver the Set of MDPP services in-person, precluding organizations with CDC DPRP recognition solely in the distance learning or online modalities from participating in MDPP during the COVID–19 PHE. Interested parties commented that some beneficiaries may have limited access or ability to use the technology required for participation in virtual MDPP sessions.

In the CY 2022 PFS, although outside the scope of rule, interested parties recommended that we continue the virtual option following the end of the COVID–19 PHE to assist in increasing access to MDPP, especially for those with transportation needs as well as for beneficiaries in rural and low-income communities, who may suffer from a lack of in-person suppliers. As a result of these recommendations, in this rule, we proposed to extend the PHE flexibilities, specific to allowing synchronous virtual delivery of MDPP, also known as distance learning.

Currently, there are numerous large geographic gaps of MDPP supplier locations, and synchronous virtual delivery may be part of the solution to increasing the accessibility of MDPP to more beneficiaries. It is unclear how the market will respond to the extension of the PHE flexibilities allowed during the COVID–19 PHE, especially since we are still requiring suppliers to have and maintain an in-person DPRP recognition, but we believe organizations will be ready to engage in the delivery of the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning. We also believe that having more flexibility in how the Set of MDPP services are delivered will make MDPP more accessible to beneficiaries, particularly those who live in rural areas or in communities with gaps in MDPP supplier locations.

c. Payment for MDPP Services

Regulations at § 414.84 specify MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. However, we have consistently heard from suppliers and interested parties that the MDPP performance-based payment structure has been confusing to some suppliers, including those new to Medicare as well as existing suppliers. Approximately 37 percent of MDPP suppliers have submitted FFS claims for MDPP.[572] Confusion with claims submission has been due, in part, to the MDPP payment structure, which pays for performance-based milestones versus paying for traditional fee-for-service. The performance-based payment structure requires 15 HCPCS G-codes if including ongoing maintenance sessions, and 11 G-codes for the 12-month MDPP service period. Therefore, we proposed to shift this payment structure to pay for attendance on a fee-for-service basis while retaining the diabetes risk reduction performance milestones, for example 5 percent and 9 percent weight loss as well as the maintenance of the 5 percent weight loss in months 7–12. This streamlined payment structure will allow suppliers to receive a more consistent set of payments for their delivery of the Set of MDPP services and reduce the number of G-codes for easier billing.

We anticipate that this updated payment structure will reduce the upfront beneficiary retention costs while motivating eligible suppliers to enroll in Medicare to become MDPP suppliers and provide the Set of MDPP services to eligible Medicare beneficiaries. In the current MDPP payment structure, suppliers submit claims after the 1st, 4th, and 9th sessions attended during the core sessions interval, and following attendance of the two (2) sessions during each of the core maintenance intervals. Although the per session payment of $25 is less than the current per session payment of $38, suppliers will receive up to 22 payments for attendance in the payment structure compared to seven attendance-based payments, for participants who began participation in 2022 or later, or 11 attendance-based payments for participants whose first core session was in 2021 or earlier. The total attendance-based payments will increase by $54 to $550 in the payment structure, compared to $496 in the current one.

This payment schedule will not only eliminate gaps in payment by providing smaller but more frequent per-session payments, it will also reduce or eliminate some of the coding challenges related to the number of existing HCPCS codes. We proposed to decrease the one-time performance payments for beneficiary achievement of the 5 percent and 9 percent weight loss goals as well as proposed a new HCPCS G-code for the maintenance of the 5 percent weight

[572] Unpublished data from Acumen LLC, Quarter 4 2022 Quarterly Monitoring Report to CMS.

loss during months 7–12. The total maximum payment of $768 consists of the attendance-based payments and the weight loss performance payments. Although the maximum payment of $768 over a one-year service period is the same as the current maximum payment, we believe this simplified payment structure will lead to fewer claims rejections while encouraging more suppliers to submit MDPP claims for the beneficiaries they serve, as well as motivate more eligible organizations enroll in Medicare to participate in MDPP.

d. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

There are two changes to the Medicare Diabetes Prevention Program (MDPP) which are relevant to this impact analysis. Both changes will be implemented in 2024: Simplifying the MDPP payment schedule; and allowing specified Public Health Emergency (PHE) flexibilities to continue for 4 years after the PHE ends—namely, allowing for synchronous virtual delivery of the Set of MDPP services.

Table 127 shows the estimated impact (in millions) of these two changes on Medicare spending:

TABLE 127: Estimated Impact (in millions) of the Two Changes on Medicare Spending

Year	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact on Medicare Spending	$0.3	$0.3	$0.1	$0.0	−$0.2	−$0.8	−$0.7	−$0.6	−$0.5	−$0.3	−$2.4

(b) Assumptions/Notes

- Simplifying the payment schedule will lead to fewer claim denials and more participation from MDPP suppliers. For example, only 55–62 percent of FFS participants listed in the supplier crosswalks have an associated MDPP claim over the past 2 years, meaning that organizations have submitted data to the CDC as part of their Diabetes Prevention Recognition Program (DPRP) requirements, and also have FFS claims submitted for the same participants for the same sessions recorded in the DPRP data. The payment schedule will reduce the number of HCPCS codes to from 15 to 6 and eliminate some of the coding issues. It will also eliminate the gaps in payment by providing smaller but more frequent per-session payments.
- The average payment per MDPP participant will increase by $150. The new payment schedule will likely lead to more successful claim payment submissions and will motivate MDPP providers to retain participating beneficiaries for longer periods of time.
- In 2022, 551 FFS claims were paid for the initial MDPP session, compared with 514 in 2021. According to counts of new FFS participants, there have been about 700 new entrants per year in recent years. With the implementation of a simpler payment schedule and the extension of PHE flexibilities, we assume that new participation will be more in line with claim payments for HCPCS code G9873 and will increase to 1,000 in 2024 and 1,250 during the following years until the extended flexibilities end. We estimated that there will be 500 new (in-person only) participants each year starting in 2029.
- Since the start of the PHE, synchronous virtual delivery of MDPP services has been more prevalent than in-person delivery. However, given the coding/reporting issues during the PHE, it is difficult to determine how many beneficiaries are still receiving MDPP services in-person. Without the changes, we assume that new participation will be capped at 400 beneficiaries per year.
- For preventing diabetes progression, synchronous virtual delivery of the Set of MDPP services has the same level of effectiveness as in-person delivery. Following 3 years of delivering MDPP almost solely virtually, suppliers and beneficiaries have become adept at utilizing virtual delivery, as many providers in numerous healthcare settings have shifted to utilizing technology. Furthermore, preliminary MDPP data collected during the PHE indicates that beneficiaries have achieved similar weight loss and attendance goals as participants in both the in-person DPP test and MDPP participants who enrolled in MDPP prior to the pandemic. This assumption is revisited in the Sensitivity Analysis section.

(c) Sensitivity Analysis

On March 14, 2016, the Office of the Actuary (OACT) published a certification memorandum setting out the conditions for expansion of the Medicare Diabetes Prevention Program (MDPP), which can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*. Assumptions about the 10-year cost impacts of virtual delivery of MDPP services takes into account the assumptions of the original certification, and adjusts for diabetes costs in 2023 dollars, and trends those costs over the next 10 years.

Since both the effectiveness and the future participation level of synchronous virtual delivery of MDPP services are largely unknown, Table 128 shows 10-year cost impacts (in millions) of varying levels of effectiveness of the virtual delivery of the Set of MDPP services relative to the in-person delivery of the Set of MDPP services, paired with varying levels of virtual MDPP participation.

TABLE 128: 10-year Cost Impacts (in millions) of Virtual Delivery of MDPP Services

Virtual Beneficiaries Per Year/Effectiveness	25%	50%	75%
1,000	$0.7	−$0.8	−$2.3
2,000	$1.3	−$1.6	−$4.6
3,000	$2.0	−$2.4	−$6.9

As indicated in Table 128, virtual delivery of MDPP services is estimated to produce savings when it is at least 50 percent as effective as in-person delivery.

13. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q)(2) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for applicable imaging services furnished in an applicable setting.

As discussed in detail in section III.J. of this final rule, since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As codified at § 414.94, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification and prior authorization, leading to prior authorization, by establishing the priority clinical areas (PCAs). We began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. However, as explained previously in this final rule, at this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we are finalizing our proposal to pause implementation of the AUC program for reevaluation and to rescind and reserve for future use the current AUC program regulations at § 414.94.

In the CY 2019 PFS final rule (83 FR 59452), we performed an RIA for this program and updated that RIA in the CY 2022 PFS final rule (86 FR 64996). The estimated impacts in the CY 2022 PFS final rule were as follows:

- Cost to ordering clinicians of required AUC consultation: $51,039,109 annually.
- Cost to Medicare beneficiaries for additional office visit time: $54,789,518 annually.
- Cost to ordering clinicians of transmitting consultation information: $94,495,192 annually.
- Cost to furnishing clinicians to update processes to report AUC information: $1,851,356,888 (one time).
- Potential savings to Medicare program from decrease in imaging utilization: $700,000,000 annually.

The prior savings estimate is no longer an accurate reflection of savings that could be achieved and CMS will not realize the estimated $700,000,000 annual savings because, as described in section III.J. of this final rule, the AUC program cannot be implemented as written in statute; therefore, expected savings are negligible.

Table 129 includes the previous AUC program-related activities and their corresponding impact estimates from the CY 2022 PFS rule.

TABLE 129: AUC Program Related Activities with Impact Estimates From CY2022 PFS

AUC Program Related Activity	CY 2022 **PFS Rule Impact Estimate**
Impact of required AUC consultations by ordering professional	$51,039,109
Impact to Medicare beneficiaries	$54,789,518
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192
AUC automated solution	$1,851,356,888
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000

Note: These previously estimated costs and savings are no longer accurate and will not be realized because we cannot implement the program as written in statute as described in section III.J. of this final rule; because the statute cannot be implemented, the savings are negligible.

14. Medicare and Medicaid Provider and Supplier Enrollment Changes

In this section, we outline the impact of our Medicare provider enrollment revocation provisions and our Medicaid termination database proposal. For all provider enrollment proposals not referenced in this section, we have determined that they will not have an economic impact.

a. Medicare Revocation Reasons

As outlined in section III.K. of this final rule, we proposed several new or expanded revocation reasons in § 424.535(a).

First, we proposed to expand § 424.535(a)(1) to include instances where the provider or supplier is non-compliant with the enrollment requirements in Title 42. Paragraph (a)(1) would no longer be restricted to non-compliance with the provisions of 42 CFR part 424, subpart P.

Second, new § 424.535(a)(15) will give CMS the authority to revoke enrollment if the provider or supplier, an owning or managing employee or organization thereof, or an officer or director thereof has had a civil judgment under the False Claims Act (31 U.S.C. 3729–3733) imposed against them within the previous 10 years.

Third, we proposed in new § 424.535(a)(23) that CMS may revoke an IDTF's, DMEPOS supplier's, OTP's, or HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), 424.68(c) or (e), or 424.205(b) or (d).

Fourth, § 424.535(a)(16) would permit CMS to revoke enrollment if a provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has been convicted of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best

interests of the Medicare program and its beneficiaries.

For reasons outlined in section III.K. of this final rule, we are finalizing the first three revocation proposals, but not proposed § 424.535(a)(16).

Based on CMS statistics concerning the average annual amount of Medicare payments a provider or supplier receives, we project a figure of $50,000. We note that we have recently used this figure when estimating the potential savings associated with several new revocation reasons.[573] For purposes of consistency and accuracy, we will use this $50,000 amount in this final rule.

Table 130 outlines the estimated annual number of revocations that would ensue with these three revocation proposals:

TABLE 130: Annual Number of Revocations

Revocation Reason	Number of Revocations
§ 424.535(a)(1)	5
§ 424.535(a)(15)	5
§ 424.535(a)(23)	5
Total	15

These revocations will represent a savings to the Federal Government because Trust Fund dollars will no longer be paid to the revoked providers and suppliers. Accordingly, we projected an annual savings to the Federal Government of $750,000 ($50,000 × 15 revocations).

b. Medicaid Termination Database

As outlined in section III.K. of this final rule, we proposed certain provisions in 42 CFR part 455 concerning the length of time a provider remains in the Medicaid termination database and how this interacts with the termination periods that States impose upon terminated providers. We do not believe these proposals involve any additional impact or burden on providers or States. In fact, it could result in a reduction of burden because a provider's potential length of time in the termination database would be capped at 10 years, although we have no data available with which to assist us in calculating the possible burden reduction. As a result, since we are uncertain of how much of the burden will be reduced, we solicited public comments from the public to aid in understanding how to measure said burden reduction.

We received no comments regarding our revocation savings estimate or any burden reduction associated with our Medicaid termination database proposals.

15. Expand Diabetes Screening and Diabetes Definitions

As outlined in section III.L. in this final rule, we are finalizing our proposal to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT).

As we described in the PFS proposed rule, we anticipate that expanding coverage of diabetes screening to include the HbA1c test and expanding and simplifying the frequency limitations for diabetes screening to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part, by potential long term benefits and savings resulting from increased prevention and early detection (allowing for less invasive and more effective treatment). As outlined earlier, Medicare currently covers the Fasting Plasma Glucose (FPG) test and the Glucose Tolerance Test (GTT) for diabetes screening. The HbA1c test does not require fasting and is more convenient than the currently covered FPG and GTT. We also proposed to expand and simplify the frequency limitations for diabetes screening by aligning to the statutory limitation of ''not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.''

As described in the PFS proposed rule, we estimate our final rule to expand diabetes screening to result in approximately $68.5 million in additional annual expenditures for the Medicare Program. Our estimate is based on the following assumptions. Based on calendar year 2022 actual experience, approximately 27.3 percent of beneficiaries had a blood panel test that did not include the HbA1c test. Medicare currently pays approximately $9.50 per HbA1c test for diabetes management. The Medicare statutory and regulatory eligibility factors for an individual at risk for diabetes (section 1861(yy)(2) of the Act, 42 CFR 410.18(e)) cover much of the current Medicare beneficiary population. We assume that approximately 7.6 million potential additional HbA1c tests for diabetes screening to be billed under our proposal in calendar year 2024 and that the HbA1c test would be billed with a blood panel 95 percent of the time. Our estimate does not reflect secondary effects of the policies, such as increased utilization of preventive screening services, additional follow-up services, and potential offsetting savings (including prevention and more effective treatment through early detection) that may result from these coverage expansions. Secondary effects are difficult to predict, may materialize many years after the intervention and may, in part, offset one another.

As described in the PFS proposed rule, we do not anticipate that our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare program. As outlined earlier, we proposed to remove the regulatorily codified clinical test requirements from the definition of ''diabetes'' for diabetes screening, MNT and DSMT and proposed a shortened version of the existing definition that will simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We believe that our proposal will empower health care

[573] For example, see the final rule published in the **Federal Register** on November 18, 2022 (87 FR 69404), titled Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules''.

professionals to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. We do not anticipate our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare Program because the regulatory simplification will not otherwise change requirements or conditions of coverage and payment.

16. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.M. of this final rule, we finalized several updates to the CMS EPCS Program. We removed the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program and to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). Under this provision, prescriptions that are prescribed and dispensed within the same legal entity are included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5). This provision provides flexibility to prescribers and dispensing pharmacies that are the same entity to choose either of the electronic standards available at § 423.160(a)(3)(iii) to conduct e-prescribing appropriate for their internal systems without us having to exclude these prescriptions completely from the CMS EPCS Program. This provision will affect prescriptions where the prescriber and the dispensing pharmacy are part of the same legal entity. Due to the limitations in identifying these prescriptions in the Prescription Drug Event (PDE) data, the ability to quantify the impact of this proposal is unknown. Please see section III.M. of this final rule for additional discussion of this provision.

We specified how we count prescriptions for the compliance calculation by using the unique identifier given to a prescription by the pharmacy in the measurement year and included in the Part D claims data. We will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year. If each refill included on the original prescription were counted as a separate prescription, we believe there will be an incremental impact on small prescribers. Preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers will no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers will be noncompliant.

We finalized updates to the CMS EPCS Program recognized emergency exception and waiver exception previously found at § 423.160(a)(5)(iii) and (iv), and now codified at § 423.160(a)(5)(ii) and § 423.160(a)(5)(iii) respectively (as finalized in this final rule). We finalized the proposal to have discretion to determine which emergencies trigger the recognized emergency exception starting in the 2024 measurement year and specified that prescribers to whom the exception applies will be excepted from the CMS EPCS Program requirements for the entire measurement year. We modified how we have previously defined ''extraordinary circumstance'' for purposes of the waiver exception. We finalized that an ''extraordinary circumstance'' means a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug and does not exclude ''cases of an emergency or disaster.'' In cases of extraordinary circumstances, we finalized the timeframe that would be covered by a waiver authorized under the CMS EPCS Program to be the entire measurement year. We finalized that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers will apply to prescriptions written by a prescriber for the entire measurement year, and the waiver will expire on December 31 of the applicable measurement year.

Although we are modifying the situations in which a prescriber can apply for an extraordinary circumstances waiver and limiting the recognized emergencies exception that applies to the CMS EPCS Program, we do not anticipate these proposals to affect many clinicians compared to the current policies. First, we believe that the provision for CMS to identify which emergencies trigger the recognized emergency exception will still capture the vast majority of emergencies or disasters that affect a prescriber's ability to achieve EPCS compliance and will remove any need for additional prescribers to apply for a waiver. Second, some prescribers who experience an emergency may still meet the 70 percent compliance threshold by the end of the emergency period and will not need to apply for a waiver exception. Finally, we are unable to quantify the additional number of potential disasters or emergencies prescribers might experience due to variability in the number of disasters and emergencies in a given measurement year. Therefore, we are not increasing our assumption that 100 waiver requests will be submitted to the CMS EPCS program, as we outlined in the CY 2022 PFS final rule (86 FR 65562).

We finalized our policy to continue sending non-compliance notices to prescribers identified as non-compliant with the CMS EPCS Program for any individual measurement year, and we do not believe that causes additional costs or will require additional time. Please see section III.M. of this final rule for additional discussion on this provision. We do not anticipate the provisions to have any incremental impact on the cost or time associated with prescriber compliance with the electronic prescribing for controlled substances requirement or the cost to interested parties. We did not receive any public comments on our impact assumptions.

17. Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

As outlined in section III.N. of this final rule, section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions legislative provisions. We have estimated cost of these provisions to be $50 million in 2023, $100 million in 2024, and $40 million in 2025 and the Congressional Budget Office (CBO)'s estimated cost of these provisions was $55 million in 2023, $91 million in 2024, and $29 million in 2025 (*https://www.cbo.gov/system/files/2023-01/PL117-328_1-12-23.pdf*, p. 17).

We did not receive any public comments on the impacts of the ambulance extender provisions. In this final rule, we are finalizing our

proposals only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as outlined in section III.N. of this final rule, we proposed the following changes to the Medicare Ground Ambulance Data Collection Instrument: Adding the ability to address partial year responses from ground ambulance organizations, introducing a minor edit to improve the reporting consistency of hospital-based ambulance organizations, and four technical corrections to typos. The changes and clarifications aimed to reduce burden on respondents, improve data quality, or both.

While we believe that these changes and clarifications will be well received by the ground ambulance interested parties, we do not believe that these changes will have any substantive impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. We noted that the overall length of the Medicare Ground Ambulance Data Collection Instrument will be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we proposed to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

We did not receive any public comments on the impacts of our proposed changes to the Medicare Ground Ambulance Data Collection Instrument. In this final rule, we are finalizing our proposed changes to the Medicare Ground Ambulance Data Collection Instrument.

18. Hospice CoP Changes

a. Permitting MFT and MCH To Serve as Members of the Interdisciplinary Group (IDG)

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we proposed conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. These changes will require hospices to include one SW, MFT or MHC to serve as a member of the IDG. Hospices will have the flexibility to determine which discipline(s) are appropriate to serve on the IDG.

b. Modification of the Hospice Personnel Requirements With the Addition of MFT and MHC

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we proposed conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. With the addition of MFT and MHC into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114. However, in section III.C. of this rule, we proposed to add both MHC and MFT to the provider requirements under 42 CFR subpart B Medical and Other Health Services at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we added both MFT and MHC to the requirements at § 418.114(b)(9) and (10) and referencing the new requirement at §§ 410.53 and 410.54 respectively. We do not expect any increase in burden for this modification. In addition, we do not expect the changes for this provision to cause any appreciable amount of expense or anticipated saving and we do not believe this standard will impose any additional regulatory burden.

19. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

We published this RFI in the proposed rule to seek comments from interested parties. There is no impact for this RFI.

20. Basic Health Program Provisions

In this final rule, we updated the requirements for a BHP Blueprint revision. We also are finalizing our proposal to allow a State with a BHP to suspend its BHP, if a State elects and specified conditions are met, and are providing requirements related to a BHP suspension. We also finalized our proposal to update the annual report content and timing, if a BHP is suspended. We finalized our proposal for accessible notices. Finally, we finalized our proposed changes related to an individual's appeals rights. We do not anticipate that these provisions will impose any additional regulatory burden.

21. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

As described in section III.S., we are finalizing our proposal to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We proposed that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. Our final rule builds upon our separate proposal described earlier to establish a stand-alone G code (G0136) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit. See sections III.E. and III.S. of this final rule for additional information on coding, pricing, and additional conditions of payment for the new SDOH Risk Assessment service. As described in the proposed rule, we anticipate our final policy to add a SDOH Risk Assessment as an optional, additional element with additional payment within the AWV to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part or in whole, by potential long term benefits and savings resulting from a more effective AWV and increased prevention and early detection (allowing for less invasive and more effective treatment). We do not anticipate that the addition of an optional SDOH Risk Assessment to the AWV will result in a significant impact to the Medicare Program.

22. Updates to the Quality Payment Program

In this section, we estimated the overall and incremental impacts of the Quality Payment Program policies in this rule. We estimated participation, final scores, and payment adjustment for clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also presented the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall MIPS Modeling Approach and Data Assessment

(1) MIPS Modeling Approach

For this final rule, we used a similar modeling approach as the CY 2024 PFS proposed rule (88 FR 52717 through 52718). We created two MIPS RIA models: a baseline and final policy model. Our baseline model includes previously finalized policies that will be in effect for the CY 2024 performance period/2026 MIPS payment year in the absence of any of the newly finalized policies in this final rule. Examples of previously finalized policies included in the baseline model are an updated methodology for calculating the

complex patient bonus, and an increase in the data completeness threshold for quality measures. The final policies model builds off the baseline model and incorporates the MIPS policies that we are finalizing for the CY 2024 performance period/2026 MIPS payment year included in this final rule. The aim of the baseline and policy models is to estimate the incremental impacts of the specific policies in this final rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This modeling approach enables our model to align as much as possible with actual MIPS scoring and minimizes differences between our projections and policy implementation. There are still some limitations to our model due to data limitations and assumptions. These limitations are discussed later in this RIA.

(2) Data Used To Estimate Future MIPS Performance

In the CY 2024 PFS proposed rule (88 FR 52718) we indicated that once the CY 2022 performance period submissions data became available, we would assess if it were an appropriate source of data to use to estimate participation, final scores, and payment adjustments in this RIA.

After reviewing the CY 2022 performance period data we determined that it was the most appropriate and accurate source to use for our estimation of clinician performance for several reasons. First, the data is the most recently available data and is more likely to reflect current physician performance and behaviors in the program. Secondly, during the CY 2022 performance period we did not apply an automatic EUC policy, and this data is the most likely to reflect post-PHE participation in the program. Finally, in the CY 2024 PFS proposed rule (88 FR 52719) we indicated our use of a ''2019 data supplement to our 2021 data to estimate participation more accurately. We indicated that this approach had several limitations. Specifically, while using the ''2019 data supplement'' allowed us to estimate participation we relied on the 2021 data to estimate performance. In this final rule, by using the data from the 2022 MIPS performance period we avoid the need to use this supplement, present the most current data, and align our participation, final scoring, and payment adjustment analysis around the same common data set. For these reasons we used 2022 MIPS performance period data as the basis of our RIA baseline and final policies models.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2025, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs for the applicable QP Performance Period for a year and the corresponding payment year. In payment years 2019 through 2024 these QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the calendar year immediately preceding the payment year. In payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. Thus, eligible clinicians who are QPs for the year will receive differentially higher PFS payment rates than those who are not QPs. We incorporated this change in our baseline and final policies model.

In addition, the thresholds to achieve QP status beginning in the 2024 QP Performance Period will increase to 75 percent for the payment amount method, and 50 percent for the patient count method. Overall, we estimated that for the 2024 QP Performance Period between 316,767 and 407,272 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section the CY 2023 proposed rule (88 FR 52617), we proposed to make QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. In section IV.A.4.m.(2) of this final rule we stated that we were not finalizing this policy as proposed. Therefore, we do not implement this change in either the baseline or final policies models.

We projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2024 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2024 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2024 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- Primary Care First (PCF) Model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

• Making Care Primary (MCP) tracks 2 and 3

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 42 CFR 414.1425(a) for information on the APM Participant Lists and QP determinations) for the 2022 QP performance period third snapshot QP determination date to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2024 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2024 Performance Period/2026 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Final Policies Models

For this final rule, we applied the same assumptions as in the CY 2024 PFS proposed rule (88 FR 52719) to estimate our initial population of clinicians based on CY 2022 performance period/2024 MIPS payment year data.

Our analysis found that there were 1,820,899 clinicians who had PFS claims in this initial population.

In the CY 2024 PFS proposed rule (88 FR 52719), we explained our use of the CY 2021 final reconciled eligibility determination file. This file reconciles eligibility from two determination periods and aligns with the CY 2022 performance period submissions data on which we based this model. In this final rule, we used the final reconciled 2022 eligibility determination file which aligns with CY 2022 performance period submissions data.

This initial population of clinicians was used to determine eligibility using the processes described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims we applied the same eligibility assumptions and determination process described in the CY 2024 PFS proposed rule (88 FR 52719) except that we did not use the ''2019 data supplement'' and instead we based eligility determinations on the CY 2022 performance period data.

In the CY 2024 PFS proposed rule (88 FR 52617) we proposed calculate QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. As discussed in section IV.A.4.m.(2) of this final rule, we are not finalizing this policy as proposed. Therefore, we are not finalizing any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and final policies model.

For our RIA model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all three criteria and is subject to a payment adjustment. We base this estimate on the CY 2022 performance period data described above which includes the three low volume criteria. Within this category we divide clinicians into two groups—clinicians who report data and clinicians who do not report data.

Our next two eligibility assumptions concern clinicians and groups who may participate in MIPS but are not required to. First, we estimate group eligibility. These are the clinicians who, in our data, have a group submission and their group exceeds the low-volume threshold in all three criteria. Next, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in one criterion but not all three may elect to opt-in. Based on the 2022 data described above we determine which individuals opted-in to MIPS and for the purposes of our model estimate that these clinicians will continue to opt-in to MIPS.

After applying the criteria mentioned above, we next estimate the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These are clinicians who are not MIPS eligible individually but who could either opt-in because they exceed the low volume threshold in at least one criterion but not all three or who could report as part of a group which exceeds all three low volume criteria.

Finally, we estimate the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. First, we estimate the number of MIPS eligible clinicians who are below all three low-volume criteria (both as an individual and as a group) again using the CY 2022 performance period data as described above.

Next, we estimate the number of QPs who are not MIPS eligible. In section VI.E.22.b. of this final rule, we estimated a range of QPs. For the purposes of our RIA population, we estimate a specific number of QPs. This is because it is necessary to establish a specific population of clinicians to use to simulate the impacts of our final policies on participation, final scores, and payment adjustments. Finally, we estimate the number of clinicians who are excluded for other reasons including that they are a non-eligible clinician type, or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimate 686,650 MIPS eligible clinicians with $4.90 billion in allowed charges. However, this number could be as high as 1,270,806 MIPS eligible clinicians and $6.25 billion allowed charges if *all potentially* MIPS eligible [574] clinicians either opt-in or report as a group. This is an extremely unlikely scenario, but it quantifies the range of possible MIPS eligible clinicians in our initial population.

(b) MIPS Eligibility Estimates

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in: therefore, we will not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we use the estimated population of 686,650 MIPS eligible clinicians described in previously in this section of the final rule. Table 131 summarizes our eligibility estimates for the final policies model after applying our assumptions discussed previously.

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[574] We define potentially MIPS eligible clinicians as those clinicians who are not required to participate in MIPS but *may* either opt-in or join a group that exceeds the low-volume threshold in all three criteria.

TABLE 131: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the CY 2023 PFS Final Rule Assumptions**

		CY 2024 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians ***	**Number of Clinicians**	**PFS allowed charges ($ in mil)****
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	104,757	$26,305
	Did not Report to MIPS	41,899	$10,634
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	533,440	$11,776
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	6,554	$318
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**686,650**	**$49,034**
Not MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	178,216	$4,958
	Group Eligible; Did not Report	405,940	$8,539
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	129,806	$714
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	60,471	$450
Qualified Participant (QP)***	Not applicable	359,816	$15,817
Total Number of Clinicians Not MIPS Eligible		1,134,249	$30,479
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,**820,899	$79,513

* Participation excludes facility-based clinicians who do not have scores in the 2021 MIPS submission data.
** Allowed charges estimated in 2021 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VI.E.22.b. of this final rule because, for purposes of establishing the population used in our modeling, we estimate an absolute number of QPs rather than a range.

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d. Modeling Approach and Methods for MIPs Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this final rule, we present several proposals which impact the measures and activities, the performance category scores, final score calculation, and the MIPS payment adjustment of MIPS eligible clinicians. We outline these changes in more detail in section VII.E.22.d. of this final rule as we

describe our methodology to estimate MIPS payments for the CY 2024 performance period/2026 MIPS payment year. We then present the impact of the finalized policies in the CY 2024 performance period/2026 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2024 performance period/2026 MIPS payment year. By comparing the baseline model to the policies model, we are able to estimate the incremental impact of the policies for the CY 2024 performance period/2026 MIPS payment year.

MIPS eligible clinician's final scores are calculated based on the clinician's performance on measures and activities under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway (APP), or through an MVP. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. For each of the performance categories we construct a simulation which applies the final policies for those performance periods as applicable to the CY 2022 MIPS performance period/2024 MIPS payment year data on which we base our model.

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MIPS Value Pathways beginning in the CY 2023 performance period/2025 MIPS payment year. We incorporate MVP participation and scoring rules in this RIA where applicable as described in the following section.

(2) Methodology To Assess Impact for MIPS Value Pathways

In this RIA, we take a similar approach to modeling MVP participation and scoring as described in the CY 2022 PFS final rule (87 FR 70204), incorporating changes to our policies model as described in this section.

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. As we do not yet have information on who will register, we assume for purposes of this model, that MVP Participants are MIPS eligible individual clinicians or groups that currently submit at least four quality measures that are in an MVP. For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the existing scoring hierarchy which was finalized in the CY 2023 PFS final rule (86 FR 65537). For the baseline model, we used the quality measures finalized for MVPs in the CY 2023 PFS final rule Appendix 3: MVP Inventory.

In section IV.A.4.a. and Appendix 3: MVP Inventory of this final rule, we finalized modifications to the 12 existing MVPs finalized in the CY 2022 PFS final rule (86 FR 65998 through 66031) and CY 2023 PFS final rule (87 FR 70037) and the consolidation of the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care.

In Appendix 3: MVP Inventory of this final rule, we finalized the inclusion of 5 new MVPs:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disease Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorder;
- Quality Care for Ear, Nose, and Throat (ENT); and
- Rehabilitative Support for Musculoskeletal Care.

For the policies model, we incorporated the quality measure revisions for the existing MVPs and use the quality measures to model scores for the new MVPs in Appendix 3: MVP Inventory of this final rule.

Our MVP Participant assumptions have limitations: we are not incorporating subgroups due to a lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to § 414.1365(d) and (e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2021 performance period (upon which our model is based). Therefore, we scored any improvement activities the MVP Participants submitted in 2021 as if those improvement activities are in the MVP inventory.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we generally used the CY 2022 performance period's submissions data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2024 performance period/2026 MIPS payment year for the baseline and policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, and our final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and policies RIA models for the CY 2024 performance period/2026 MIPS payment year.

To create the baseline policies RIA model, which does not reflect the policies that we are finalizing in this rule, we made the following modifications to the CY 2023 PFS final rule final policies model to reflect the previously finalized quality performance category policies for the CY 2024 performance period/2026 MIPS payment year:

- As outlined in the CY 2023 PFS final rule (87 FR 70049), we increased the data completeness criteria threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

For the policies model, we did not implement any changes to the quality performance category relative to the baseline model because we use 2021 data and cannot simulate the addition of new measures.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and the proposed policies RIA models.

For this final rule, the baseline policies RIA model included the same method used for the final policies RIA model in the CY 2023 PFS final rule (87 FR 70205). The policies finalized in the CY 2023 PFS final rule are now part of the CY 2024 proposed rule baseline. The final policies RIA model incorporated and implemented the following changes:

- In section IV.A.4.f.(2)(a) of this final rule, we are finalizing the addition of 5 new episode-based cost measures and the removal of the Simple Pneumonia with Hospitalization measure, from the cost performance category beginning with CY 2024 performance period/2026 MIPS payment year.
- In section IV.A.4.g.(1)(d)(i) of this final rule, we are finalizing the proposed cost improvement scoring methodology in CY 2024 PFS proposed rule (88 FR 52595 through 52596).

For the RIA models we:

- Calculated the current year (PY 2024) cost performance category score,
- Calculated the cost improvement score over the previous year's cost performance category score.

Calculated the final individual MIPS-eligible clinicians and groups' cost performance category score by adding the cost improvement score to the current year (PY 2024) cost performance category score.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

A limitation of using data from the CY 2021 performance period is that we are not able to estimate facility-based scores because there are no Hospital Value-Based Purchasing total performance scores calculated for the performance period due the COVID–19 PHE. However, for clinicians who did not participate in MIPS during the CY 2021 performance period, we did use the 2019 data supplement to identify final scores based on the CY 2019 performance period submission and these scores include facility-based scores.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the baseline Promoting Interoperability performance category score by using the same methodology that we used in the CY 2023 PFS final rule (87 FR 70206) final policies. We incorporated the final policies model from that rule into our baseline model. In section IV.A.4.f.(4)(f) of this final rule, we proposed to only continue reweighting Clinical Social Workers in the promoting interoperability category. On this basis, we removed reweighting for the following clinicians: Audiologist (Billing Independently), Certified Clinical Nurse Specialist, Certified Registered Nurse Anesthetist (CRNA), Clinical Psychologist, Nurse Practitioner, Occupational Therapist in Private Practice, Physical Therapist in Private Practice, Physician Assistant, Registered Dietician/Nutrition Professional, and Speech Language Pathologists. This is incorporated into our policies model. We used the following scoring weights for the Promoting Interoperability objectives and measures:

- ePrescribing objective is worth a total of 20 maximum points,
- Health Information Exchange (HIE) objective is worth a total of 30 total maximum points,
- Provider to Patient Exchange measure is worth a total of 25 maximum points, and
- Public Health and Clinical Data Exchange objective is worth a total of 25 maximum points.

We did not incorporate changes to the performance period or measure level changes because we are not able to model this using data for the CY 2021 performance period.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2023 PFS final rule (87 FR 70206).

(f) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2022 PFS final rule (86 FR 65519 through 65524).

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a clinician received a reweighting of their final score under our extreme and uncontrollable in the CY 2022 performance period (which was the performance period of the data source used in our model) we continue to apply that reweighting in the CY 2023 performance period by assigning them a neutral score equal to the performance threshold. Although it is unlikely (but possible) that the exact same clinicians will apply for and receive EUC reweighting in both the CY 2022 MIPS performance period/CY 2024 MIPS payment year (which our data is based on) and the CY 2024 MIPS performance period/CY 2026 payment year (which we are simulating) we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same clinicians may not receive EUC reweighting 2 years in a row, we believe that this assumption allows us to quantify the impact of the EUC on a population level. In other words, even if the same clinicians to not apply for and receive EUC reweighting 2 years in a row, the absolute number of EUC reweighting and the characteristic of practices who receive an EUC reweighting is likely to remain similar. Secondly, if we were to not assign reweighting to those clinicians many of them would receive a very low final score because they did not submit data during the year in which they received an EUC reweighting. We do not believe that it is realistic to assume that, in the absence of an EUC reweighting, those clinicians would continue to not submit data. For these reasons, clinicians who received an EUC reweighting in the CY 2022 MIPS performance period/CY 2024 MIPS payment year also are assigned an EUC reweighting in our CY 2024 MIPS performance period/CY 2026 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this

corresponds with a neutral (0 percent) payment adjustment.

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold of 75 points finalized in the CY 2023 PFS final rule (87 FR 70097). In the CY 2024 proposed rule (88 FR 52598 through 52600), we proposed a performance threshold of 82 points for the CY 2024 performance period/2026 MIPS payment year; however, as described in section IV. of this final rule, we are not finalizing that policy as proposed. Therefore, for both the baseline and final policies models we used a performance threshold of 75 to calculate the exchange function used for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and final policies model. This is because the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments and those adjustments differ slightly as final scores are not identical between both models.

For both the baseline and policies models, we used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in the proceeding sections we created a baseline and final policies simulation. Using this simulation, we estimate the impact of the policies finalized in this rule on clinician eligibility, final scores, and payment adjustments

(a) Impact to Clinician Eligibility

In section VI.E.22.c.(2)(a) of this final rule, we noted that we are not proposing any modification to clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact to Clinician's Final Scores

Table 132 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive or neutral or negative adjustment.

TABLE 132: CY 2024 Final Score Estimates by Practice Size

Practice Size*	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate***	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline				
1) Solo	18,867	75.00	53.72%	46.28%
2) Small (2-15)	71,908	82.36	76.35%	23.65%
3) Medium (15-99)	150,382	82.33	76.11%	23.89%
4) Large (99+)	445,493	84.55	80.55%	19.45%
Overall	686,650	83.46	78.40%	21.60%
Final Rule Policies				
1) Solo	18,867	75.00	53.72%	46.3%
2) Small (2-15)	71,908	82.36	76.36%	23.6%
3) Medium (15-99)	150,382	82.33	76.09%	23.9%
4) Large (99+)	445,493	84.52	80.51%	19.5%
Overall	686,650	83.40	78.37%	21.6%

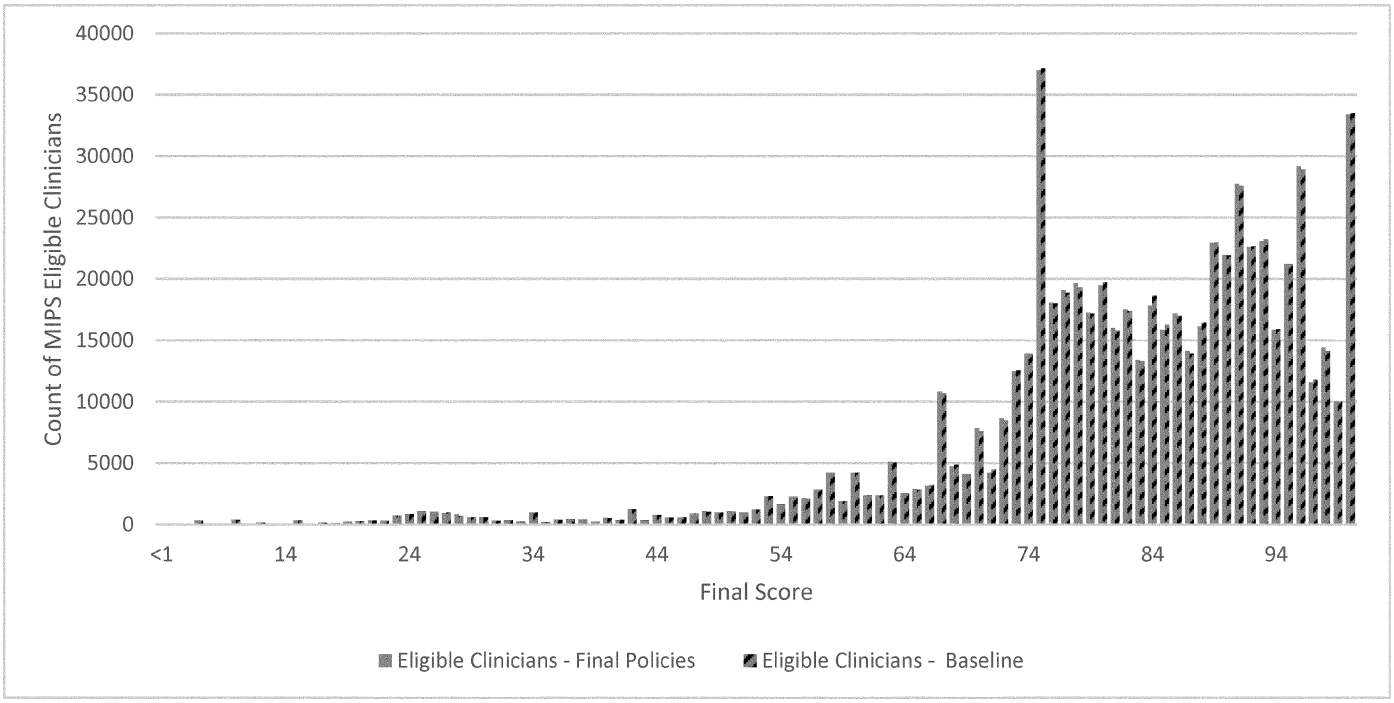
*Practice size is the total number of TIN/NPIs in a TIN.
**2022 data used to estimate 2024 performance period payment adjustments. Payments estimated using 2022 dollars trended to 2024. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
*** The median final score includes clinicians who receive reweighting under the Extreme and Uncontrollable Circumstances (EUC) Policy. These clinicians are assigned a score of 75 (neutral payment adjustment) in our model.

The median final score is 83.46 in our baseline model and 83.40 in our final policies model. Across all practices sizes there is minimal to no difference in median final scores for the baseline and final policies model. Additionally, the percentage of clinicians receiving a positive or neutral adjustment[575] varies little between the two models with slight variation for medium and large practices. We project that 78.40 percent of clinicians will receive a positive or neutral adjustment in the baseline model and 78.37 percent of clinicians will receive a positive or neutral adjustment in the final policies model. The largest difference (0.03 percentage points) in the proportion of clinicians with a positive or neutral adjustment between the baseline and final policies model occurs among large practices. Figure 4 shows the distribution of final scores for all clinicians. Note that there are a relatively large number of MIPS eligible clinicians with a final score of 75. As stated in section VI.E.22.d.(3)(g) of this final rule, clinicians who have their final score reweighted under our extreme and uncontrollable circumstances (EUC) policy are assigned a final score of exactly the performance threshold (75). Overall, the distribution is skewed to the right indicating that

[575] In other words, clinicians who received a score between the performance threshold (75) and 100.

clinicians tend to receive final scores on the higher end of the distribution.

FIGURE 4: Count of MIPS Eligible Clinicians by Final Score



(i) Impact to Small and Solo Practices

18,867 MIPS eligible clinicians or 2.7 percent of all MIPS eligible clinicians are solo practitioners in both the baseline and final policies models. The median final score for solo practitioners is exactly equal to the performance threshold in both the baseline and final policies model. As stated in section VI.E.22.d.(3)(g) of this final rule, clinicians receiving reweighting under our extreme and uncontrollable circumstances policy are assigned a final score exactly equal to the performance threshold. These clinicians are why the median final score for solo practitioners is exactly 75.

While the proportion of solo practitioners receiving a negative payment adjustment and the median final score of solo practitioners does not vary much between the baseline and final policies models, these practitioners do have a lower median final score than other practice sizes. This is largely due to the fact that many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.55 percent of solo practitioners submit data to MIPS[576] compared to 93.70 percent of all clinicians. The median final score in our final policies model is 75.00 for all solo practitioner but for solo practitioners who submit data the median final score is 85.28 which is slightly higher than the median final score for all clinicians who submit data which is 84.75. These findings indicate that the lower final scores among solo practitioners is likely due to not reporting data to MIPS.

Small practices, defined as groups with a range between 2 and 15 clinicians, have a median final score of 82.36 in both the baseline and final policies model. This is slightly but not substantially less than the overall median final score of 83.40. Among small practices who submit data the median final score is 87.29 in the final policies model (and 87.30 in the baseline). This is significantly higher than the median final score for all clinicians who submit data which is 84.74. This indicates that small practices perform similarly to other practice sizes but may have slightly more clinicians who do not submit data than medium and large practices. Table 133 shows the percentage of clinicians by practice size who either do or do not submit data to MIPS and the corresponding median final score. Note that the median final score for non-engaged clinicians is 75 for all practice sizes except solos for whom it is 0. This indicates that many of the clinicians who belong to a small, medium, or large practice do not submit data to MIPS possibly because they are being reweighted under our extreme and uncontrollable circumstances policy but that many solo practitioners who do not submit data are doing so despite not being eligible for the EUC reweighting policy. A large majority of all practice sizes except solo practitioners do submit data to MIPS. It is possible that the small percentage who do not are primarily clinicians who have received reweighting under our extreme and uncontrollable circumstances policy. As shown in Figure 5 clinicians who do not submit data have a final score tend to either have a final score of 0 or a final score of exactly 75. This indicates that there are two ''types'' of clinicians who do not submit data: those who receive reweighting under the EUC policy and those who do not and receive a final score of approximately zero. This is true across all practice sizes, however solo practitioners are the only practice size

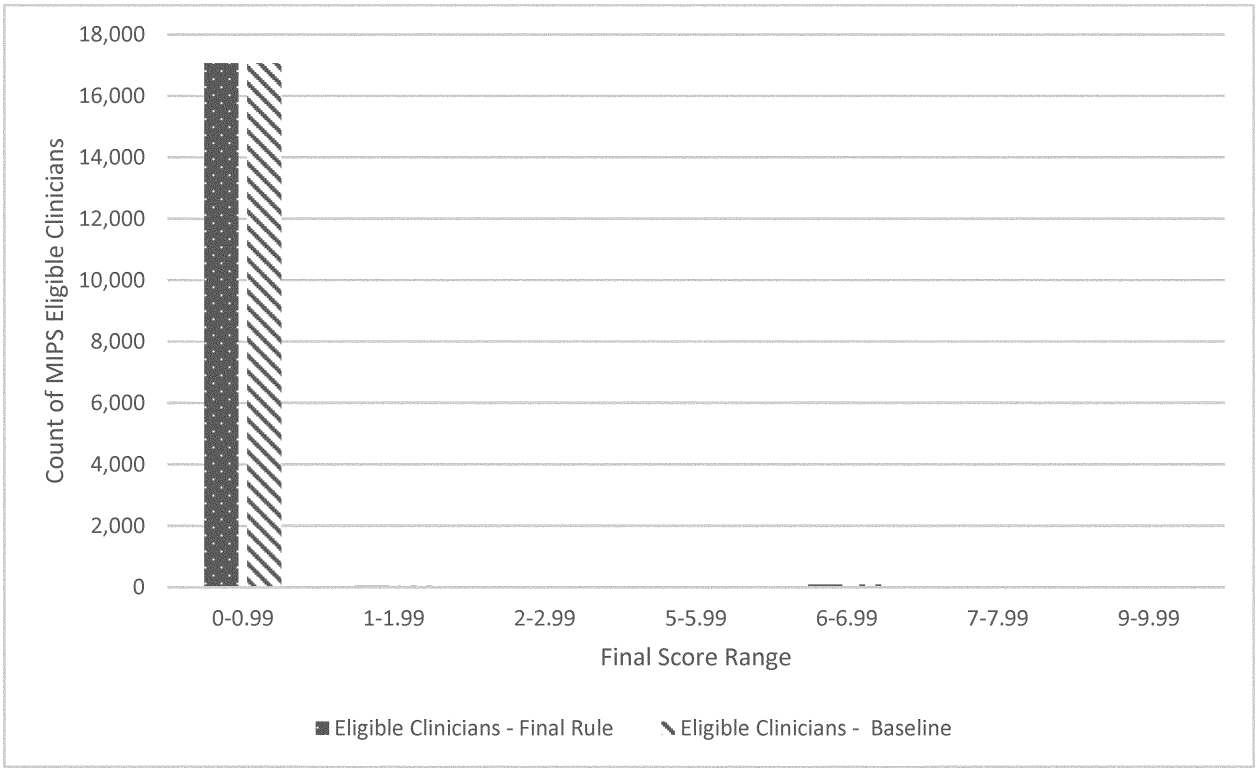
[576] Submitting data to MIPS is defined as any interaction with MIPS. Including beginning a submission but not finishing.

where more clinicians receive a score of 0 than of 75 which is why the median final score of MIPS eligible clinicians for that group is 0.

TABLE 133: Percentage of MIPS Eligible Clinicians who Submit Data and Median Final Score

	Percentage **of MIPS** Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	**Median Final Score of MIPS Eligible Clinicians who Do not submit data.**
Baseline			
1) Solo	49.44%	85.32	0
2) Small (2-15)	79.41%	87.3	75
3) Medium (16-99)	91.96%	84.11	75
4) Large(100+)	98.48%	84.83	75
Overall	93.70%	84.86	75
Final Policies			
1) Solo	49.44%	85.32	0
2) Small (2-15)	79.41%	87.29	75
3) Medium (16-99)	91.96%	84.09	75
4) Large(100+)	98.48%	84.71	75
Overall	93.70%	84.75	75

FIGURE 5: Final Score Distribution for MIPS Eligible Clinicians That Do Not Submit Data



(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Analysis of this group of clinicians indicates that their final scores are similar to the overall population of MIPS Eligible Clinicians across all practice sizes. Table 134 shows the median final score and the percentage of eligible clinicians with a positive or neutral or negative adjustment by practice size.

TABLE 134: Percentage of MIPS Eligible Clinicians who Submit Data and Median Final Score for *Rural Practitioners Only*

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline				
1) Solo	2,694	75.00	64.85%	35.15%
2) 2-15	11,760	84.03	76.79%	23.21%
3) 16-99	30,445	85.41	79.66%	20.34%
4) 100+	43,286	80.99	75.50%	24.50%
Overall	88,184	82.58	76.41%	23.59%
Final Rule Policies				
1) Solo	2,694	75.00	64.85%	35.15%
2) 2-15	11,760	84.00	76.79%	23.21%
3) 16-99	30,445	85.33	79.66%	20.34%
4) 100+	43,286	80.98	75.50%	24.50%
Overall	88,184	82.57	76.41%	23.59%

The median final score for all rural practitioners is 82.58 in our baseline model and 82.57 in our final policies model. This is slightly lower than the median final score for all practitioners which is 84.86 in our baseline model and 84.75 in our final policies model. A larger portion of Solo rural practitioners receive a positive adjustment than solo practitioners generally. As shown in Table 135, 53.72 percent of all solo practitioners receive a positive or neutral adjustment. Among rural practitioners 64.85 percent of solo practitioners receive a positive adjustment. A similar proportion of medium practices receive a positive adjustment among rural practitioners and our overall population but medium practices have a slightly larger median payment adjustment. Large practices are the only practice size where rural practitioners score measurably worse in our model. Among large rural practices 75.50 percent of MIPS eligible clinicians receive a positive or neutral payment in our final policies model compared 80.51 percent of all large practices. Overall rural practitioners perform similarly or better in our simulation compared to all practitioners with the exception of larger rural practitioners who perform slightly worse.

(iii) Impact to Safety Net Providers

In the CY 2023 PFS final rule (87 FR 70094) we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

To assess the impact of our finalized polices on these clinicians we compared the performance of clinicians who received the complex patient bonus with our overall population. We refer to this group of clinicians (those who have received the complex patient bonus) as ''safety net providers'' for the purpose of this analysis. The results of this analysis are in Table 135.

TABLE 135: Percentage of MIPS Eligible Clinicians who Submit Data and Median Final Score for *Safety Net Practitioners Only*

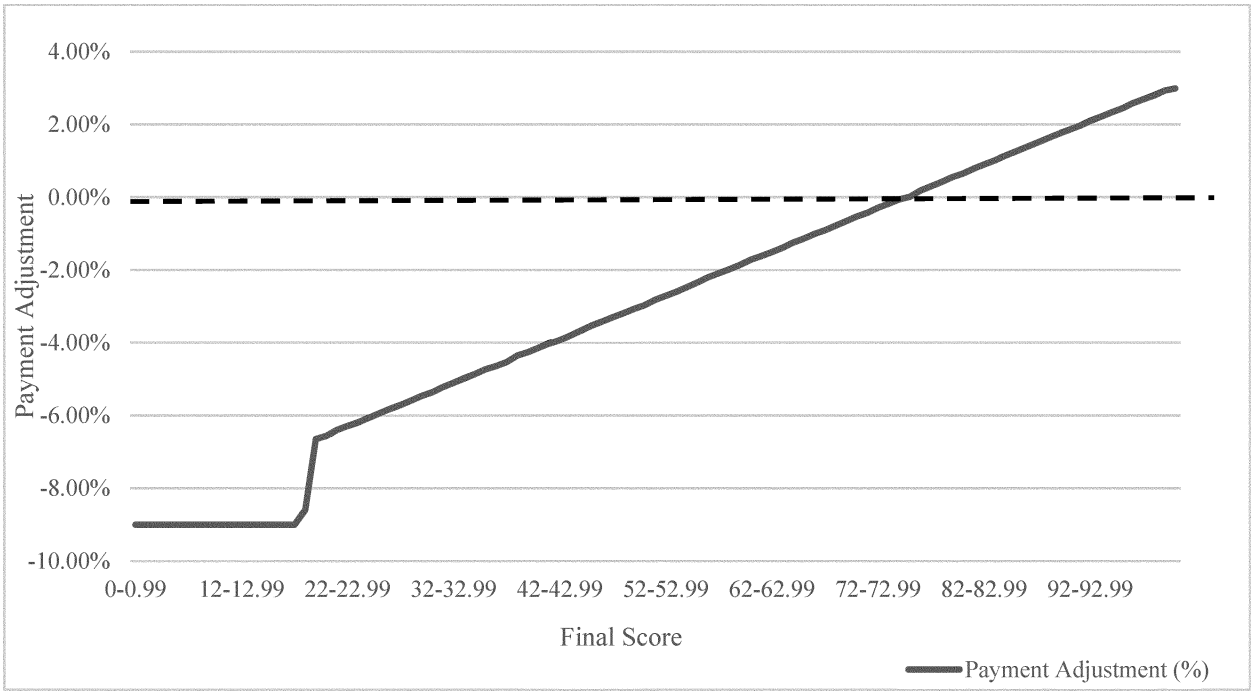
Practice Size*	Total Number of MIPS Eligible Clinicians	Median Final Score	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline				
1) Solo	11,464	75.00	52.41%	47.59%
2) 2-15	37,872	81.98	75.23%	24.67%
3) 16-99	99,945	83.58	78.69%	21.31%
4) 100+	306,476	84.71	81.38%	18.62%
Overall	455,757	83.96	79.56%	20.44%
Final Rule Policies				
1) Solo	11,464	75.00	52.41%	47.59%
2) 2-15	37,873	81.98	75.31%	24.68%
3) 16-99	99,947	83.58	78.67%	21.32%
4) 100+	306,476	84.71	81.38%	18.62%
Overall	455,767	83.93	79.56%	20.44%

Across every practice size safety net provers perform very similarly to our overall population of MIPS eligible clinicians.

(c) Impact to Clinicians Payment Adjustments

In section IV.A.4.h.(2) of this final rule we state that we are not finalizing an increase in the performance threshold. However, payment adjustments still differ slightly between the baseline and final policies model. This is because final scores are slightly different, and the parameters of the exchange function used to determine payment adjustments depends on the final score distribution of MIPS eligible clinicians. However, the difference between the payment adjustment function in the baseline and final rule is negligible. Figure 6 shows the payment adjustment function for the baseline and final rule. Since these functions are virtually identical these two lines overlap.

FIGURE 6: Payment Adjustment Function



Payment adjustments range from -9 percent to a maximum of 2.985 percent in the baseline and 2.989 percent in our final policies model. We project redistributing $491 million in both the baseline and final policies models.

We also report the median positive and negative payment adjustments by practice size.

TABLE 136: CY 2024 Median Positive and Negative Payment Adjustment Estimates By Practice Size

Practice Size	Median Positive Payment Adjustment*	Median Negative Payment Adjustment*
Baseline		
Solo (1)	2.08%	-9.00%
Small (2-15)	1.83%	-5.17%
Medium (16-99)	1.69%	-1.32%
Large (>99)	1.73%	-0.95%
Overall	1.73%	-1.24%
Final Rule Policies Model		
Solo (1)	2.08%	-9.00%
Small (2-15)	1.83%	-5.18%
Medium (16-99)	1.69%	-1.34%
Large (>99)	1.73%	-0.95%
Overall	1.74%	-1.24%

*The median positive payment adjustment is defined as the medium payment adjustment among clinicians with a final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal the performance threshold.

For solo practitioners the median negative payment adjustment is equal to the maximum negative adjustment of −9.00 percent. As discussed in section VI.E.22.(4)(b)(i) of this final rule, this is largely due to the fact that many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.55 percent of solo practitioners submit data to MIPS [577] compared to 93.70 percent of all clinicians. In Table 137, we report the proportion of clinicians with either did or did not submit data with the maximum negative adjustment (−9 percent).

[577] Submitting data to MIPS is defined as any interaction with the MIPS program.

TABLE 137: CY 2024 CY 2024 Clinicians With The Maximum Negative Adjustment

Practice Size	Percent of **Clinicians who Did NOT Submit Data** with Maximum Negative Adjustment	Percent of **Clinicians Who Submit Data** With Maximum Negative Adjustment
Baseline (-9%)		
Solo (1)	67.17%	2.86%
Small (2-15)	49.00%	0.83%
Medium (16-99)	24.52%	0.38%
Large (>99)	15.43%	0.12%
Overall	40.86%	0.28%
Final Policies Model (-9%)		
Solo (1)	67.17%	2.86%
Small (2-15)	49.00%	0.83%
Medium (16-99)	24.52%	0.38%
Large (>99)	15.43%	0.12%
Overall	40.86%	0.28%

While the median negative adjustment is the maximum (-9 percent) for solo practitioners only 2.86 percent of solo practitioners who submit data receive the maximum negative adjustment. In contrast, 67.17 percent of solo practitioners who do not submit data receive the maximum negative adjustment.

The median positive adjustment for solo practitioners is 2.08 percent which is higher than the median positive adjustment for any other practice size. This indicates that, while many solo practitioners do not submit data to MIPS, those solo practitioners who do report data to MIPS and receive a positive adjustment receive a higher median adjustment than other practice sizes. As shown in Table 138, 11.97 percent of solo practitioners who submit data to MIPS receive the maximum positive adjustment. This is larger than the other practice sizes which indicates that the solo practitioners who do submit data perform as well or better than the rest of the population of clinicians who submit data.

TABLE 138: CY 2024 CY 2024 Clinicians With The Maximum Positive Adjustment

Practice Size	Percent of **Clinicians who Did NOT Submit Data** with Maximum Positive Adjustment	Percent of **Clinicians Who Submit Data** With Maximum Positive Adjustment
Baseline (2.98%)		
Solo (1)	0%	11.97%
Small (2-15)	0%	10.08%
Medium (16-99)	0%	5.62%
Large (>99)	0%	4.30%
Overall	0%	5.21%
Final Rule Policies Model (2.99%)		
Solo (1)	0%	11.95%
Small (2-15)	0%	9.99%
Medium (16-99)	0%	5.61%
Large (>99)	0%	4.29%
Overall	0%	5.19%

e. Additional Impacts from Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we are finalizing several policies that have an impact on burden in the CY 2024 performance period/2026 MIPS payment year. In section V.B.11. of this final rule, we outline estimates of the costs of data collection that includes both the effect of policy updates and adjustments due to the use of updated data sources. For each provision included in this final rule which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 139. We also provided additional burden discussions that we are not able to quantify.

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TABLE 139: Incremental Burden from Associated Finalized Policies

Burden Description and associated finalized provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year with updated data and assumptions (as outlined in section V.B.11.p. of this final rule).	728,359	$81,799,657
Burden change for MVP registration ICR due to the provision of additional MVPs (as outlined in section V.B.11.e.(7)(a)(i) of this final rule). *	+341	+$35,285
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.11.e.(4) of this final rule). *	-4,430	-$495,550
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.11.e.(5) of this final rule). *	-3,506	-$401,263
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as outlined in section V.B.11.e.(6) of this final rule). *	-5,336	-$618,682
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (as outlined in section V.B.11.e.(7)(a)(iii) of this final rule). *	+8,784	+$1,003,109
Total change in burden due to policy for CY 2024	-4,147	-$477,101
Total burden set forth in the CY 2024 PFS final rule	724,212	$81,322,556

* The total change in burden due to this provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the proposed addition of new MVPs. Therefore, there will be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.11.e. of this final rule.

(2) Additional Impacts to Clinicians

(a) Impact on Third Party Intermediaries

In section IV.A.4.k. of this final rule, we proposed to: (1) add requirements for third party intermediaries to obtain documentation; (2) add requirements for third party intermediaries to submit data in the form and manner specified by CMS; (3) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (4) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (5) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (6) Modify requirements for QCDRs and qualified registries to support MVP reporting; (7) Specify requirements for a transition plan for QCDRs and qualified registries; (8) Specify requirements for data validation execution reports; (9) Add additional criteria for rejecting QCDR measures; (10) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits. Due to the technical nature of these changes, we are unable to quantify the burden for third party intermediaries during the CY 2024 performance period/2026 MIPS payment year. We refer readers to section IV.A.4.k. of this final rule for additional information on changes to the third party intermediary requirements.

(b) Compare Tools: Public Reporting

As discussed in section IV.A.4.1. of this final rule, we are finalizing our proposals to: (1) use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth; (2) update the PDC Utilization Data File Policy, remove the PUF subset file from the PDC and only keep the utilization data file that reflects the information on clinician profile pages in the PDC; (3) modify the Procedure Grouping Policy for Publicly Reporting Utilization Data as proposed. Specifically, in addition to Restructured BETOS and code sources used in MIPS, we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists; and (4) incorporate Medicare Advantage data to FFS procedure volume counts and amend § 422.310(f)(3) to add a new paragraph

(iv) authorizing CMS to release aggregated risk adjustment data before the reconciliation for the applicable payment year has been completed if CMS determines that releasing aggregated data is necessary and appropriate for activities to support administration of the Medicare program. While the Compare tool provisions do not increase the burden of collections, we note that the PRA package may require relevant modification to reflect the Compare tool's new uses and public display. We refer readers to section IV.A.4.l. of this final rule for additional details on the changes to public reporting on Compare tools.

(c) Data Completeness Criteria for the Quality Measures, Excluding the Medicare CQMs

As discussed in section IV.A.4.f.(1)(d) of this final rule, we are finalizing to maintain the data completeness criteria threshold at 75 percent for the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years. We are not finalizing our proposal to increase the data completeness criteria threshold by 5 percent from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year. We believe that the policy to maintain the threshold for data completeness at 75 percent for the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years is consistent with the existing data completeness criteria and therefore, will not result in additional burden to the applicable interested parties. We refer readers to section IV.A.4.f.(1)(d) of this final rule for additional information on the data completeness threshold criteria.

(d) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.f.(2)(b)(ii) of this final rule, we are finalizing changes to the improvement activities Inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities. We refer readers to Appendix 2: Improvement Activities of this final rule for further details. We do not believe these changes to the improvement activities inventory will significantly impact time or financial burden on interested parties because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these changes to the improvement activities inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities under the policies in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2024 performance period/2026 MIPS payment year. We refer readers to section IV.A.4.f.(3)(b)(ii) of this final rule for additional information on changes to the improvement activities Inventory.

(3) Update to CEHRT Definition for the Medicare Promoting Interoperability Program and the Quality Payment Program

As discussed in section III.R. of this final rule, we are finalizing our proposal to update the definitions of CEHRT for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and for the MIPS Promoting Interoperability performance category. Under this provision, we will revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305. Specifically, we are finalizing the proposal to add a reference to the ''Base EHR Definition'' where the regulatory text refers to the ''2015 Edition Base EHR definition,'' remove ''2015 Edition'' where we reference ''2015 Edition health IT certification criteria,'' and add a cross-reference to health IT certification criteria at § 170.315. We also are finalizing the proposal to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria at § 170.315, ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions will ensure that updates to the definition at § 170.102 and updates to applicable health IT certification criteria in § 170.315 will be incorporated into CEHRT definitions, without requiring additional regulatory action by CMS. Finally, we noted that while this provision is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize their proposed revisions for us to be able to finalize the changes in this section for our regulatory definitions of CEHRT. These changes will not impact EHR requirements in the CY 2024 EHR reporting period or the CY 2024 performance period, and therefore we predict that it will have no impact on clinicians.

f. Assumptions & Limitations

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2021 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2023 performance period/2025 MIPS payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the policies.

As discussed in section VI.E.22.c. of this final rule, we are unable to predict which specific clinicians would receive reweighting under our extreme and uncontrollable circumstances policies in the CY 2024 Performance period/CY 2026 Payment Year and so we make the assumption that those clinicians who received the reweighting under our extreme and uncontrollable circumstances policy are representative of the number and attributes of clinicians who will receive reweighting under this policy in the future.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 132.

We received public comments on the Regulatory Impact Analysis for the Quality Payment Program.

The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS analyze the impact of QP policy changes, including the QP determination policy proposal and proposed change to the QP threshold, in the Regulatory Impact Analysis of the rule. Commenters were interested in how these policy changes would impact the engagement of specific types of practices and patient populations such as rural clinicians, ACOs, and specialists in the program.

Response: We thank these commenters for their feedback on the regulatory impact analysis. We note that our analysis incorporates QP policy changes. This is described in more detail in section VI.E.22.c.(2) of this final rule. We also note that, as stated in section IV.A.4.m.(2) of this final rule we are not finalizing the change in individual level QP determination proposed in the CY 2024 PFS proposed

rule. We note that we describe the overall impact to rural clinicians in section VI.E.22.d.(4)(b)(ii) of this final rule. We are continuously refining and improving the model used for this regulatory impact analysis and will consider the specific suggestions raised by these commenters in future iterations.

F. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to the O/O E/M Visit Inherent Complexity Add-On Separate Payment

We considered alternatives to our policy to make separate payment for the O/O E/M visit inherent complexity add-on code, including proposing to maintain our current utilization assumptions. Maintaining our current utilization assumption as finalized in CY 2021 would result in an estimated impact or change to the CF of −3.2 percent (Table 140). However, maintaining the CY 2021 policy utilization assumption would not reflect our limitation on billing of the O/O E/M visit inherent complexity add-on code for services billed with modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit by the same practitioner. It seems likely that visits reported with payment modifiers have resources sufficiently distinct from stand-alone office/outpatient E/M visits (85 FR 84571). Interested parties unlikely to bill for the O/O E/M visit inherent complexity add-on code have continued to express concerns about potential associated reductions to the CF and redistributive impacts among specialties. Our proposal to better target the add-on code would partially allay those concerns. Under our proposed utilization assumption for CY 2024, we estimated the effect of making separate payment for the O/O E/M visit complexity add-on code to be −2.0 percent.

TABLE 140: Conversion Factor Effect Attributable to the Inherent Complexity Add-on Code

As finalized for CY 2021	-3.2%
As proposed for CY 2024	-2.0%

We also considered proposing not to make separate payment for the O/O E/M visit inherent complexity add-on code for CY 2024, continuing to consider the utilization data, and solicited comment on not making separate payment until CY 2025 instead of CY 2024.

While doing so would reduce the change to the CF and the redistributive impacts among specialties our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients with a single, serious, or complex chronic condition would remain present.

We received public comments on these proposals. Generally, commenters who believed that E/M visits that are associated with medical care services that serve as the continuing focal point for all needed health care services or with medical care services that are part of ongoing care related to a patient's single, serious or complex condition expressed support for our proposal. Commenters who believed that the code was duplicative or some who believed that the negative impact on the conversion factor outweighed the benefit opposed the code. Many commenters across the board recommended lowering utilization estimates in the proposed rule. For a summary of the comments we received and our responses see section II.F.2, of this final rule. After consideration of public comments, we are finalizing as proposed.

We believe separate payment for the O/O E/M visit inherent complexity add-on code will improve accuracy in payment for resource costs inherent to primary care and other medical care services that are part of ongoing care for a patient's single, serious or complex condition in the office setting. This will be particularly important for people without access to such care. We also believe that utilizing high-value preventive services and promoting healthy behaviors leveraged by these kinds of longitudinal patient relationships could result in positive patient outcomes and positive health equity impacts. Primary care practitioners and other practitioners who rely heavily on these visit codes and will use the add-on code will likely raise strong objections if CMS does not propose to make separate payment for a code that is intended to address long-standing distortions in PFS payment that CMS has repeatedly acknowledged through notice and comment rulemaking.

2. Alternatives to Provider Enrollment Provisions

We did not consider alternatives to our provider enrollment provisions. We believe these changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes.

3. Alternatives Considered Medicare Diabetes Prevention Program

No alternatives were considered. The MDPP flexibilities resulting from the PHE for COVID–19 lasted over 3 years of the initial 5 years of the expanded model. During this time, supplier and beneficiary expectations changed, resulting in the synchronous virtual delivery of healthcare services becoming normalized. Requiring the MDPP expanded model to return to primarily in-person services following over 3 years of synchronous virtual delivery may have an extremely negative impact for both MDPP suppliers and beneficiaries, which could threaten the success of the entire expanded model.

4. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran separate policies RIA models based on the actual mean for the CY 2019 performance period/2021 MIPS payment year with a performance

threshold of 86. This model has the same mean and median final score as our policies RIA model since the performance threshold does not change the final score. In our analysis of the alternative performance threshold of 86, 56.09 percent of all MIPS eligible clinicians who submitted data will receive a negative payment adjustment.

In the CY 2024 PFS proposed rule (88 FR 52598 through 52598), we proposed to increase the performance threshold to 82 points. In section IV.A.4.h.(2) of this final rule, we indicated that we are not finalizing this increase. Under the performance threshold of 82 we project that 46.67 percent of all MIPS eligible clinicians would receive a negative payment adjustment.

We also reported the findings for the baseline RIA model which describes the impact for the CY 2024 performance period/2026 MIPS payment year if this proposal is not finalized. The baseline RIA model has a median final score of 83.46. We estimated that $491 million will be redistributed based on the budget neutrality requirement. The baseline includes a maximum payment adjustment of 2.98 percent. In addition, 21.60 percent of MIPS eligible clinicians would receive a negative payment adjustment.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in this final rule, the cap on an ACO's regional service area risk score growth is expected to increase the incentive for ACOs to participate in regions with high risk score growth, improving the incentive for ACOs to join and/or sustain participation when serving regions with increasingly medically complex beneficiaries. Similarly, the use of a uniform approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s) is anticipated to increase participation (and reduce the potential for attrition) particularly from ACOs serving greater proportions of complex beneficiaries exhibiting high risk scores. Mitigating the impact of the negative regional adjustments on benchmarks is expected to increase participation from ACOs serving up to 500,000 new assigned beneficiaries per year. The revised definition of assignable beneficiary is expected to allow more than 760,000 additional beneficiaries to be included in the population of assignable beneficiaries, many of whom would be eligible to be assigned to ACOs. Taken together, these provisions are expected to increase participation in the Shared Savings Program over the 2024–2033 period by roughly 10 to 20 percent.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In addition, ACOs continued to achieve better average performance rates than comparably sized MIPS group practices on all 10 of the CMS WI measures and had higher scores on the CAHPS for MIPS patient experience survey in PY 2022. ACO performance was statistically better on 6 out of 10 CMS WI measures compared to comparably sized MIPS group practice reporters in PY 2022. Those measures include diabetes control, blood pressure control, breast cancer screening, colorectal cancer screening, depression screening and follow-up, and tobacco screening and cessation intervention.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management.

2. Quality Payment Program

There are several changes in this final rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the policies in this final rule will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Medicare Diabetes Prevention Program

The changes will have a positive impact on eligible MDPP beneficiaries, as it increases the accessibility of MDPP, particularly among beneficiaries residing in rural and underserved areas of the US, where access to a supplier offering in-person Set of MDPP services may not exist or be geographically feasible.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of last year's proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's proposed rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours × $123.06). Therefore, we estimated that the total cost of reviewing this regulation is 21,677,265 ($984.48 × 22,019 reviewers on this year's proposed rule).

As for the Medicare Diabetes Prevention Program, given that we tried to align this rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and

eligible beneficiaries who have started the MDPP program or are interested in enrolling in MDPP.

I. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Tables 138 through 140 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2023 to CY 2024 based on the FY 2024 President's Budget baseline.

TABLE 141: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2024 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.4 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 142: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2024 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.6billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 143: Accounting Statement for Provisions for Medicare Shared Savings Program (CYs 2024-2033)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-15 million	-171 million	174 million	Tables 120 through 123
Annualized monetized: Discount rate: 3%	-25 million	-189 million	172 million	

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations,

Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 600

Administrative practice and procedure, Health care, Health insurance, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.400 is amended by revising the definition of ''Practitioner'' to read as follows:

§ 405.400 Definitions.

* * * * *

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, mental health counselor, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

* * * * *

■ 3. Section 405.800 is amended by adding paragraph (d) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(d) *Scope of supplier.* For purposes of this subpart, the term ''supplier'' includes all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202 of this chapter.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

■ 4. In § 405.2401amend paragraph (b) by adding the definitions of ''Marriage and family therapist (MFT)'' and ''Mental health counselor (MHC)'' in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Marriage and family therapist (MFT) means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

* * * * *

Mental health counselor (MHC) means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

■ 5. Section 405.2411 is amended by revising paragraphs (a)(4), (a)(6), and (b)(2) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(b) * * *

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

* * * * *

■ 6. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 7. Section 405.2415 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(3), and (a)(5) and

■ b. Adding paragraphs (b)(6) and (7).

The revisions and additions read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant,

certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) * * *

(6) Marriage and family therapist.

(7) Mental health counselor.

* * * * *

■ 8. Section 405.2446 is amended by revising paragraphs (b)(5) and (6) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

* * * * *

■ 9. Section § 405.2448 is amended by revising paragraphs (a)(2) introductory text and (a)(2)(i) to read as follows:

§ 405.2448 Preventive primary services.

(a) * * *

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

* * * * *

■ 10. Section 405.2450 is amended by revising the section heading and paragraphs (a) introductory text, (a)(2), (a)(3), and (c) to read as follows:

§ 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

* * * * *

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

* * * * *

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

■ 11. Section 405.2452 is amended by revising the section heading, and paragraphs (a) introductory text, (a)(3), (a)(5) and (b) to read as follows:

§ 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is —

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

* * * * *

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

■ 12. Section 405.2463 is amended by—

■ a. Adding paragraphs (a)(1)(i)(I) and (a)(1)(i)(J);

■ b. Revising paragraph (b)(3) introductory text;

■ c. Redesignating paragraph (b)(3)(iii) as paragraph (b)(3)(v); and

■ d. Adding paragraphs (b)(3)(iii) and (b)(3)(iv).

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(i) * * *

(I) Marriage and family therapist.

(J) Mental health counselor.

* * * * *

(b) * * *

(3) *Visit-Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2025, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

(iii) Marriage and family therapist.

(iv) Mental health counselor.

* * * * *

■ 13. Section 405.2464 is amended by revising paragraph (c) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician

fee schedule national non-facility payment rate. For care management services furnished between January 1, 2018 and December 31, 2023, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services. For general care management services furnished on or after January 1, 2024, the payment amount is based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data.

* * * * *

■ 14. Section 405.2468 is amended by revising paragraphs (b)(1), (b)(3), and (d)(2)(ii) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(b) * * *

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

* * * * *

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(d) * * *

(2) * * *

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

* * * * *

■ 15. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 16. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 17. Section 410.10 is amended by revising paragraph (l) and adding paragraphs (z) and (aa) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(l) Pneumococcal, influenza, and COVID–19 vaccines (or monoclonal antibodies used for preexposure prophylaxis of COVID–19) and their administration.

* * * * *

(z) Marriage and Family Therapist services, as provided in § 410.53.

(aa) Mental Health Counselor services, as provided in § 410.54.

■ 18. In § 410.15 amend paragraph (a) by:

■ a. In the definition of ''First annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xiii) as paragraph (xiv); and

■ ii. Adding a new paragraph (xiii).

■ b. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xi) as paragraph (xii); and

■ ii. Adding a new paragraph (xi).

The additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services * * *

(xiii) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(xi) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

■ 19. Amend § § 410.18 by:

■ a. In paragraph (a):

■ (i) Revising the definition of ''Diabetes''; and

■ (ii) Removing the definition of ''Pre-diabetes''.

■ b. Redesignating paragraph (c)(3) as paragraph (c)(4) and adding a new paragraph (c)(3); and

■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 410.18 Diabetes screening tests.

(a) * * *

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism.

* * * * *

(c) * * *

(3) Hemoglobin A1C test.

* * * * *

(d) *Amount of testing covered.* Medicare covers two tests within the 12-month period following the date of the most recent diabetes screening test of that individual.

* * * * *

■ 20. Section 410.32 is amended by revising paragraphs (a)(2) and (b)(3)(ii) to read as follow:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) * * *

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, marriage and family therapists, mental health counselors, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

* * * * *

(b) * * *

(3) * * *

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 21. Section § 410.33 is amended by revising paragraph (g)(2) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(g) * * *

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location (including additions and deletions of locations), changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

* * * * *

■ 22. Amend § 410.47 by:

■ a. In paragraph (a):

■ i. Adding the definition of ''Nonphysician practitioner'' in alphabetical order;

■ ii. Revising the definitions of ''Pulmonary rehabilitation''

■ iii. Removing the definition of ''Supervising physician'' and adding, in alphabetical order, a definition for ''Supervising practitioner'';

■ b. Revising paragraphs (b)(3)(ii)(A) and (d) introductory text; and

■ c. Removing paragraph (d)(3).

The addition and revisions read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions of coverage.

(a) * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Pulmonary rehabilitation means a physician or nonphysician practitioner supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

(b) * * *

(3) * * *

(ii) * * *

(A) A physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(d) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 23. Amend § 410.49 by:

■ a. In paragraph (a):

■ i. Revising the definitions of ''Cardiac rehabilitation'' and ''Intensive cardiac rehabilitation (ICR) program'';

■ ii. Adding the definition of ''Nonphysician practitioner'' in alphabetical order; and

■ iii. Removing the definition of ''Supervising physician'' and adding, in alphabetical order, the definition of ''Supervising practitioner'';

■ b. Revising paragraphs (b)(3)(ii) and (e) introductory text; and

■ c. Removing paragraph (e)(3).

The revisions and addition read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) * * *

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

* * * * *

Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

* * * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) * * *

(3) * * *

(ii) All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(e) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 24. Add § 410.53 to subpart B to read as follows:

§ 410.53 Marriage and family therapist services.

(a) *Definition: marriage and family therapist.* For purposes of this part, a marriage and family therapist is defined as an individual who -

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

(b) *Covered marriage and family therapist services.* Medicare Part B covers marriage and family therapist services.

(1) *Definition: marriage and family therapist services* means services furnished by a marriage and family therapist (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not marriage and family therapist services for purposes of billing Medicare Part B under the MFT and MHC statutory benefit category:

(i) Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A marriage and family therapist may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A marriage and family therapist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 25. Add § 410.54 to subpart B to read as follows:

§ 410.54 Mental health counselor services.

(a) *Definition: mental health counselor.* For purposes of this part, a *mental health counselor* is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a mental health counselor, clinical professional counselor, professional counselor by the State in which the services are performed.

(b) *Covered mental health counselor services.* Medicare Part B covers mental health counselor services.

(1) *Definition: Mental health counselor services* means services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not mental health counselor services for purposes of billing Medicare Part B:

(i) Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A mental health counselor may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A mental health counselor or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 26. Section 410.57 is amended by revising paragraph (c) to read as follows:

§ 410.57 Preventive vaccines.

* * * * *

(c) Medicare Part B pays for the COVID–19 vaccine (or monoclonal antibodies used for pre-exposure prophylaxis of COVID–19) and its administration.

* * * * *

■ 27. Section 410.59 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph, occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

* * * * *

■ 28. Section 410.60 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph, physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly

supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

* * * * *

§ 410.67 [Amended]

■ 29. In § 410.67 in paragraph (b) amend paragraph (vii) in the definition of ''Opioid use disorder treatment service'' by removing the reference ''through the end of CY 2023'' and adding in its place the reference ''through the end of CY 2024''.

■ 30. Section 410.72 is amended by revising paragraph (d) to read as follows:

§ 410.72 Registered dietitians' and nutrition professionals' services.

* * * * *

(d) *Professional services.* Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

* * * * *

■ 31. Section 410.78 is amended by—
■ a. Adding paragraphs (b)(2)(x) through (xii);
■ b. Revising paragraphs (b)(3)(xiv) introductory text, (b)(4)(iv)(D), and (e)(1); and
■ c. Adding paragraph (e)(3).

The additions and revisions read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(x) Any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

(xi) A marriage and family therapist as described in 410.53.

(xii) A mental health counselor as described in 410.54.

(3) * * *

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services that are furnished during the period beginning on the first day after the end of the emergency period as defined in our regulation at § 400.200 and ending on December 31, 2024 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(4) * * *

(iv) * * *

(D) Services furnished on or after January 1, 2025 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

* * * * *

(e) * * *

(1) A clinical psychologist and a clinical social worker, a marriage and family therapist (MFT), and a mental health counselor (MHC) may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

* * * * *

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

* * * * *

■ 32. Amend § 410.79 by:
■ a. In paragraph (b):
■ i. Adding the definition of ''Combination delivery'' in alphabetical order;
■ ii. Removing the definition of ''Core maintenance session interval'';
■ iii. Adding the definitions of ''Distance learning'', ''Extended flexibilities'', ''Extended flexibilities period'', and ''Full-Plus CDC DPRP recognition'' in alphabetical order;
■ iv. Revising the definitions of ''Make-up session'', ''MDPP services period'', and ''MDPP session''
■ v. Adding the definition ''Online delivery'' in alphabetical order;
■ vi. Removing the definition of ''Ongoing maintenance sessions'';
■ vii. Adding the definition of ''Virtual session'' in alphabetical order.
■ b. Removing paragraphs (c)(1)(ii) and (iii);
■ c. Redesignating paragraph (c)(1)(iv) as paragraph (c)(1)(ii);
■ d. Revising paragraphs (c)(2)(i)(A) and (B);
■ e. Removing and reserving paragraph (c)(2)(ii);
■ f. Revising paragraph (c)(3)(i);
■ g. Removing and reserving paragraph (c)(3)(ii); removing paragraph (c)(3)(iii), removing and reserving paragraphs (d)(2)(iii)(B) and (d)(3)(ii);
■ h. Revising paragraphs (e)(3)(iv) introductory text, (e)(3)(iv)(D), (e)(3)(iv)(F)(*1*) and (*2*).

The additions and revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

* * * * *

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

* * * * *

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

* * * * *

Make-up session means a core session or a core maintenance session furnished

to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the Set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section.

MDPP session means a core session or a core maintenance session.

* * * * *

Online delivery refers to an MDPP session that is delivered online for all participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

* * * * *

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) * * *

(2) * * *

(i) * * *

(A) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period

(ii) [Reserved]

(3) * * *

(i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section.

* * * * *

(e) * * *

(3) * * *

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually, through distance learning or a combination of in-person or distance learning, during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the Set of MDPP services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

* * * * *

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

* * * * *

(F) * * *

(*1*) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

* * * * *

§ 410.130 [Amended]

■ 33. Amend § 410.130 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

§ 410.140 [Amended]

■ 34. Amend § 410.140 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

■ 35. Amend § 410.150 by adding paragraphs (b)(21) and (22) to read follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(21) To a marriage and family therapist on the individual's behalf for marriage and family therapist services.

(22) To a mental health counselor on the individual's behalf for mental health counseling services.

■ 36. Section 410.152 is amended by:

■ a. Revising paragraphs (b) introductory text, (h)(2) and (h)(3), (h)(4) introductory text, (h)(5); and

■ b. Adding paragraphs (m) and (n).

The revisions and additions read as follows:

§ 410.152 Amounts of payment.

* * * * *

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) and (m) and (n) of this section, Medicare Part B pays the following amounts:

* * * * *

(h) * * *

(2) For the administration of a COVID–19 vaccine:

(i) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(ii) For services furnished on or after January 1 of the year following the year in which the Secretary ends the March 27, 2020 Emergency Use Authorization declaration for drugs and biologicals (issued at 85 FR 18250) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1) of this section.

(3) Subject to conditions specified in this paragraph, in addition to the payment described in paragraph (h)(1) or (2) of this section, an additional payment for preventive vaccine administration in the patient's home:

(i) Effective January 1, 2022 for administration of a COVID–19 vaccine in the home, an additional payment of $35.50.

(ii) Effective January 1, 2024, for the administration of one or more of the preventive vaccines described in paragraphs (h)(1) and (2) of this section in the home, a payment equal to that of the payment in paragraph (h)(3)(i) of this section.

(iii) An additional payment for preventive vaccine administration in the home can be made if:

(A) The patient has difficulty leaving the home, or faces barriers to getting a vaccine in settings other than their home.

(B) The sole purpose of the visit is to administer one or more preventive vaccines.

(C) The home is not an institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, or §§ 409.42(a) of this subchapter.

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is adjusted to reflect geographic cost variations:

* * * * *

(5) For services furnished on or after January 1, 2023, the payment amount for administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is updated annually using the percentage change in the Medicare Economic Index (MEI), as described in section 1842(i)(3) of the Act and § 405.504(d) of this subchapter.

* * * * *

(m) *Amount of payment: Rebatable drugs.* In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished by providers on or after April 1, 2023, in a calendar quarter during which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, Medicare Part B pays, subject to the deductible, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount, which is applied as a percent to the payment amount for such calendar quarter.

(n) *Amount of payment: Insulin furnished through an item of durable medical equipment.* For insulin furnished on or after July 1, 2023 through an item of durable medical equipment (as defined in § 414.202), Medicare Part B pays the difference between the applicable payment amount for such insulin and the coinsurance amount, with the coinsurance amount not to exceed $35 for a month's supply.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 37. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 38. Section 411.15 is amended by:
■ a. Revising paragraph (i)(3)(i)(A); and
■ b. Adding paragraph (i)(3)(i)(E).

The revision and addition read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures, chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

* * * * *

(E) Dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 39. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 40. Section 414.53 is added to read as follows:

§ 414.53 Fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services.

The fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services is set at 75 percent of the amount determined for clinical psychologist services under the physician fee schedule.

■ 41. Amend § 414.84 by:
■ a. In paragraph (a):
■ i. Adding the definition of ''Attendance payment'' in alphabetical order;
■ ii. Revising the definition of ''Performance goal'';
■ b. Revising paragraph (b) introductory text;
■ c. Removing paragraphs (b)(1) through (5);
■ d. Redesignating paragraphs (b)(6) and (7) as paragraphs (b)(1) and (2), respectively;
■ e. Revising newly redesignated paragraphs (b)(1) paragraph heading and (b)(1)(i);
■ f. Adding paragraph (b)(1)(iii);
■ g. Revising newly redesignated paragraphs (b)(2) paragraph heading and (b)(2)(i);
■ h. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively;
■ i. Adding new paragraph (c); and
■ j. Revising newly redesignated paragraphs (d)(1) and (e).

The additions and revisions read as follows:

§ 414.84 Payment for MDPP Services.

(a) * * *

Attendance payment means a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. CMS will allow up to 22 sessions (alone or in combination with other codes, not to exceed 22 sessions in a 12- month timeframe).

* * * * *

Performance goal means a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

* * * * *

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph (b). Each type of performance payment is made only if the beneficiary achieves the applicable performance goal. Certain performance goals are allowed only once per MDPP beneficiary and include the performance goals in paragraphs (b)(1)(i) and (b)(2)(i) of this section. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment

only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The two types of performance payments are as follows:

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $145.

* * * * *

(iii) If the beneficiary maintains the required minimum weight loss during a core maintenance session, as measured in-person or described in § 410.79(e)(3)(iii) the amount is $8.

(2) *Performance Goal 2: Achieves 9-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024. $25.

* * * * *

(c) *Attendance payment: Attends a core session or core maintenance session.* CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends a core session or core maintenance session. An attendance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make an attendance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session.

(1) The first core session attended, which initiates the MDPP services period, and that first core session was furnished by that supplier.

(2) For the Extended flexibilities period described in § 410.79(e)(2)(iii), the distance learning HCPCS G-code applies for any Set of MDPP services that are delivered by distance learning, as described in § 410.79(b).

(3) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) For a core session or core maintenance session furnished January 1, 2024 through December 31, 2024. $25.

(ii) [Reserved]

(d) * * *

(1) For core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $25.

* * * * *

(e) *Updating performance payments, attendance payments, and the bridge payment.* The performance payments, attendance payments, and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

§ 414.94 [Removed and Reserved]

■ 42. Remove and reserve § 414.94.

■ 43. Amend § 414.502 by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2024 through March 31, 2024, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2024 through March 31, 2024.

* * * * *

§ 414.504 [Amended]

■ 44. Amend § 414.504 in paragraph (a)(1) by removing the reference ''January 1, 2023'' and adding in its place the reference ''January 1, 2024''.

■ 45. Amend § 414.507 by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(6); and

■ b. Adding paragraph (d)(9).

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2026, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(6) 2023–0.0 percent of the payment rate established in 2022.

* * * * *

(9) 2026—15 percent of the payment rate established in 2025.

* * * * *

§ 414.610 [Amended]

■ 46. In § 414.610 amend paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date ''December 31, 2022'' and adding in its place the date ''December 31, 2024''

■ 47. Section 414.902 is amended by adding the definitions of ''Applicable five-year period'', ''Low volume dose'', ''New refund quarter'', ''Qualifying biosimilar biological product'', and ''Updated refund quarter'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Applicable five-year period means:

(1) For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) of the Act as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(2) For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) of the Act during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

* * * * *

Low volume dose means, with respect to determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

* * * * *

New refund quarter means a calendar quarter that is included in a report

described in § 414.940(a) that is sent in the first year following the year in which the calendar quarter occurs.

* * * * *

Qualifying biosimilar biological product means a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an average sales price (as described in section 1847A(b)(8)(A)(i) of the Act) less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

* * * * *

Updated refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the second year following the year in which the calendar quarter occurs.

* * * * *

■ 48. Section 414.904 is amended by revising paragraphs (e)(4) and (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(4) *Payment amount in a case where the average sales price during the first quarter of sales is unavailable.* During an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price:

(i) *In general.* Except as provided in paragraph (e)(4)(ii) of this section,

(A) For dates of service before January 1, 2019, the payment amount for the drug is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(B) For dates of service on or after January 1, 2019, the payment amount for the drug is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003.

(ii) *Limitation on payment amount for biosimilar biological products during initial period.* For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902) during the initial period is the lesser of the following:

(A) The payment amount for the biosimilar biological product as determined under clause (e)(4)(i)(B) of this section or

(B) 106 percent of the amount determined under section 1847A(b)(1)(B) of the Act for the reference biological product (as defined in § 414.902).

* * * * *

(j) *Biosimilar biological products*—(1) *In general.* Except as provided in paragraph (j)(2), effective January 1, 2016, the payment amount for a biosimilar biological product (as defined in § 414.902), for all NDCs assigned to such product, is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act, and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

(2) *Temporary increase in Medicare Part B payment for qualifying biosimilar biological products.* In the case of a qualifying biosimilar biological product (as defined in § 414.902) that is furnished during the applicable 5-year period (as defined in § 414.902) for such product, the payment amount for such product with respect to such period is the sum determined under as determined under section 1847A(b)(6) of the Act and 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

■ 49. Section 414.940 is amended by—

■ a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv).

■ b. Adding new paragraph (a)(1)(iii).

■ c. Revising paragraphs (a)(3), (b)(1) and (2), (c), and (d);

■ d. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively; and

■ e. Adding new paragraph (e).

The revisions and additions read as follows:

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) * * *

(1) * * *

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at § 414.902).

* * * * *

(3) *Report Timing.* Reports are sent once annually.

(b) * * *

(1) Refund amounts for which the manufacturer is liable, pursuant to this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

* * * * *

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section is negative, the amount will be netted from refunds owed for other updated and new refund quarters included in the same report as such updated refund quarter.

(4) Exception when there are multiple manufacturers. If there is more than one

manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at § 414.902) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in § 414.902) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year. A drug is furnished to fewer than 100 unique beneficiaries per calendar year when one of the following two conditions is met:

(i) The number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or

(ii) Either:

(A) In the case of a drug for which 3 or more years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the 2 previous calendar years is less than 100; or

(B) In the case of a drug for which at least 2 but less than 3 years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the previous calendar year is less than 100.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling for the drug, or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review;

(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply. An application for a drug that is not FDA-approved by February 1 must have FDA approval by August 1 and the manufacturer must notify and submit the FDA-approved label to CMS by September 1 of the calendar year prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) of this section beginning as of the following January 1.

* * * * *

■ 50. Section 414.1305 is amended by—

■ a. In the definition of ''Attestation'', by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, subgroup, or group''.

■ b. In the definition of ''Certified Electronic Health Record Technology (CEHRT)'', by revising paragraphs (2) introductory text and (2)(ii) introductory text, and adding paragraph (3);

■ c. By revising the definition of ''Collection type'';

■ d. By adding the definition of ''Qualified posting''.

■ e. In the definition of ''Submitter type'', by removing both instances of the term ''MIPS eligible clinician, group, Virtual Group, APM Entity'' and adding in their places the term ''MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity''.

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * **

* * * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102), and has been certified to the ONC health IT certification criteria as adopted and updated in 45 CFR 170.315—

* * * * *

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

* * * * *

(3) For purposes of determinations under §§ 414.1415 and 414.1420, beginning for CY 2024, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets—

(i) The 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102); and

(ii) Any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of

this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).

* * * * *

Qualified posting means the document made available that lists qualified registries or QCDRs available by CMS for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities.

* * * * *

■ 51. Section 414.1320 is amended by—

■ a. Revising paragraph (h) introductory text; and

■ b. Adding paragraph (i).

The addition and revision read as follow:

§ 414.1320 MIPS performance period.

* * * * *

(h) For purposes of the 2024 MIPS payment year and the 2025 MIPS payment year, the performance period for:

* * * * *

(i) For purposes of the 2026 MIPS payment year and each subsequent payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 52. Section 414.1325 is amended by revising paragraphs (a)(1), (c) introductory text, and (d) to read as follows.

§ 414.1325 Data submission requirements.

(a) * * *

(1) Except as provided in paragraph (a)(2) of this section, or under § 414.1370 or § 414.1365(c), as applicable, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by a third party intermediary described at § 414.1400.

* * * * *

(c) *Data submission types for groups, virtual groups, subgroups, and APM Entities.* Groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using:

* * * * *

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year as applicable to MIPS eligible clinicians, groups, and virtual groups, beginning with the 2023 MIPS payment year as applicable to APM Entities, and beginning with the 2025 MIPS payment year as applicable to subgroups, MIPS eligible clinicians, groups, virtual groups, APM Entities, and subgroups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, virtual group, APM Entity, or subgroup uses the same identifier for all performance categories and all data submissions.

■ 53. Section 414.1335 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1), (a)(3) paragraph heading, and (a)(3)(i); and

■ b. Adding paragraph (a)(4).

The revisions and additions read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* A MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

(ii) A MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

* * * * *

(3) *For the CAHPS for MIPS survey measure.* (i) For the 12-month performance period, a group, virtual group, subgroup, or APM Entity that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

* * * * *

■ 54. Section 414.1340 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(2), (3), and (4);

■ b. Revising paragraph (b) introductory text;

■ c. Adding paragraphs (b)(2)(i) and (ii) and (b)(3)(i) and (ii);

■ d. Revising paragraphs (b)(4) and (d); and

■ e. Adding paragraph (e).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

* * * * *

(2) At least 60 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

(i) Applicable to an APM Entity for MIPS payment years 2023, 2024, and 2025.

(ii) Applicable to a subgroup for MIPS payment year 2025.

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, and 2028.

(b) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on Medicare Part B claims measures must submit data on:

* * * * *

(2) * * *

(i) Applicable to virtual groups starting with MIPS payment year 2020.

(ii) [Reserved]

(3) * * *

(i) Applicable to APM Entities starting with MIPS payment year 2023 and subgroups starting with MIPS payment year 2025.

(ii) [Reserved].

* * * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, and 2028.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment years 2026, 2027, and 2028.

(2) [Reserved]

(e) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 55. Section 414.1350 is amended by revising paragraphs (c)(4) through (6) and adding paragraph (c)(7) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(c) * * *

(4) For the procedural episode-based measures specified beginning with and after the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

(5) For the acute inpatient medical condition episode-based measures specified beginning with and after CY 2019 performance period/2021 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(6) For the chronic condition episode-based measures specified beginning with and after the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(7) For the care setting episode-based measures specified beginning with and after the CY 2024 performance period/2026 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

* * * * *

■ 56. Section 414.1360 is amended by revising paragraph (a) introductory text to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years, MIPS eligible clinicians, subgroups, or groups must submit data on MIPS improvement activities in one of the following manners:

* * * * *

■ 57. Section 414.1365 is amended by—

■ a. Revising paragraphs (e)(2)(ii) introductory text and (e)(3); and

■ b. Adding paragraphs (e)(4)(i) and (ii).

The revisions and addition read as follow:

§ 414.1365 MIPS Value Pathways.

* * * * *

(e) * * *

(2) * * *

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

* * * * *

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) * * *

(i) For subgroups, the affiliated group's complex patient bonus will be added to the final score.

(ii) [Reserved]

■ 58. Section 414.1375 is amended by revising paragraph (b)(2)(ii)(C), and adding paragraph (b)(2)(ii)(D) to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(A) * * *

(B) * * *

(C) Beginning with the 2024 MIPS payment year through the 2025 MIPS payment year, submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

(D) Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

* * * * *

■ 59. Section 414.1380 is amended by—

■ a. Revising paragraphs (a)(1)(i) and (ii), (b)(1)(v)(A), (b)(2)(iv)(A), (B), (C) and (E), (b)(3)(i), and (c)(2)(i)(A)(*4*)(*iii*);

■ b. Adding paragraphs (c)(2)(iv);

■ c. In paragraph (c)(3)(v) removing the term ''MIPS eligible clinicians, groups, subgroups, APM Entities and virtual groups'' and adding in its place the term ''MIPS eligible clinicians, groups, APM Entities and virtual groups;'' and

■ d. In paragraph (c)(3)(vi) removing the term ''MIPS eligible clinicians, groups, and subgroups'' and adding in its place the term ''MIPS eligible clinicians and groups''.

The revisions and additions read as follow:

§ 414.1380 Scoring.

(a) * * *

(1) * * *

(i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Prior to the CY 2023 performance period/2025 MIPS payment year, measure bonus points are available for submitting high-priority measures and submitting measures using end-to-end electronic reporting. Measure bonus points are available for small practices that submit data on at

least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Beginning with the 2025 MIPS payment year, improvement scoring is available in the cost performance category.

* * * * *

(b) * * *

(1) * * *

(v) * * *

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning in the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points.

* * * * *

(2) * * *

(iv) * * *

(A) The cost improvement score is determined at the category level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement are available. Sufficient data are available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data are not available, then the cost improvement score is zero.

(C) The cost improvement score is determined at the category-level by subtracting the cost performance category score from the previous performance period from the cost performance category score from the current performance period, then by dividing the difference by the cost performance category score from the previous performance period, and multiplying the result with the maximum available cost improvement score.

* * * * *

(E) The maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment year is zero percentage points. The maximum cost improvement score beginning with the 2025 MIPS payment year is 1 percentage point.

* * * * *

(3) * * *

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. MIPS eligible clinicians participating in APMs must attest to having completed an improvement activity or submit data for the quality and Promoting Interoperability performance categories in order to receive such credit.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) * * *

(*iii*) For the 2024 through 2026 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be distributed.

* * * * *

(iv) If CMS has granted an application for a hardship exception or any other type of exception to a MIPS eligible clinician under paragraph (c)(2)(i)(A)(*6*) or (c)(2)(i)(C)(*2*) of this section, or has identified a MIPS eligible clinician in a CMS-designated region as being affected by an automatic extreme and uncontrollable circumstances event under paragraph (c)(2)(i)(A)(*8*) or (c)(2)(i)(C)(*3*) of this section, CMS will not apply the improvement activities score described in paragraph (b)(3)(i) of this section to the MIPS eligible clinician's score.

* * * * *

■ 60. Section 414.1385 is amended—

■ a. In paragraph (a) by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, virtual group, subgroup, or group;''

■ b. In paragraph (a)(1) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group;''

■ c. By revising paragraph (a)(2);

■ d. In paragraph (a)(3) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group;''

■ e. By revising paragraph (a)(5); and

■ f. In paragraph (a)(6) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group''.

The revisions read as follows:

§ 414.1385 Targeted review and review limitations.

(a) * * *

(2) All requests for targeted review must be submitted during the targeted review request submission period, which begins on the day CMS makes available the MIPS final score, and ends 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

* * * * *

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician, virtual group, subgroup. or group that is the subject of a request for a targeted review, the information must be provided and received by CMS within 15 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for targeted review may be submitted before the end of the targeted review request submission period.

* * * * *

■ 61. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(1)(iii), (a)(2)(i), (a)(2)(ii)(A), (a)(3), and (b)(1)(ii);

■ b. Adding paragraphs (b)(1)(iii);

■ c Revising paragraphs (b)(2), (b)(3)(v)(E)(*1*) and (*2*);

■ d. Adding paragraphs (b)(3)(ix) through (xvii);

■ e. Revising paragraph (b)(4)(i)(B);

■ f. Adding paragraphs (b)(4)(i)(C) and (b)(4)(iv)(O) and (P);

■ g. Revising paragraph (e)(1) introductory text;

■ h. Adding paragraph (e)(1)(i)(F);

■ i. Revising paragraph (e)(1)(ii);

■ j. Adding paragraphs (e)(2)(iv) and (v);

■ k. Revising paragraphs (e)(3) and (4) and (f).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(1) * * *

(iii) Before the CY 2025 performance period/2027 payment year, Health IT vendor;

* * * * *

(2) * * *

(i) To be approved as a third party intermediary, an organization must meet the following requirements:

(A) The organization's principal place of business and the location in which it stores data must be in the U.S.

(B) The organization must have the ability to indicate the source of any data it will submit to CMS if the data will be derived from CEHRT, a QCDR, qualified registry, or health IT vendor.

(C) The organization must certify that it intends to provide services throughout the entire performance period and applicable data submission period.

(ii) * * *

(A) Whether the organization failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary, including past compliance; and

* * * * *

(3) For third-party intermediary program requirements:

(i) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(ii) All data submitted to CMS by a third party intermediary must be submitted in the form and manner specified by CMS.

(A) The submission of data on measures by a third party intermediary to CMS must include data on all of the MIPS eligible clinician's patients, regardless of payer, unless otherwise specified by the collection type.

(B) [Reserved]

(iii) If the clinician chooses to opt-in to participate in MIPS in accordance with § 414.130, the third party intermediary must be able to transmit that decision to CMS.

(iv) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, a third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period.

(B) Impacted entities:

(*1*) The number of clinicians, groups, virtual groups, subgroups or APM entities (inclusive of MIPS eligible, opt-in and voluntary participants) that would need to find another way to report.

(*2*) As applicable, identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition.

(C) The steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in paragraph (a)(3)(iv)(B)(1) of this section are notified of the transition in a timely manner, and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable.

(D) A detailed timeline that outlines timing for communications, the start of the transition, and completion of the transition of these clinicians, groups, virtual groups, subgroups, or APM Entities.

(E) The third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline.

(v) As a condition of its qualification and approval to participate in MIPS as a third party intermediary, a third party intermediary must:

(A) Make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

(B) Retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(C) Upon request, provide CMS with any records or data retained in connection with its operation as a third party intermediary for up to 6 years from the end of the MIPS performance period.

(vi) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(b) * * *

(1) * * *

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(A) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(B) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, A QCDR or qualified registry must support subgroup reporting.

(2) *Self-nomination.* For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the Simplified Self-Nomination process form during the self-nomination period, from July 1 and September 1 of the CY preceding the applicable performance period.

(3) * * *

(v) * * *

(E) * * *

(*1*) Uses a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

* * * * *

(ix) During the self-nomination period, a QCDR or a qualified registry must submit to CMS quality measure numbers, Promoting Interoperability identifiers, improvement activity identifiers and MVP titles.

(x) A QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) If no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) [Reserved]

(xi) A QCDR or a qualified registry must submit to CMS risk-adjusted measure results when submitting data for measures that include risk adjustment in the measure specification.

(xii) A QCDRs or qualified registry must enter into appropriate Business Associate Agreements with MIPS eligible clinicians to collect and process their data.

(xiii) A QCDR or a qualified registry must maintain records of their authorization to submit data to CMS for the purpose of MIPS participation for each NPI whom the QCDR or qualified registry will submit data to CMS for. The records must:

(A) Be annually obtained by the QCDR or qualified registry at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry.

(B) Be signed by an eligible clinician, if reporting individually, or by an authorized representative of the reporting group, subgroup, Virtual Group, or APM Entity.

(C) Records of the authorization must be maintained for 6 years after the performance period ends.

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate.

(xv) A QCDR or a qualified registry must provide to CMS, upon request, the data submitted by the QCDR or qualified registry *for purposes of MIPS.*

(xvi) A QCDR or qualified registry must attest to the following:

(A) A QCDR or a qualified registry must attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry.

(B) A QCDR or qualified registry must also attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in paragraph (b)(3)(xviii)(A) of this section to CMS upon request.

(xvii) A QCDR or a qualified registry must accept and maintain clinician data by January 1 of the applicable performance period.

(4) * * *

(i) * * *

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. The approved QCDR measure specifications must remain published through the performance period and data submission period.

(C) For a QCDR measure, the QCDR must provide, if available, data from years prior before the start of the performance period.

* * * * *

(iv) * * *

(O) QCDR measures submitted after self-nomination.

(P) More than 30 QCDR measures are submitted by a single QCDR.

* * * * *

(e) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, failed to comply with the program requirements of this section, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) * * *

(F) Once the issue has been resolved, the detailed final resolution and an update, if any, to the monitoring plan provided pursuant to § 414.1400(e)(1)(i)(C).

(ii) Publicly disclose as follows:

(A) For the purposes of the CY 2025 performance period/2027 MIPS payment year and prior reporting periods and payment years, publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary.

(2) * * *

(iv) The third party intermediary has not maintained current contact information for correspondence.

(v) The third party intermediary is on remedial action for 2 consecutive years.

(3) A data submission that contains data inaccuracies affecting the third party intermediary's clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, if the submitted data includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

* * * * *

(f) *Auditing of entities submitting MIPS data.* Third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include, but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary.

■ 62. Section 414.1405 is amended by adding paragraph (b)(9)(iii) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) * * *

(iii) The performance threshold for the 2025 MIPS payment year is 75 points. The prior period to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

■ 63. Section 414.1415 is amended by revising paragraph (a) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology (CEHRT)*—(1) *Required use of CEHRT.* To be an Advanced APM, an APM must:

(i) For QP Performance Periods ending with 2018, require at least 50 percent, or for QP Performance Periods beginning with 2019 and ending with 2024, 75 percent, of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers;

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity; and

(iii) For QP Performance Periods beginning with 2025, require use of CEHRT as defined at paragraph (3) under CEHRT at § 414.1305.

(2) [Reserved].

* * * * *

■ 64. Section 414.1420 is amended by revising paragraph (b) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM:

(1) CEHRT must be used, for QP Performance Periods ending with 2019, by at least 50 percent; and for QP Performance Periods for 2020 through 2024, by at least 75 percent, of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care; and

(2) For QP Performance Periods beginning on or after January 1, 2024, use of CEHRT (as defined in § 414.1305, paragraph (3) in the definition of ''Certified Electronic Health Record Technology (CEHRT)''), must be a requirement of participation in the APM.

* * * * *

■ 65. Section 414.1430 is amended by—
■ a. Revising paragraph (a)(1)(iv);
■ b. Adding paragraph (a)(1)(v);
■ c. Revising paragraph (a)(2)(iv);
■ d. Adding paragraph (a)(2)(v);
■ e. Revising paragraph (a)(3)(iv);
■ f. Adding paragraph (a)(3)(v);
■ g. Revising paragraph (a)(4)(iv);
■ h. Adding paragraph (a)(4)(v); and
■ i. Revising paragraph (b)(1)(i)(A) and (B), (b)(2)(i)(A) and (B), (b)(3)(i)(A) and (B), (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *
(1) * * *
(iv) 2025: 50 percent.
(v) 2026 and later: 75 percent.
(2) * * *
(iv) 2025: 40 percent.
(v) 2026 and later: 50 percent.
(3) * * *
(iv) 2025: 35 percent.
(v) 2026 and later: 50 percent.
(4) * * *
(iv) 2025: 25 percent.
(v) 2026 and later: 35 percent.
(b)
(1) * * *
(i) * * *
(A) 2021 through 2025: 50 percent.
(B) 2026 and later: 75 percent.

* * * * *

(2) * * *
(i) * * *
(A) 2021 through 2025:40 percent.
(B) 2026 and later: 50 percent.

* * * * *

(3) * * *
(i) * * *
(A) 2021 through 2025: 35 percent.
(B) 2026 and later: 50 percent.

* * * * *

(4) * * *
(i) * * *
(A) 2021 through 2025: 25 percent.
(B) 2026 and later: 35 percent.

* * * * *

■ 66. Section 414.1450 is amended by—
■ a. Adding paragraphs (a)(1)(i) and (ii); and
■ b. Revising paragraph (b)(1).

The addition and revision read as follows:

§ 414.1450 APM incentive payment.

(a) * * *

(i) For payment years 2019 through 2025, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

(ii) [Reserved]

* * * * *

(b) * * *

(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent or, with respect to payment year 2025, 3.5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 67. The authority for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 68. Amend § 415.140 in paragraph (a) by revising the definition of ''Substantive portion'' to read as follows:

§ 415.140 Conditions of payment: Split (or shared) visits.

(a) * * *

Substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit, or a substantive part of the medical decision making except as otherwise provided in this paragraph. For critical care visits, substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.

* * * * *

PART 418—HOSPICE CARE

■ 69. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Section 418.56 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

* * * * *

(a) * * *
(1) * * *

(iii) A social worker, marriage and family therapist, or a mental health counselor.

* * * * *

■ 71. Section 418.114 is amended by adding paragraphs (b)(9) and (10) to read as follows:

§ 418.114 Condition of participation: Personnel qualifications.

* * * * *

(b) * * *

(9) Marriage and family counselor as defined at § 410.53.

(10) Mental health counselor as defined at § 410.54.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 72. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–22 through 1395w–28, and 1395hh.

■ 73. Section 422.310 is amended by adding paragraph (f)(3)(iv) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *
(3) * * *

(iv) CMS determines that releasing aggregated data before reconciliation is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 74. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 75. Section 423.160 is amended by—
■ a. Revising paragraph (a)(5) introductory text;
■ b. Removing paragraph (a)(5)(i);
■ c. Redesignating paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively and revising newly redesignated paragraph (a)(5)(ii).

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

* * * * *

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 76. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 77. Section 424.205 is amended by—
■ a. In paragraph (a), by removing the definition of ''MDPP interim preliminary recognition'';
■ b. Revising paragraph (b)(1);
■ c. Removing paragraph (c);
■ d. Redesignating paragraphs (d) through (i) as paragraphs (c) through (h), respectively; and
■ e. Revising newly designated paragraph (c)(1);
■ f. Removing newly redesignated paragraph (c)(10)(iii);
■ g. Revising newly redesignated paragraph (c)(14);
■ h. Revising newly redesignated paragraphs (f)(2)(i);
■ i. Removing newly redesignated paragraph (f)(5)(iii);
■ j. Redesignating newly redesignated paragraphs (f)(5)(iv) and (v) as paragraphs (f)(5)(iii) and (iv), respectively;
■ k. Revising newly redesignated paragraph (f)(5)(iii) and paragraph (g)(1)(i)(C).

The revisions read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(b) * * *

(1) Has either preliminary, full, full plus CDC DPRP recognition.

* * * * *

(c) * * *

(1) The MDPP supplier must have and maintain preliminary, full, or full plus CDC DPRP recognition.

* * * * *

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who ever attended ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

* * * * *

(f) * * *

(2) * * *

(i) Documentation of the type of session, whether a core session, a core maintenance session, an in-person make-up session, or a virtual make-up session.

* * * * *

(5) * * *

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

* * * * *

(g) * * *

(1) * * *

(i) * * *

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves preliminary, full, or full plus CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

* * * * *

■ 78. Section 424.210 is amended by revising paragraphs (b)(2) and (d)(1) to read as follows:

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

* * * * *

(b) * * *

(2) The item or service must be reasonably connected to the CDC-approved National Diabetes Prevention Program curriculum furnished to the MDPP beneficiary during a core session or core maintenance session furnished by the MDPP supplier.

* * * * *

(d) * * *

(1) Attendance at core sessions or core maintenance sessions.

* * * * *

■ 79. Section 424.502 is amended by—
■ a. Revising the definition of ''Authorized official''; and
■ b. Adding the definitions of ''Indirect ownership interest,'' and ''Supplier'' in alphabetical order.

The revision and additions read as follows:

§ 424.502 Definitions.

* * * * *

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term ''organization'' means the enrolling entity as identified by its legal business name and tax identification number.

* * * * *

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

* * * * *

Supplier means, for purposes of this subpart, all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

* * * * *

■ 80. Section 424.516 is amended by revising paragraphs (d)(1)(iii) and (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(d) * * *

(1) * * *

(iii) A change, addition, or deletion of a practice location.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)) or a change, addition, or deletion of a practice location;

* * * * *

■ 81. Section 424.530 is amended by revising paragraph (a)(1) and adding paragraphs (a)(16), (17) and (18) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

* * * * *

(16) [Reserved]

(17) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502 of this chapter).

(F) Any other information that CMS deems relevant to its determination.

(18) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in § 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

■ 82. Section 424.535 is amended by—

■ a Revising paragraphs (a)(1) introductory text;

■ b. Adding paragraph (a)(15);

■ c. Revising paragraph (a)(17) introductory text;

■ d. Redesignating paragraphs (a)(17)(i) through (vi) as paragraphs (a)(17)(i)(A) through (F);

■ e. Adding paragraph (a)(17)(ii);

■ f. Adding paragraph (a)(23); and

■ g. Revising paragraphs (e) and (g).

The additions and revisions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

* * * * *

(15) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

(F) Any other information that CMS deems relevant to its determination.

* * * * *

(17) *Debt referred to the United States Department of Treasury.* (i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

* * * * *

(ii) Paragraph (17)(i) of this paragraph does not apply to the following situations:

(A) The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or

(B) The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.

* * * * *

(23) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 15 days of the revocation notification.

* * * * *

(g) *Effective date of revocation.* (1) Except as described in paragraphs (g)(2) and (g)(3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) Except as described in paragraph (g)(3) of this section, the revocation effective dates in the situations identified in this paragraph (g)(2) are as follows:

(i) For revocations based on a Federal exclusion or debarment, the date of the exclusion or debarment.

(ii) For revocations based on a felony conviction, the date of the felony conviction.

(iii) For revocations based on a State license suspension or revocation, the date of the license suspension or revocation.

(iv) For revocations based on a CMS determination that the provider's or supplier's practice location is non-operational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(v) For revocations based on a State license surrender in lieu of further disciplinary action, the date of the license surrender.

(vi) For revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid), the date of the termination.

(vii) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or

(B) The date that CMS establishes under § 489.55.

(viii) For revocations based on § 424.535(a)(23), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (A) through (C), the effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not.

(3) If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation is the same as the effective date of enrollment.

* * * * *

■ 83. Section 424.541 is added to read as follows:

§ 424.541 Stay of enrollment.

(a)(1) CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

(i) Is non-compliant with at least one enrollment requirement in Title 42; and.

(ii) Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

(2) During the period of any stay imposed under this section, the following apply:

(i) The provider or supplier remains enrolled in Medicare;

(ii)(A) Except as stated in paragraph (a)(2)(ii)(B) of this section, claims submitted by the provider or supplier with dates of service within the stay period will be rejected.

(B) Notwithstanding paragraph (a)(2)(ii)(A), claims submitted by the provider or supplier with dates of service within the stay period are eligible for payment (and may be resubmitted by the provider or supplier within applicable timeframes specified in Title 42) if:

(*1*) CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and

(*2*) The stay ends (as described in subsection (a)(5) of this section) on or before the 60th day of the stay period.

(*3*) A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay.

(*4*) CMS notifies the affected provider or supplier in writing of the imposition of the stay.

(*5*) A stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first.

(b)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under this section, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in paragraph (b) of this section.

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1) of this section.

(3) Any rebuttal submitted pursuant to paragraph (b) of this section must:

(i) Be in writing.

(ii) Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.

(iii) Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.

(iv) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If

the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(4) The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of this section constitutes a waiver of all rebuttal rights under this section.

(5) Upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

(6) A determination made under paragraph (b) of this section is not an initial determination under 42 CFR 498.3(b) and therefore not appealable.

(7) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5) of this section.

(8)(i) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a deactivation or revocation, pending the completion of the review described in paragraph (b)(5) of this section.

(ii)(A) If CMS deactivates the provider or supplier during the stay, any rebuttal to the stay that the provider or supplier submits that meets the requirements of paragraph (b) of this section is combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal pursuant to this section.

(B) In all cases other than that described in paragraph (b)(8)(ii)(A) of this section, a stay rebuttal that was submitted in compliance with the requirements of paragraph (b) of this section is considered separately and independently of any review of any other rebuttal or, for revocations, appeal under 42 CFR part 498.

■ 84. Section 424.555 is amended by revising paragraph (b) to read as follows:

§ 424.555 Payment liability.

* * * * *

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked, or if the provider or supplier is currently under a stay of enrollment (except as stated in § 424.541(a)(2)(ii)(B)). The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 85. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 86. Section 425.20 is amended—

■ a. By revising the definitions of ''Assignable beneficiary'' and ''Assignment window'';

■ b. In the definition of ''At-risk beneficiary'' by—

■ i. Removing the periods at the end of paragraphs (5) and (6), and adding in their places semicolons; and

■ ii. Revising paragraph (7);

■ c. By adding the definitions of ''Beneficiary eligible for Medicare CQMs'' and ''Expanded window for assignment'' in alphabetical order;

■ d. In the definition of ''Experienced with performance-based risk Medicare ACO initiatives'' by revising paragraph (2);

■ e. In the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives'' by revising paragraph (2);

■ f. In the definition of ''Rural health center'' by—

■ i. Removing the word ''center'' and adding in its place the word ''clinic''; and

■

■ ii. Removing the phrase ''under § 405.2401(b)'' and adding in its place the phrase ''under § 405.2401(b) of this chapter''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). For performance year 2025 and subsequent performance years, a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary—

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

* * * * *

Assignment window means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

At-risk beneficiary * * *

(7) Is entitled to Medicare because of disability; or

* * * * *

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

(1) A Medicare fee-for-service beneficiary (as defined at § 425.20) who –

(i) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(ii) Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(2) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

* * * * *

Expanded window for assignment means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

Experienced with performance-based risk Medicare ACO initiatives * * *

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO

initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives

* * *

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

■ 87. Section 425.106 is amended by revising paragraph (c)(5) to read as follows:

§ 425.106 Shared governance.

* * * * *

(c) * * *

(5)(i) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

(ii) For agreement periods beginning before January 1, 2024, in cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance.

* * * * *

■ 88. Section 425.204 is amended by—

■ a. In paragraph (c)(3)(ii), by removing the reference ''(c)(2)'' and adding in its place the reference ''§ 425.106(c)(2)''; and

■ b. Revising paragraph (c)(3)(iii).

The revision reads as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(3) * * *

(iii) If seeking an exception to the requirement at § 425.106(c)(3), for agreement periods beginning before January 1, 2024, why the ACO is unable to meet the requirement and how it will involve ACO participants in innovative ways in ACO governance.

* * * * *

■ 89. Section 425.302 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) For performance years starting on January 1, 2019 through 2024, the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

■ 90. Section 425.308 is amended by adding paragraph (b)(9) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(9) For performance year 2025 and subsequent performance years, the total number of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants (QPs), or Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category as set forth in § 425.507 that is comprised of the following—

(i) The number of ACO participants, ACO providers/suppliers, and ACO professionals that meet the requirements of § 425.507(a) and are not excluded under § 425.507(b) for the applicable performance year; and

(ii) The number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under § 425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable performance year.

* * * * *

■ 91. Section 425.316 is amended by revising paragraphs (e)(2) introductory text and (e)(2)(i) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(e) * * *

(2) If CMS determines that an ACO participating in advance investment payments became experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high revenue ACO during any performance year of its agreement period, CMS—

(i) Will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

* * * * *

■ 92. Section 425.400 is amended—

■ a. By revising paragraph (a)(2)(ii);

■ b. In paragraph (a)(3)(i), by removing the phrase ''most recent 12 months'' and adding in its place the phrase ''most recent 12 or 24 months, as applicable,'';

■ c. By revising paragraph (c)(1)(vii) introductory text;

■ d. By adding paragraph (c)(1)(viii); and

■ e. By revising paragraphs (c)(2)(i) introductory text and (c)(2)(ii).

The revisions and addition read as follows:

§ 425.400 General.

(a) * * *

(2) * * *

(ii) Assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404.

* * * * *

(c) * * *

(1) * * *

(vii) For the performance year starting on January 1, 2023 as follows:

* * * * *

(viii) For the performance year starting on January 1, 2024, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*5*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*6*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*7*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*8*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(viii)).

(*9*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*10*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*11*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*12*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*13*) 99439 (code for non-complex chronic care management).

(*14*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*15*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*16*) 99495 and 99496 (codes for transitional care management services).

(*17*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for social determinants of health risk assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in ETA hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G2010 (code for the remote evaluation of patient video/images).

(*14*) G2012 and G2252 (codes for virtual check-in).

(*15*) G2058 (code for non-complex chronic care management).

(*16*) G2064 and G2065 (codes for principal care management services).

(*17*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*18*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*19*) G2214 (code for psychiatric collaborative care model).

(*20*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(viii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(viii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) * * *

(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, when the assignment window or applicable expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

* * * * *

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window or applicable expanded window for assignment (as defined in § 425.20), when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 93. Section 425.402 is amended—

■ a. By revising paragraph (b)(1);

■ b. By adding paragraph (b)(5);

■ c. By revising paragraph (c) introductory text; and

■ d. In paragraph (e)(2)(ii)(A), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)''.

The revisions and addition read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(b) * * *

(1) Identify all beneficiaries that had at least one primary care service during the applicable assignment window with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

* * * * *

(5) For performance year 2025 and subsequent performance years, CMS employs the following third step to assign Medicare fee-for-service beneficiaries who were not identified by the criterion specified in paragraph (b)(1) of this section:

(i) Identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window.

(ii) For the beneficiaries identified in paragraph (b)(5)(i) of this section, identify those beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iii) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(5)(ii) of this section by ACO professionals in the ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iv) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations

as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second and third step of the assignment methodology in paragraphs (b)(4) and (5) of this section include physicians who have one of the following primary specialty designations:

* * * * *

■ 94. Section 425.506 is amended by revising paragraph (f) introductory text to read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019 through 2024, ACOs in a track that—

* * * * *

■ 95. Section 425.507 is added to subpart F to read as follows:

§ 425.507 Incorporating Promoting Interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2025.

(a) For performance years beginning on or after January 1, 2025, unless otherwise excluded under paragraph (b) of this section, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305 of this chapter) must satisfy all of the following:

(1) Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O at the individual, group, virtual group, or APM entity level.

(2) Earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

(b) An ACO participant, ACO provider/supplier, or ACO professional is excluded from the requirements specified in paragraph (a) of this section in accordance with applicable policies that exclude or otherwise exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414 subpart O, provided however, that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified in paragraph (a) solely on the basis of being a QP or Partial QP. Applicable exclusions may include:

(1) Low volume threshold as set forth at § 414.1310(b)(1)(iii) of this chapter.

(2) Eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician as set forth in § 414.1310(b)(2) of this chapter.

(3) Reweighting of the MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2) of this chapter.

■ 96. Section 425.512 is amended—

■ a. By revising paragraph (a)(2);

■ b. In paragraph (a)(5)(i) introductory text, by removing the phrase ''paragraph (a)(2) of this section'' and adding in its place the phrase ''paragraphs (a)(2) and (a)(7) of this section'';

■ c. By revising paragraphs (a)(5)(i)(A)(*2*), (a)(5)(iii)(A) and (B);

■ d. By adding paragraph (a)(7);

■ e. In paragraph (b)(1)—

■ i. By adding a new first sentence;

■ ii. By removing the reference ''paragraph (b)(2)'' and adding in its place the reference ''paragraph (b)(3)'';

■ f. By redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;

■ g. By adding new paragraph (b)(2);

■ h. By revising the newly redesignated paragraph (b)(3)(ii)(B);

■ i. In newly redesignated paragraph (b)(3)(iii), by removing the phrase ''paragraph (b)(2)(ii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(ii) of this section'';

■ j. By revising newly redesignated paragraph (b)(3)(iv)(A);

■ k. In newly redesignated paragraph (b)(3)(iv)(B), by removing the phrase ''paragraph (b)(2)(iv)(A) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(A) of this section'';

■ l. In newly redesignated paragraph (b)(3)(v)—

■ i. By removing the phrase ''paragraph (b)(2)(iv)(B) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(B) of this section'';

■ ii. By removing the phrase ''paragraph (b)(2)(iii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iii) of this section'';

■ iii. By removing the phrase ''paragraph (b)(2)(iv) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv) of this section'';

■ m. In newly redesignated paragraph (b)(4) introductory text, by removing the phrase ''paragraphs (b)(1) and (b)(2) of this section'' and adding in its place the phrase ''paragraphs (b)(1) through (b)(3) of this section'';

■ n. By revising newly redesignated paragraph (b)(4)(i); and

■ o. By revising paragraph (c)(3).

The revisions and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO will meet the quality performance standard if it meets the requirements under this paragraph (a)(2).

(i) For performance years 2022 and 2023. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey, for the applicable performance year.

(ii) For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iii) For performance year 2025 and subsequent performance years. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

* * * * *

(5) * * *

(i) * * *

(A) * * *

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or

higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

* * * * *

(iii) * * *

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

(B) For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

* * * * *

(7) For performance years 2024 and subsequent performance years, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP measure set and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when the ACO meets either of the following:

(i) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(ii) At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(b) * * *

(1) For performance year 2023. * * *

(2) For performance year 2024 and subsequent performance years. For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

(3) * * *

(ii) * * *

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

* * * * *

(iv) * * *

(A) (*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(3)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

* * * * *

(4) * * *

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

* * * * *

(c) * * *

(3) If CMS determines the ACO meets the requirements of paragraph (c)(1) of this section and the ACO reports quality data via the APP, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

§ 425.600 [Amended]

■ 97. Amend § 425.600 in paragraph (f)(4)(ii) by removing the reference ''425.656(d)'' and adding in its place the reference ''425.656(e)''.

§ 425.601 [Amended]

■ 98. Amend § 425.601 in paragraph (a) introductory text by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)''.

§ 425.611 [Amended]

■ 99. Amend § 425.611 in paragraph (c)(2)(iii) by removing the reference ''§ 425.652(a)(8)(iv)'' and adding in its place the reference ''§ 425.658(c)(1)(ii)''.

■ 100. Section 425.630 is amended—

■ a. By revising paragraphs (b)(2) and (3), (e)(3), (f) introductory text, and (g)(4);

■ b. In paragraph (h)(1)(i), by removing ''or'' at the end of the paragraph;

■ c. In paragraph (h)(1)(ii), by removing ''.'' at the end of the paragraph, and adding in its place ''; or''; and

■ d. By adding paragraph (h)(1)(iii) and paragraph (i).

The revisions and additions read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(b) * * *

(2) CMS has determined that the ACO is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years and participates in the BASIC track's glide path as follows:

(i) For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.

(ii) For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.

(iii) For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

* * * * *

(e) * * *

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period, except if the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later and immediately enters a new agreement period to continue its participation in the Shared Savings Program, the ACO must spend its advance investment payments within 5 performance years of when it first received advance investment payments and repay to CMS any unspent funds remaining at the end of that fifth performance year.

* * * * *

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

* * * * *

(g) * * *

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received, unless the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later during the agreement period in which it received advance investment payments and immediately enters a new agreement period to continue its participation in the program. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

* * * * *

(h) * * *

(1) * * *

(iii) Voluntarily terminates its participation agreement in accordance with § 425.220(a).

* * * * *

(i) *Reporting information on advance investment payments.* The ACO must report information on its receipt of and use of advance investment payments, as follows:

(1) The ACO must publicly report information about the ACO's use of advance investment payments for each performance year, in accordance with § 425.308(b)(8).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(8).

§ 425.650 [Amended]

■ 101. Amend § 425.650 in paragraph (a) by removing the references ''§§ 425.601, 425.602, and 425.603'' and adding in their place the references ''§§ 425.601, 425.602, 425.603, and 425.659''.

■ 102. Section 425.652 is amended—

■ a. In paragraph (a) introductory text, by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)'';

■ b. By revising paragraphs (a)(5)(v)(A), (a)(8), (a)(9) introductory text, and (a)(9)(ii);

■ c. In paragraph (a)(9)(iv), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)'';

■ d. In paragraph (a)(9)(v), by removing the phrase '', or a combination of these two adjustments'';

■ e. By adding paragraphs (a)(9)(vi) and (b)(2)(ii)(C); and

■ f. By revising paragraph (b)(2)(iv)(A).

The revisions and additions read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(5) * * *

(v) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(8) Except as provided in paragraph (a)(8)(iii) of this section, adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(i) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(ii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(iii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(iv) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(A) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) The prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(v) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, and for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. To adjust the benchmark, CMS does the following:

* * * * *

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(vi) Redetermines factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1).

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) Multiply the growth rate calculated in this paragraph (b)(2)(ii) by a regional risk score growth cap adjustment factor computed as described in § 425.655.

* * * * *

(iv) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 103. Section 425.654 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 425.654 Calculating county expenditures and regional expenditures.

(a) * * *

(1) * * *

(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 104. Section 425.655 is added to subpart G to read as follows:

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

(a) *General.* This section describes the methodology for calculating the regional risk score growth cap adjustment factor that will be applied to the regional growth rate component of the three-way blend used to update the historical benchmark as described in § 425.652(b) for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculating county risk scores.* CMS does all of the following to determine county prospective HCC and demographic risk scores for use in calculating the ACO's regional risk scores:

(1) Determines average county prospective HCC and demographic risk scores for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(2) Makes separate risk score calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Calculating regional risk scores.* CMS calculates an ACO's regional prospective HCC and demographic risk scores by:

(1) Weighting the county-level risk scores determined under paragraph (b) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (c)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

(d) *Determining aggregate growth in regional risk scores.* CMS determines aggregate growth in regional prospective HCC and demographic risk scores by:

(1) Determining growth in regional prospective HCC and demographic risk scores determined in paragraph (c) of this section (expressed as a ratio of the performance year regional risk score to the BY3 regional risk score) for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's regionally adjusted historical benchmark expenditures for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(e) *Determining the cap on regional risk score growth.* CMS determines the cap on regional prospective HCC risk score growth by:

(1) Computing the sum of the aggregate growth in regional demographic risk scores as determined in paragraph (d)(2) of this section and 3 percentage points.

(2) Calculating the ACO's aggregate market share by calculating the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the performance year as determined in § 425.652(b)(2)(iv) across the populations described in § 425.652(b)(1). In calculating this weighted average, the weight applied to the share for each Medicare enrollment type is equal to the ACO's performance year assigned beneficiary person years for that enrollment type.

(3) Adding to the sum computed in paragraph (e)(1) of this section an amount equal to the product of:

(i) The ACO's aggregate market share as determined in paragraph (e)(2) of this section.

(ii) The difference between the aggregate growth in regional prospective HCC risk scores as determined in paragraph (d)(2) of this section and the sum determined in paragraph (e)(1) of this section. This difference is subject to a floor of zero.

(f) *Determining the regional risk score growth cap adjustment factor.* CMS determines the regional risk score growth cap adjustment factor for each Medicare enrollment type to be applied in calculating the regional growth rate described in § 425.652(b) by comparing the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section and, if applicable, the growth in regional prospective HCC risk scores for individual Medicare enrollment types as determined in paragraph (d)(1) of this section with the cap determined in paragraph (e) of this section.

(1) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal to 1 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section exceeds the cap determined in paragraph (e) of this section, CMS will compare the growth in regional prospective HCC risk scores for each Medicare enrollment type as determined in paragraph (d)(1) of this section with the cap on regional risk score growth determined in paragraph (e) of this section.

(i) If the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to 1.

(ii) If the growth in regional prospective HCC risk scores determined in paragraph (d)(1) for the enrollment type exceeds the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section divided by the cap on regional risk score growth determined in paragraph (e) of this section.

■ 105. Section 425.656 is amended—

■ a. By revising paragraph (b)(3);

■ b. In paragraph (c)(2), by removing the phrase ''paragraph (d) of this section'' and adding in its place the phrase ''paragraph (e) of this section'';

■ c. By redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively;

■ d. By adding new paragraph (d);

■ e. In newly redesignated paragraph (e)(5)(ii), by removing the phrase ''paragraph (d)(5)(i) of this section'' and adding in its place the phrase ''paragraph (e)(5)(i) of this section'';

■ f. In newly redesignated paragraph (e)(5)(iv), by removing the phrase ''paragraphs (d)(1) through (3)'' and adding in its place the phrase ''paragraphs (e)(1) through (3)''; and

■ g. In newly redesignated paragraph (f) introductory text, by removing the phrase ''paragraphs (b) through (d)'' and adding in its place the phrase ''paragraphs (b) through (e)''.

The revision and addition read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

* * * * *

(b) * * *

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(d) *Expression of the regional adjustment as a single value.* (1) CMS expresses the regional adjustment as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values determined in paragraph (c) of this section.

(2) CMS uses the regional adjustment expressed as a single value for purposes of determining the adjustment, if any, that will be applied to the benchmark in accordance with § 425.652(a)(8).

* * * * *

■ 106. Section 425.658 is amended—

■ a. In paragraph (b)(3)(i), by removing the sentence ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.'';

■ b. By revising paragraph (c) and adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(c) *Calculate the per capita prior savings adjustment.* (1) If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 50 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(2) [Reserved]

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

(e) *Recalculation of the prior savings adjustment during an agreement period.* (1) The ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

(2) For a new ACO identified as a re-entering ACO, the prior savings adjustment is recalculated for changes to savings or losses for a performance year used in the prior savings adjustment calculation, if the savings or losses of the ACO in which the majority of the new ACO's participants were participating change in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

■ 107. Section 425.659 is added to subpart G to read as follows:

§ 425.659 Calculating risk scores used in Shared Savings Program benchmark calculations.

(a) *General.* CMS accounts for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting, and updating the ACO's historical benchmark.

(b) *Prospective Hierarchical Condition Category (HCC) risk score calculation.* In determining Medicare FFS beneficiary prospective HCC risk scores for a performance year and each benchmark year of the ACO's agreement period, CMS does the following:

(1) CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations as follows:

(i) In calculating risk scores for Medicare FFS beneficiaries for a performance year, CMS applies the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.

(ii) For agreement periods beginning before January 1, 2024, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(iii) For agreement periods beginning on January 1, 2024, and in subsequent years, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year, as specified under paragraph (b)(1)(i) of this section, in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(2) CMS does the following to calculate the prospective HCC risk scores identified in paragraph (b)(1) of this section for a benchmark or performance year:

(i) Removes the Medicare Advantage coding intensity adjustment, if applicable.

(ii) Renormalizes prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on the national assignable FFS population for the relevant benchmark or performance year.

(iii) Calculates the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries).

■ 108. Section 425.702 is amended—

■ a. In paragraph (c)(1)(ii) introductory text, by removing the phrase ''process development'' and adding in its place the phrase ''protocol development'';

■ b. By revising paragraph (c)(1)(ii)(A)(*3*); and

■ c. By adding paragraph (c)(1)(iii).

The revision and addition read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) * * *

(*3*) Beneficiary identifier.

* * * * *

(iii) For performance year 2024 and subsequent performance years, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Beneficiary name.

(*2*) Date of birth.

(*3*) Beneficiary identifier.

(*4*) Sex.

(B) Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Demographic data such as enrollment status.

(*2*) Health status information such as risk profile and chronic condition subgroup.

(*3*) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 109. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 110. Section 455.416 is amended by revising paragraph (c) to read as follows:

§ 455.416 Termination or denial of enrollment.

* * * * *

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act and under the Medicaid program or CHIP of any other State, and is currently included in the termination database under § 455.417.

* * * * *

■ 111. Section 455.417 is added to read follows:

§ 455.417 Termination periods and termination database periods.

(a)(1) Subject to paragraph (c) of this section, a provider remains in the termination notification database referenced in section 1902(ll) of the Act for a period that is the lesser of:

(i) The length of the termination period imposed by the State that initially terminated the provider or the reenrollment bar (as described in § 424.535(c) of this chapter) imposed by the Medicare program in the case of a Medicare revocation; or

(ii) 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

(2) All other State Medicaid agencies or CHIPs must terminate or deny the provider from their respective programs (pursuant to § 455.416(c)) for at least the same length of time as the termination database period described in paragraph (a)(1) of this section.

(b)(1) Nothing in paragraph (a) of this section prohibits:

(i) The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

(ii) Another State from terminating the provider, based on the original State's termination, for a period:

(A) Of greater than 10 years; or

(B) That is otherwise longer than that imposed by the initially terminating State.

(2) The period established under paragraph (b)(1)(ii) of this section must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a) of this section.

(c)(1) If the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State agency or Medicare, CMS removes the provider from the termination database after the reinstatement has been reported to CMS.

(2) If the provider is removed from the database pursuant to paragraph (c)(1), CMS may immediately reinclude the provider in the database (with no interval between the 2 periods) if a basis for doing so exists under part 455 or 424 of this chapter.

(d) For purposes of this section only, terminations under § 455.416(c) are not considered ''for cause'' terminations and therefore need not be reported to CMS for inclusion in the termination database.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 112. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 113. Section 489.30 is amended by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraphs (b)(6) and (7).

The revision and additions read as follows:

§ 489.30 Allowable charges: Deductibles and coinsurance.

* * * * *

(b) * * *

(1) The basic allowable charges are the Part B annual deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible, except as specified in paragraphs (b)(6) and (7) of this section.

* * * * *

(6) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished on or after April 1, 2023, in a calendar quarter in which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, the basic allowable charges are the Part B annual deductible and 20 percent of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter.

(7) In the case of insulin furnished on or after July 1, 2023 through an item of durable medical equipment covered under section 1861(n) of the Act, the coinsurance amount shall not exceed $35 for a month's supply of such insulin each calendar month. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs. In addition, the coinsurance amount shall not exceed $105.00 for 3 months' supply of insulin. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs and the 2 following calendar months.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 114. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 115. Section 491.2 is amended by—

■ a. Adding the definitions of ''Certified nurse-midwife (CNM)'', ''Clinical psychologist (CP)'', ''Clinical social worker'', ''Marriage and family therapist'', and ''Mental health counselor'' in alphabetical order; and

■ b. Revising the definition of ''Nurse practitioner''.

The additions and revisions read as follows:

§ 491.2 Definitions.

* * * * *

Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable

education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.

* * * * *

Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at § 410.53 of this chapter.

Mental health counselor means an individual who meets the applicable education, training, and other requirements at § 410.54 of this chapter.

Nurse practitioner means a person who meets the applicable State requirements governing the qualifications for nurse practitioners, and who meets at least one of the following conditions:

(1) Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

* * * * *

■ 116. Section 491.8 is amended by revising paragraphs (a)(3) and (6) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(3) The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

* * * * *

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

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PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 117. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 118. In § 495.4 amend the definition of ''Certified electronic health record technology (CEHRT)'' by revising paragraph (2) introductory text to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315–

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 119. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 120. In § 498.2 amend the definition of ''Supplier'' by revising paragraph (6) to read as follows:

§ 498.2 Definitions.

* * * * *

Supplier * * *

(6) For purposes of this part, a physical therapist in private practice, an occupational therapist in private practice, or a speech-language pathologist.

* * * * *

PART 600—ADMINISTRATION, ELIGIBILITY, ESSENTIAL HEALTH BENEFITS, PERFORMANCE STANDARDS, SERVICE DELIVERY REQUIREMENTS, PREMIUM AND COST SHARING, ALLOTMENTS, AND RECONCILIATION

■ 121. The authority citation for part 600 continues to read as follows:

Authority: Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111—152, 124 State. 1029).

■ 122. Section 600.125 to revised read as follows:

§ 600.125 Revisions to a certified BHP Blueprint.

(a) *Submission of revisions.* A State may seek to revise its certified Blueprint in whole or in part at any time through the submission of a revised Blueprint to HHS. A State must submit a revised Blueprint to HHS whenever necessary to reflect—

(1) Changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the certified Blueprint;

(2) Significant changes that alter core program operations under 600.145(f) or the BHP benefit package; or

(3) Changes to enrollment, disenrollment, and verification policies described in the certified Blueprint.

(b) *Submission and effective dates.* The effective date of a revised Blueprint may not be earlier than the first day of the quarter in which an approvable revision is submitted to HHS. A revised Blueprint is deemed received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes in track changes.

(c) *Timing of HHS review.* (1) A revised Blueprint will be deemed approved unless HHS, within 90 calendar days after receipt of the revised Blueprint, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) If HHS requests additional information, the 90-day review period for HHS action on the revised Blueprint—

(i) Stops on the day HHS sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day of the original 90-day review period after HHS receives a complete response from the State including all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(3) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, HHS will consider the 90th day to be the next business day.

(4) HHS may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the revised Blueprint.

(5) HHS may disapprove a Blueprint that is not consistent with section 1331 of the ACA or the regulations set forth in this Part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

(d) *Continued operation.* The State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless—

(1) The State adopts a revised Blueprint by obtaining approval by HHS under this section;

(2) The State follows the procedures described in § 600.140(a) for terminating a BHP;

(3) The State follows the procedures described in § 600.140(b) for suspending a BHP;

(4) The Secretary withdraws certification of a BHP under 600.142.

(e) *Withdrawal of a revised Blueprint.* A State may withdraw a proposed Blueprint revision during HHS' review if the State has not yet implemented the proposed changes and provides written notice to HHS.

(f) *Reconsideration of decision.* HHS will accept a State request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against the standards for certification if requested.

(g) *Public health emergency.* For the Public Health Emergency, as defined in § 400.200 of this chapter, the State may submit to the Secretary for review and certification a revised Blueprint, in the form and manner specified by HHS, that makes temporary significant changes to its BHP that are directly related to the Public Health Emergency and would increase enrollee access to coverage. Such revised Blueprints may have an effective date retroactive to the first day of the Public Health Emergency and through the last day of the Public Health Emergency, or a later date if requested by the State and certified by HHS. Such revised Blueprints are not subject to the public comment requirements under § 600.115(c).

■ 123. Section 600.135 is amended by revising the section heading and paragraph (a) to read as follows:

§ 600.135 Notice and timing of HHS action on an initial BHP Blueprint submission.

(a) *Timely response.* HHS will act on all initial Blueprint certification requests in a timely manner.

* * * * *

■ 124. Section 600.140 is amended by adding introductory text and paragraphs (b) and (c) to read as follows:

§ 600.140 State termination or suspension of a BHP.

A State that no longer wishes to operate a BHP may terminate or suspend its BHP.

* * * * *

(b) If a State decides to suspend its BHP, or to request an extension of a previously-approved suspension, the State must:

(1) Submit to the Secretary a suspension application or a suspension extension application, as applicable. The suspension or suspension extension application must:

(i) Demonstrate that the benefits BHP-eligible individuals will receive during the suspension are at least equal to the benefits provided under the certified BHP Blueprint in effect on the effective date of suspension;

(ii) Demonstrate that the median actuarial value of the coverage provided to the BHP-eligible individuals during the suspension is no less than the median actuarial value of the coverage under the certified BHP Blueprint in effect on the effective date of suspension;

(iii) Demonstrate that the premiums imposed on BHP-eligible individuals during the suspension are no higher than the premiums charged under the certified BHP Blueprint in effect on the effective date of suspension, except that premiums imposed during the suspension may be adjusted for inflation, as measured by the Consumer Price Index;

(iv) Demonstrate that the eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305;

(v) Describe the period, not to exceed 5 years, that the State intends to suspend its BHP or to extend a previously-approved suspension;

(vi) Be submitted at least 9 months in advance of the proposed effective date of the suspension or extension, except States seeking to suspend a BHP in 2024 must submit an application within 30 days of the effective date of this provision; and

(vii) Include an evaluation of the coverage provided to BHP eligible individuals during the suspension period, if the State is seeking an extension.

(2) Resolve concerns expressed by HHS and obtain approval by the Secretary of the suspension or suspension extension application. Suspensions may not be in effect prior to approval by HHS, except for States seeking to suspend a BHP in 2024.

(3) At least 90 days prior to the effective date of the suspension, provide written notice to all enrollees and participating standard health plan offerors that it intends to suspend the program, if the enrollees will experience a change in coverage, or standard health plan offerors will experience a change in the terms of coverage. The notices to enrollees must include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State. Notices must meet the accessibility and readability standards at 45 CFR 155.230(b).

(4) Within 12 months of the suspension effective date, submit to HHS the data required by § 600.610 to complete the financial reconciliation process with HHS.

(5) Submit the annual report required by § 600.170(a)(2), describing the balance of the trust fund, and any interest accrued on such amount.

(6) Annually, remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period in the form and manner specified by HHS.

(7) At least 9 months before the end of the suspension period described in paragraph (b)(1)(iv) of this section, or earlier date elected by the State, the State must submit to HHS a transition plan that describes how the State will reinstate its BHP consistent with the requirements of this part, or terminate the program in accordance with paragraph (a) of this section. The State must meet the noticing requirements of paragraph (b)(3) of this section prior to terminating or reinstating the BHP.

(c) The Secretary may withdraw approval of the suspension plan, if the terms of paragraph (b) of this section are not met, if the State ends implementation of the alternative

coverage program for any reason, or if HHS finds significant evidence of beneficiary harm, financial malfeasance, fraud, waste, or abuse by the BHP agency or the State consistent with § 600.142 of this part. If HHS withdraws the approved suspension plan, the State must reinstate its BHP under the terms of this part, or terminate the program under paragraph (a) of this section.

(1) The Secretary may withdraw approval of a suspension under this section only after the Secretary provides the State with notice of the findings upon which the Secretary is basing the withdrawal; a reasonable period for the State to address the finding; and an opportunity for a hearing before issuing a final finding.

(2) The Secretary must make every reasonable effort to work with the State to resolve proposed findings without withdrawing approval of a suspension and in the event of a decision to withdraw approval, will accept a request from the State for reconsideration.

(3) The effective date of an HHS determination withdrawing approval of the suspension plan shall not be earlier than 120 days following issuance of a final finding under paragraph (d)(1) of this section.

(4) Within 30 days following a final finding under paragraph (d)(1) of this section, the State must submit a transition plan to HHS.

■ 125. Section 600.145 is amended by revising paragraphs (a) and (f)(2) to read as follows:

§ 600.145 State program administration and operation.

(a) *Program operation.* The State must implement its BHP in accordance with:

(1) The approved and fully certified State BHP Blueprint, any approved modifications to the State BHP Blueprint and the requirements of this chapter and applicable law; or

(2) The approved suspension application described in § 600.140.

* * * * *

(f) * * *

(2) Eligibility and health services appeals as specified in 600.335.

* * * * *

■ 126. Section 600.170 amended by revising paragraph (a) to read as follows:

§ 600.170 Annual report content and timing.

(a) *Content.* (1) The State that is operating a BHP must submit an annual report that includes any evidence of fraud, waste, or abuse on the part of participating providers, plans, or the State BHP agency known to the State, and a detailed data-driven review of compliance with the following:

(i) Eligibility verification requirements for program participation as specified in § 600.345.

(ii) Limitations on the use of Federal funds received by the BHP as specified in § 600.705.

(iii) Requirements to collect quality and performance measures from all participating standard health plans focusing on quality of care and improved health outcomes as specified in sections 1311(c)(3) and (4) of the Affordable Care Act and as further described in § 600.415.

(iv) Requirements specified by the Secretary at least 120 days prior to the date of the annual report as requiring further study to assess continued State compliance with Federal law, regulations and the terms of the State's certified Blueprint, based on a Federal review of the BHP pursuant to § 600.200, and/or a list of any outstanding recommendations from any audit or evaluation conducted by the HHS Office of Inspector General that have not been fully implemented, including a statement describing the status of implementation and why implementation is not complete.

(2) A State that has suspended its BHP under § 600.140(b) of this part must submit an annual report that includes the following:

(i) The balance of the BHP trust fund and any interest accrued on that balance;

(ii) An assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 of this part continues to meet the standards described in § 600.140(b)(1)(i), (ii), and (iii) of this part; and

(iii) Any additional information specified by the Secretary at least 120 days prior to the date of the annual report.

* * * * *

■ 127. Section 600.330 is amended by adding paragraph (f) to read as follows:

§ 600.330 Coordination with other insurance affordability programs.

* * * * *

(f) *Accessibility.* Eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency.

■ 128. Section 600.335 is amended by—

■ a. Revising paragraph (b);

■ b. Redesignating paragraph (c) as paragraph (d); and

■ c. Adding new paragraph (c).

The revision and addition read as follows:

§ 600.335 Appeals.

* * * * *

(b) *Appeals process.* Individuals must be given the opportunity to appeal the following actions through the appeals rules of the State's Medicaid program, unless granted an exception under paragraph (c) of this section:

(1) BHP eligibility determinations; and

(2) Delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service, after individuals exhaust appeals or grievances through the BHP standard health plans.

(c) *Exception.* Subject to HHS approval, a state may request to follow an appeals process for BHP eligibility determinations and health service matters that differs from the State's Medicaid program. In its request, the State must provide a clear description of the responsibilities and functions delegated to such an entity and ensure that:

(1) The State has oversight of any entity delegated the authority to administer appeals;

(2) The agency to which eligibility determinations or appeals decisions are delegated complies with all relevant Federal and State law, regulations and policies; and

(3) The agency to which eligibility determinations or appeals decisions are delegated informs applicants and beneficiaries how they can directly contact and obtain information from the agency.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures, and specialty measures sets will continue to apply for the CY 2024 performance period/2026 MIPS payment year and future years. Previously finalized measures and specialty measures sets are located in the CY 2017 through CY 2023 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, and 87 FR 70250 through 70633. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a consensus-based entity (CBE) are shown in Table A of this Appendix as follows: CBE # / eCQM CBE #.

Table Group A: New Quality Measures Finalized and Not Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

A.1. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)

Category	Description
CBE # / eCQM CBE #:	CBE 3633e (clinician level) CBE 3662e (clinician group level)
Quality #:	494 eCQM ID CMS1056v1
Description:	This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.
Measure Steward:	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)
Numerator:	Calculated CT size-adjusted dose greater than or equal to a threshold specific to the CT dose and Image Quality Category, or Calculated CT Global Noise value greater than or equal to a threshold specific to the CT Dose and Image Quality Category.
Denominator:	All CT scans in adults aged 18 years and older at the start of the measurement period that have a CT Dose and Image Quality Category and were performed during the measurement period.
Exclusions:	Denominator, where a CT scan with a CT Dose and Image Quality Category = full body.
Measure Type:	Intermediate Outcome
High Priority Measure:	Yes
Collection Type:	eCQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure to enhance patient safety and drive quality care in diagnostic radiology and assess outcomes of care for patients undergoing diagnostic CT imaging. This measure will improve patient safety by supporting clinician actions that are associated with a reduction in population-level cancer risks, in addition to associated cancer-related morbidity and mortality. As a result, this measure may also reduce the cost of caring for these patients. In the U.S., over 80 million CT scans are performed annually, and the radiation doses associated with these exams are a safety issue, as unnecessarily high radiation doses lead to harm by exposing patients to elevated cancer risk.[1] Numerous consensus-based clinical recommendations and guidelines ask radiologists to track, optimize, and lower the radiation doses they use for CT. These recommendations and guidelines are based on evidence that radiation doses are highly variable across institutions, higher than needed for diagnosis, and can lead to excessive patient harm. These recommendations and guidelines also indicate that physicians collect and compare their doses to benchmarks and reduce their doses if they are found to routinely exceed these benchmarks.[2 3] This measure will support radiologists with a clinically relevant outcome measure within MIPS and meet the high priority definition for MIPS reporting as an outcome and patient safety measure. This measure received support for rulemaking from the Measure Applications Partnership (MAP) and was endorsed by a CBE (CBE 3633e/3662e). This measure will enhance the accessibility of data contained in electronic clinical data systems for increased efficiency, which could decrease clinician burden. Using electronic and standardized data already collected as part of routine clinical care, this measure assesses the radiation dose for every exam with complete information and assessment of imaging quality to ensure that efforts to reduce radiation dose do not result in poor image quality. It is also consistent with our emphasis on expanding the use of digital quality measures. The measure steward has created "as low as reasonably achievable" (ALARA) translation software that ingests radiology

	variables from Picture Archiving and Communication System (PACS), Radiology Information System (RIS), and electronic health records (EHR) systems for use with this quality measure. The software translates data from these systems into new variables that are specified in Logical Observation Identifiers Names and Codes (LOINC®), reflecting radiation dose and image quality information for each scan, that can then be used for reporting this measure. This translation software will be available to all clinicians and sites without cost, including any updates that need to be completed. Additionally, software tutorials, training, and webinars will also be provided at no cost. This measure is more robust than measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques, which is finalized for removal with a 1-year delay to the CY 2025 performance period/2027 MIPS payment year and future years under Table C.12 of this Appendix to reduce duplication concurrent to the adoption of this measure. This measure assesses actual radiation dosing in patients undergoing diagnostic CT imaging, whereas the current measure assesses only utilization of dose optimization techniques (that is, a radiologist's choice of protocol) as documented within the final report. This measure is an intermediate outcome measure of radiation dose, which is strongly associated with cancer risk. This measure covers the two key process of care components that determine the radiation doses: a) the choice of imaging protocol; and b) decisions regarding the technical settings used for that type of CT exam. It assesses radiation dose according to thresholds determined by the underlying clinical indication for imaging and not based upon radiologists' choice of protocol. In addition, this measure includes assessment of image quality as a means of thereby protecting the diagnostic value of CT imaging from unintended consequences of excessive dose reduction. Minimizing dose by adherence to these factors will reduce the number of future cancers that may result from the radiation exposure, and that could in turn lead to a reduction in morbidity, mortality, and health care costs.[4 5 6] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

Comment: Many commenters supported the addition of the new Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) measure. The commenters agreed that the measure will have a large, positive impact on patients by reducing unnecessary radiation exposure and cancer risk, without compromising diagnostic image quality. A couple of these commenters indicated the proposed measure is well designed, well tested, and feasible, as well as endorsed by the Consensus-based Entity (CBE). One commenter appreciated CMS' efforts to implement this measure across incentive programs in various settings – inpatient, outpatient, and physician – as it will encourage synergy across entities and lead to greater quality improvement for CT overall. One commenter indicated that testing found this measure to be highly feasible with satisfactory feedback on the measure performance.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: A few commenters expressed concern about the lack of national consensus of interested parties and practitioners and endorsed benchmarks on this measure.

Response: We disagree that there is a lack of national consensus of interested parties and practitioners on this measure and the guidelines used for determination of performance. The measure relies on epidemiological and biological evidence and consensus-based clinical guidelines for optimizing CT radiation doses, including guidelines developed by the American College of Radiology,[7] the Society of Interventional Radiology,[8] the Society of Cardiovascular CT,[9] cardiovascular imaging societies,[10] Image Wisely 2020,[11] and the Food and Drug Administration.[12] This measure was submitted to the CBE by the measure developer for endorsement review at both the clinician and clinician group-level (CBE 3633e, CBE 3662e) and was endorsed on August 2, 2022, through a process that is intended to build consensus on the measure. Endorsement is intended to ensure a measure is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and reportable. This measure allows clinicians to be responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level, and is consistent across types of health care providers, including hospitals and physicians.

Comment: One commenter indicated the measure was inappropriate to be added as an eCQM and does not align with the definition of an eCQM. Another commenter suggested having the measure as a type of hybrid: one that relies partially on EHR data and partially on another entity/software to calculate.

Response: This measure is suitable for eCQM reporting. As set forth in the eCQI Resource Center, we define an eCQM as a measure specified in a standard electronic format that uses data electronically extracted from EHRs and/ or health IT systems to measure the quality of health care provided (*https://ecqi.healthit.gov/glossary*). Because this measure uses patients' radiology data that exist in a structured and standard electronic format that can be electronically extracted from radiology IT data systems, this measure is an eCQM. The Alara Imaging software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to a clinical terminology for use within the eCQM logic. The measure derives standardized data elements from structured fields within both the EHR and the radiology electronic clinical data systems. This eCQM requires the use of additional software (translation software) to access the primary data elements required for measure computation and translate them into data elements that can be ingested by this eCQM. The purpose of this translation software is to access and link these primary data elements with minimal site burden, assess each CT exam for eligibility based on initial population criteria, and generate the three data elements mapped to a clinical terminology for eCQM consumption, which are required and can be stored in the EHR.

Comment: A few commenters expressed concern on limited testing supporting the measure. Commenters also noted the CT size-adjusted dose and CT global noise have not been adequately assessed and validated. There were concerns that if the measure defines quality based on noise it leaves out other considerations such as contrast resolution, lesion detection ability, and physician preference. One commenter noted that as radiation exposure is cumulative over a lifespan, age and prior or anticipated radiation exposure history, including therapeutic irradiation for malignancies, are also crucial considerations not currently considered within the measure. The commenter supported the overall goals of the measure but opposed the finalization of the measure as stated until further testing in oncology settings can be conducted.

Response: This measure has been fully developed and tested at the clinician level with adequate reliability and validity and has received CBE endorsement, which reviewed the measure's testing and validity. Measure testing by the measure developer across 16 inpatient and outpatient hospitals showed that availability, accuracy, validity, and reproducibility were high for all of the measure's required data elements and that the

variables were calculated by the translation software. The purpose of the Excessive Radiation Dose eCQM is to ensure the radiation dose and image quality fall within thresholds that are safe and appropriate. It is not intended to oversimplify the relationship between noise and radiation. The image quality component is included in the measure as a balancing component to the radiation dose thresholds, to ensure the CT image quality does not decrease as an unintended consequence of the measure. Clinicians should use the measure as a guideline for conducting CT scans while also adjusting noise and radiation doses when necessary to provide quality patient care in special circumstances, such as for oncology patients. The measure seeks to reduce harm from excessive radiation for the vast majority of patients and is not a substitute for appropriate clinical judgement.

Comment: Many commenters expressed concerns related to the measure construction, including:

- Concerns on actionability and usability of the measure.
- Scientific limitations that will impact the measure's safety and practical value and may even negatively impact image quality, patient safety, and patient outcomes.
- Lack of clarity on what is being measured and how good imaging quality will be determined, as well as any requirements for maintaining data over time. Also, concerns raised with measure not being standardized, and gross under-representation of image quality.
- Improper estimation of radiation risk. In terms of dose length product (DLP) adjusted by patient size, not the actual patient dose, the commenter indicated that radiation risk estimation is explicitly prohibited by the American Association of Physicists in Medicine (AAPM) standard.
- Over-simplified stratification of CT categories and substantial oversimplified representation of implementation, including not addressing the implementation challenges.
- Emphasis on dose reduction instead of dose optimization.
- Concern that term "excessive radiation dose" is an imprecise and inaccurate term.
- Test substitution (for example, stress echocardiography for stress nuclear perfusion imaging) may result solely for the purpose of metric performance rather than proceeding forward with what might be the better test for a particular patient.

Response: We disagree. The measure information is highly actionable as it encourages clinicians to review and optimize imaging practices that directly affect patient safety. The measure is designed to be easily used. To further improve its actionability, the measure developer has made a tool publicly available to facilitate the use of data extracted directly from the mostly commonly used imaging formats. The Alara software accepts a wide range of Fast Healthcare Interoperability Resources (FHIR), Health Level (HL) 7 formats for EHR data, as well as Digital Imaging and Communications in Medicine (DICOM) CT radiation dose and image data. This measure is ready for implementation as proposed, as it has undergone rigorous testing and received endorsement from a CBE and is based upon evidence-based guidelines. However, we acknowledge that the implementation of this measure within a clinician/group's existing systems for reporting may require more time and resources; therefore, we are delaying finalization of this measure for one year to allow time to complete these updates.

This is a measure of size-adjusted radiation dose greater than or equal to a threshold specific to the CT dose and Image Quality Category or Calculated CT Global Noise value greater than or equal to a threshold specific to the CT Dose and Image Quality Category. More details regarding the measure's specifications were posted on the eCQI Resource Center in conjunction with our proposal (*https://ecqi.healthit.gov/ecqm/ec/pre-rulemaing/2024/cms1056v1#quicktabs-tab-tabs_pre_rule_measure-0*). The scientific limitations alluded to within the comment are addressed by the use of image quality as a balancing factor, basing image quality and CT category-specific radiation dose on a study of radiologists' satisfaction, and basing performance on clinical indication for imaging and not on the exam performed.

The measure uses dose length product (DLP), which gives the total radiation imparted to the patient by the CT machine. This is a standardized data element, generated by virtually (>99%) all CT machines, that is well validated and used broadly to reflect the radiation dose delivered to the patient.[2 4] It is also commonly used in benchmarking in the U.S. and globally (ACR–AAPM–SPR: Practice parameter, European Commission: Radiation Protection No. 185, ICRP Publication135 (*https://pubmed.ncbi.nlm.nih.gov/29065694/)*). The proposed measure adjusts DLP for patient size to ensure that differences in patient mix would not result in differences in measure scores across reporting entities. By adjusting DLP for patient size, the measure will attribute patients by this parameter to create congruency for the purposes of performance calculation. This is not intended to change current dosing guidelines or best practices. The measure is adjusted to allow equitable comparisons between clinicians/groups that may otherwise be biased due to potential variance in patient demographic. When radiation dose is unadjusted for patient size, failure rates are strongly associated with size, with almost all failures occurring in larger patients. When radiation dose is adjusted for size, there is no association.

The measure optimizes radiation dose; it does not minimize radiation dose. The image quality component balances the radiation dose thresholds, to ensure the CT image quality does not decrease as a consequence of the measure. The thresholds for radiation doses are size adjusted to accommodate patients of all sizes. We emphasize that clinicians should use the measure as a guideline for conducting CT scans while also adjusting noise and radiation doses when necessary to provide quality patient care. The measure seeks to reduce harm from excessive radiation for the vast majority of patients and does not replace appropriate clinical judgement.

We encourage the commenters to reach out to the measure steward to address potential changes to terminology used within the measure; however, this title, which includes the term "excessive radiation dose", aligns with the CBE version of the measure. With respect to test substitution, we note above that compliance with this measure is not a substitute for clinical judgement. We expect clinicians to choose the most appropriate diagnostic test for the patient.

Comment: Many commenters cited concerns with attributing performance to clinicians, specifically diagnostic radiologists. Reporting this measure at the clinician level will be difficult for radiology groups without collaboration, coordination, or implementation support at hospitals, especially when CT equipment and systems are primarily owned by the hospital or imaging facility. Commenters stated the measure is better suited for healthcare system level performance.

Response: The measure is intended to reflect patient care and safety provided by diagnostic radiologists. It is CBE endorsed at both the clinician and clinician group-levels of reporting. MIPS eligible clinicians are not required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice.

Comment: One commenter cited concern related to different timeframes for adoption and reporting within each of the three quality programs (Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, and MIPS), and different timeframes for when this measure will become mandatory reporting in other settings. In addition, there were requests to delay this measure by one year or longer. A few

commenters indicated they provided similar comments on the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM measure finalized in the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rate final rule (*https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf*) beginning with the 2025 reporting period (see 88 FR 59154 through 59161).

Response: We thank the commenters for their feedback and will delay implementation for one year. This will align implementation timeframes across CMS programs. This measure is ready for implementation as proposed, as it has undergone rigorous testing and received endorsement from a CBE. However, based upon feedback received, we are delaying implementation of this measure to allow time for reporters to perform system updates. This will allow for timely and proper implementation of the software in preparation for successful reporting.

Comment: One commenter expressed concern over the additional burden for hospitals, imaging centers, and groups supporting rural or underserved communities with implementing the measure than larger, integrated hospital systems. This is due to their older equipment and lack of in-house physicists. The measure will be difficult or infeasible for many radiology practices who do not control the equipment or its data. Since many practices serve multiple locations, that may not be related, collecting the data would need to be done in a disjointed fashion.

Response: As previously noted, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. Using the UCSF International CT Dose Registry, which contains over 8 million CT exams from more than 160 imaging facilities, the measure developer has determined the important contributors to radiation dose and its variation.[13] This is the best information currently available to understand drivers of dose. The results show that patient size, the reason for the CT scan, and the machine (make and model) do influence doses, but do not drive the variation in dose. The dose variation remains after accounting for these factors. The most important determinant of dose is not the machine, but the local decisions by radiologists, medical physicists, and radiology technologists about how to perform the exam and the choice of technical parameters. Appropriately dosed scans can be obtained on all patients and on all machine types.

Comment: A few commenters indicated concern related to the timing for this measure and it encourages installation of 3rd party software that interfaces with integral healthcare system platforms. Organizations need time to review, analyze, and safely implement the recommended software tools.

Response: We stress the importance of balancing the patient safety concerns presented by exposure to excessive radiation while still providing clinicians with enough time to implement the measure. This measure is ready for implementation as proposed, as it has undergone rigorous testing and received endorsement from the CBE. The CBE endorsement process included review by the CBE-convened MAP Health Equity Advisory Group and Rural Health Advisory Group, which supported the measure.[14] However, based upon feedback received, we are delaying implementation of this measure to allow time for reporters to perform system updates. This will allow for timely and proper implementation of the software.

Comment: A couple of commenters cited concerns related to coding issues. One commenter indicated that Logical Observation Identifier Names and Codes (LOINC) codes created for the measure calculated fields exist but may not necessarily be used by every facility or group. Capturing data for the new codes will need to be configured and it may be difficult to extract these data elements and transform them into calculated fields with accuracy or consistency. In addition, the accuracy and specificity of CPT/ICD-10 codes to determine the true indication for an exam at the time of order was a cause for concern. Another commenter also mentioned the unintended consequences of the measure should be monitored over time, such as the inappropriate shifting of care or coding/billing practices, or increased patient morbidity and mortality.

Response: As previously noted, this measure is voluntary, and MIPS eligible clinicians have the flexibility to choose measures that are relevant and meaningful to their practice. The measure derives standardized data elements from structured fields within both the EHR and the radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). This eCQM may require the use of additional software (translation software) to access the primary data elements required for measure computation and translate them into data elements that can be ingested by this eCQM. The purpose of this translation software is to access and link these primary data elements with minimal site burden, assess each CT exam for eligibility based on initial population criteria, and generate the three data elements mapped to a clinical terminology for eCQM consumption, which are required and can be stored in the EHR. As with all eCQMs, it would be expected the measure is implemented in accordance with the measure specification and published logic. The measure will be maintained and updated as appropriate through the established annual update (AU) process. We do not intend for clinicians to shift billing practices to accommodate MIPS quality measure reporting, but rather to choose measures that drive quality of care and can be integrated in their workflow.

Comment: A few commenters expressed concerns on this new measure related to privacy and security issues, as well as the need for data agreements. These included:

- Transmitting data to a private vendor raises concerns related to privacy and security, as well as connectivity issues between different systems (EHR, RIS, and PACS).
- Potential for information system vulnerability (cybercrime) warrants consideration.
- Concerns on potential data breaches or security protocols and third-party business arrangements with data sharing.
- Lack of clarity on what type of agreements need to be signed between health IT vendors and the private vendor, and/or between hospitals and this private vendor.

Response: We appreciate the commenters' concerns. The Alara Imaging Software for CMS Measure Compliance does not require the transmission of data to a new vendor and thus does not require the execution of new data use agreements. The software is installed and computes the measure's elements on the system of the measure reporter's choice, behind their own firewall. Measure-related activities, including calculation, do not require the transmission of any data to outside entities as the software only works to create data elements for use with the current EHR system. Nonetheless, we note that the measure steward's security aligns with industry standards, including HIPAA and Systems and Organization Controls (SOC) 2 certification verified via ongoing third-party audits.

Comment: Many commenters expressed concern related to cost issues. These included:

- Concerns on other associated costs for the free Alara software, such as hardware, application support, and maintenance. There is an additional burden in implementing the proprietary program and ensuring compatibility within system IT networks. Due to software configuration, coding and billing issues, radiation dose, and global noise issues, costs could be high.
- Concern on costs because the software for implementing this measure was created and maintained by a single commercial vendor, in conjunction with the measure steward.
- Burden of depending on a third-party software to upload data and retrieve and integrate the results for measure reporting.

Response: We acknowledged the cost of measure implementation is a factor when choosing which quality measures to submit; however, MIPS eligible clinicians have the flexibility to choose measures that are relevant and meaningful to their practice. The Alara software accepts a wide range of FHIR, HL7 formats for EHR data, as well as DICOM CT radiation dose and image data to decrease burden. Similar to other eCQMs, the measure has also been developed using proven formats: Quality Data Model (QDM) for immediate implementation and FHIR when adopted in the future, in accordance with our aim of encouraging interoperability based on the FHIR Application Programming Interface (API). Thus, the overall burden is comparable to that of existing eCQMs. The Alara software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to clinical terminology for measure computation and can be stored in the EHR.

Comment: One commenter did not support this measure unless it was voluntary for eligible hospitals, critical access hospitals, and eligible clinicians.

Response: This measure is voluntary in MIPS and MIPS eligible clinicians have the flexibility to report on the measures most applicable and meaningful to their practice.

We appreciate the comments received and concerns regarding MIPS implementation of this eCQM. Based in part of the comments we received regarding the time necessary to test and integrate the software that MIPS eligible clinicians will use to calculate this measure, we agree a 1-year delay in measure implementation would improve clinician and system readiness to report the measure. The delay would also align with implementation timelines across other CMS programs.

After consideration of public comments, we are finalizing the *Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)* measure with modification. While we proposed to adopt the measure for the CY 2024 performance period/2026 MIPS payment year, we are instead finalizing this new measure with a 1-year delay. The measure will be available for the CY 2025 performance period/2027 MIPS payment year and future years.

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A.2. Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	495
Description:	The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.
Measure Steward:	American Academy of Hospice and Palliative Medicine (AAHPM)
Numerator:	The Feeling Heard and Understood (HU) survey is calculated using top-box scoring within 2 months (60 days) of the ambulatory palliative care visit. Numerator 1: Patient felt heard and understood by this provider and team. Numerator 2: Patient felt this provider and team put my best interests first when making recommendations about my care. Numerator 3: Patient felt this provider and team saw me as a person, not just someone with a medical problem. Numerator 4: Patient felt this provider and team understood what is important to me in my life.
Denominator:	Denominator 1, 2, 3, and 4: All patients aged 18 years and older who had an ambulatory palliative care visit between January 1 – October 31.
Exclusions:	Patients who did not complete at least one of the four patient experience HU survey items and return the HU survey within 60 days of the ambulatory palliative care visit. Patients who respond on the patient experience HU survey that they did not receive care by the listed ambulatory palliative care provider in the last 60 days (disavowal). Patients who were deceased when the HU survey reached them. Patients for whom a proxy completed the entire HU survey on their behalf for any reason (no patient involvement).
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this patient-reported outcome measure because it will fill a gap in the current quality measure inventory for patients receiving palliative care. The Feeling Heard and Understood survey was developed to capture patients' assessment of their care for ongoing quality reporting and improvement. This survey measures patients' satisfaction of their ambulatory palliative care experience based on how well they felt heard and understood by physicians, nurses, and other hospital staff. This measure captures the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Assessment of how well patients feel heard and understood complements and adds an important dimension to existing quality measures of care planning by including patient experience of care for this unique patient population. [15] This measure is intended to facilitate and improve effective patient-provider communication that better engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. The outcome of this measure is that the patient feels heard and understood by the ambulatory palliative care provider and team. Through the benefits of enhanced patient-provider communication, this measure will improve the quality of care received and outcomes for patients receiving palliative care. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure is predicated on existing guidelines including the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care and supported by a systematic review of current evidence for palliative care interventions.[16] Evidence from the systematic review supports advanced care planning. Studies have shown that quality palliative care and communication between patients and providers are associated with increased preference-concordant care.[16] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: One commenter supported the new Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure, because patient-autonomy and access to information and choice is core to palliative care. The ability to assess patient experience of feeling heard and understood is essential for clinicians to assess whether they are providing quality care.

Another commenter supported and thanked CMS for the inclusion of this important measure in MIPS, and further recommended that CMS include this measure in relevant MVPs. This rigorously tested measure holds clinicians accountable for ensuring that they understand what matters most to patients and their caregivers and is a critical component of developing patient-centered care plans. The commenter stated that while this measure has been tested in palliative care programs, the concept of patients feeling heard and understood should not be limited to this patient population. The commenter encouraged CMS to consider inclusion of this measure concept in other quality reporting programs that address care for patients with serious illness.

Another commenter supported this new measure and stated the patient experience of feeling heard and understood is a key goal and benefit of palliative care. Patients want to be treated as an individual and have their symptoms and goals of care managed effectively, which may be challenging at times given clinician time constraints. Another commenter supported this new measure, stating that palliative care, which focuses on optimizing the quality of life and reducing suffering among people with chronic and terminal illness, is essential as the number of Americans suffering with at least one chronic disease continues to grow.

Category	Description
	Response: We thank the commenters for supporting this new measure in MIPS. We will take the recommendation to include this measure concept in other quality reporting programs under advisement. *Comment:* One commenter was supportive of this measure's development and was pleased to see its addition in relevant specialty sets. The commenter requested that although the measure was developed and endorsed for home-based palliative care programs, the measure should be considered for all specialties, as it focuses on communication between the person and their clinician. *Response:* We thank the commenter for supporting this new measure in MIPS. We encourage the commenter to request this measure be added to other specialty sets through the Solicitation for Specialty Sets process. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52768), we are finalizing the *Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

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A.3. Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	496
Description:	Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.
Measure Steward:	University of California, Irvine
Numerator:	Patients who are assessed for CVD risk via California Maternal Quality Care Collaborative (CMQCC) standardized algorithm. A completed CVD risk assessment will determine the patient to be at low risk or high risk of CVD. Patients will be assessed at their initial encounter with their healthcare provider for pregnancy-related care [prenatal visit, L&D, postpartum visit] and may need to repeat assessments if new symptoms develop.
Denominator:	Patients who have an office visit for prenatal or postpartum care, regardless of gestational age or prior prenatal care at other sites, for any age (including pregnant and postpartum minors), within outpatient obstetric (OB) visit at the hospital or in affiliated clinics; and labor and delivery (L&D)
Exclusions:	Patients who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as OB provider (e.g., plan to terminate the pregnancy or seek prenatal services elsewhere). Prior history of known CVD.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will fill a high priority clinical gap area under the wellness and prevention domain for maternal health. This process measure will address screening and care for pregnant/postpartum patients by assessing for the completion of a standardized CVD risk assessment for this high-risk population. This measure will represent a new quality measure clinical concept for maternal health. CVD is the leading cause of maternal mortality in the U.S., accounting for over one-third of all pregnancy-related deaths.[17] Peripartum cardiomyopathy (PPCM) constitutes the largest group among CVD-related deaths. About 24 percent of all CVD pregnancy-related deaths (and 31 percent of cardiomyopathy deaths) were determined to be potentially preventable.[18] CVD also accounts for many folds higher maternal morbidity, a longer length of hospital stays, intensive care unit (ICU) admissions, and future pregnancy risks.[19] This measure will monitor follow-up to universal cardiovascular risk assessment in all pregnant patients at their first encounter with an obstetrics provider.[20] The measure facilitates clinicians to evaluate pregnant or postpartum patients presenting with symptoms such as shortness of breath, cough, or excessive fatigue in the context of risk factors, vital sign abnormalities, and abnormal physical examination findings.[21] Normal physiological changes in pregnancy lead to signs and symptoms that may be indistinguishable from those of CVD. The overlap of signs and symptoms of normal pregnancy with those of CVD further complicates timely diagnosis. Most women who died from CVD during pregnancy and/or the postpartum period were not suspected of having a cardiac diagnosis and symptoms were attributed to an alternate diagnosis. Roughly 84 percent of pregnant patients who died from CVD presented with symptoms concerning for cardiopulmonary disease. However, only 61.1 percent of these patients were referred to cardiologists, and, of those, only 7 percent were referred antenatally. Given the large proportion of pregnancy-related mortality attributed to cardiovascular disease, these data suggest that an implementation of universal screening may improve overall maternal outcomes and lower overall healthcare costs.[22] Use of this measure will promote improvement in the screening of pregnant and postpartum women for the accurate diagnosis of heart failure or CVD versus attributing symptoms of pneumonia or other clinical side effects from pregnancy such as persistent cough, shortness of breath, and/or bilateral infiltrates on a chest x-ray. The intent of assessing the CVD risk during pregnancy/postpartum care is to increase education and awareness in this population and will empower patients to seek early medical care if new signs and symptoms develop that may be suggestive of CVD. It may have implications for long-term health outcomes with improvements in the CVD risk factor profile in the future. The use of a standardized CVD measure to risk-stratify pregnant and postpartum patients may improve the timely identification of CVD, thereby decreasing maternal morbidity and/or mortality. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The Alliance for Innovation on Maternal Health (AIM) identified the California Maternal Quality Care Collaborative (CMQCC) CVD Assessment Algorithm for Pregnant and Postpartum Patients as an emerging best practice and an important tool for assessing symptoms and risk in a standardized way and advocated for the use of the tool in its Cardiac Conditions in Obstetrical Care Bundle (CCOC).[23] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS *at https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Category	Description
	Comment: One commenter supported the new Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/ Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument because it will help promote education and awareness of CVD risk in pregnant and post-partum patients. Another commenter indicated this new measure fills a high-priority gap in care and that assessing CVD risk during pregnancy/postpartum care promotes timely assessment of and intervention for CVD risk factors. *Response:* We thank the commenters for supporting this new measure in MIPS. *Comment:* One commenter supported this new measure to evaluate the proportion of pregnant and postpartum patients who receive a CVD risk assessment with a standardized instrument. The commenter suggested, however, that the measure be agnostic to the specific assessment tool required and instead encourage use of widely used and recommended CVD risk calculation tools (such as CMQCC standardized algorithm, AHA/ACC ASCVD Risk Estimator Plus, Framingham Risk Score Calculator, etc.). *Response***:** As currently specified, the measure utilizes the CMQCC standardized algorithm as it is currently the only pregnancy specific algorithm and was used during measure development and testing. The easy use (takes less than one minute to complete CVD risk assessment) of the tool allows for integration into the clinic flow. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. *Comment***:** One commenter requested this new measure be modified to include two CVD risk assessments, antepartum and postpartum, and confirm the reliability and validity of the measure for individual clinician reporting. *Response***:** The intent of the measure is to have all pregnant and/or postpartum patients undergo CVD risk assessment at least once during the pregnancy episode. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Measure reliability and validity testing was completed, with individual clinician level analysis breakdowns in addition to patient/encounter level testing. *Comment:* One commenter did not support this new measure because it did not achieve endorsement by the CBE due to concerns over the inadequacy of the evidence. *Response:* While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The Alliance for Innovation on Maternal Health (AIM) identified the California Maternal Quality Care Collaborative (CMQCC) CVD Assessment Algorithm for Pregnant and Postpartum Patients as an emerging best practice and an important tool for assessing symptoms and risk in a standardized way and advocated for the use of the tool in its Cardiac Conditions in Obstetrical Care Bundle (CCOC).[23] Evidence substantiates the attribution of a large proportion of pregnancy-related mortality to cardiovascular disease, and these data suggest that an implementation of universal screening may improve overall maternal outcomes and lower overall healthcare costs.[22] After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52769 through 52770), we are finalizing the *Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

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A.4. First Year Standardized Waitlist Ratio (FYSWR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	N/A
Description:	The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients in the practitioner group's denominator listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.
Denominator:	The denominator for the First Year Standardized Waitlist Ratio (FYSWR) is the expected number of waitlist or living donor transplant events in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age, incident comorbidities, dual Medicare-Medicaid eligibility, Area Deprivation Index (from patient's residence zip code) and transplant center characteristics, among patients under 75 years of age who were not already waitlisted and did not have kidney transplantation prior to the initiation of end-stage renal disease (ESRD) dialysis. The number of days at risk (time from start of dialysis to the earliest of being placed on the waitlist, receiving a living donor transplant, death, or one year from start of dialysis) for each patient is used to calculate the expected waitlist or living donor transplant events.
Exclusions:	Patients age 75 or older on their initiation of dialysis date. Patients admitted to a skilled nursing facility (SNF). Patients in hospice on their initiation of dialysis date or during the month of evaluation. Patients that were on the kidney or kidney-pancreas waitlist prior to initiation of dialysis. Patients who had a transplant prior to initiation of dialysis.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We proposed this measure because it will address a CMS high priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures (*https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease*). While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant (*https://pubmed.ncbi.nlm.nih.gov/34783494/*). This measure assesses whether patients that are in their first year of dialysis were placed on the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicated a performance gap for a process that can be directly linked to improved patient outcomes. This measure is separate from the other transplant waitlist measure, found under Table A.5 of this Appendix, as it is limited to assessing the first year after initiation of dialysis and the timely addition of those patients to the transplant waitlist—a crucial step in driving positive outcomes in the patient population. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners and subsequent patient transplant wait listing. For example, the clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[24] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[24] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation (based on reporting on the Medical Evidence Form 2728 *(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf*) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[25] Approximately 30 percent of patients were uninformed about kidney transplantation, and this was associated with half the rate of access to transplantation compared to patients who were informed.[17] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients.[26] The provision of such information was associated with a near threefold increase in likelihood of wait listing.[26] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis practitioner groups. Aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care

Category	Description
	including ensuring placement on the transplant list as quickly as possible. The MAP did not support this measure for rulemaking with the potential for mitigation. The Renal Standing Committee raised concerns regarding the evidence base and specifications and recommended that this measure be resubmitted for endorsement by a CBE. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggested a significant association between the clinician activities described above and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved outcomes associated with kidney transplant. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: One commenter supported the new First Year Standardized Waitlist Ratio (FYSWR) measure (in addition to supporting the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) under Table A.5 of this Appendix). The commenter stated that these measures will help payers understand if clinicians are connecting patients who have ESRD with the additional care and support they need to prepare for organ transplant. The commenter agreed that measures are needed to understand if patients are being referred to transplantation and if they are being appropriately supported while they are on the waiting list for an organ. These measures could help ensure clinicians are working with patients to help them access transplant waitlists and if facilities are proactively reaching out to patients on the waitlist. Another commenter supported these new measures that address the CMS high priority clinical topic of patients with ESRD. Another commenter supported this new measure and advocated for all patients to have access to the treatment modality of their choice and experience minimal time on the transplant waitlist or receive a living donor kidney transplant if circumstances permit.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: A few commenters requested clarification regarding the intent of this measure in addition to the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure (under Table A.5 of this Appendix). The commenters encouraged development and implementation of measures that support medications such as sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy, and other measures to delay CKD progression.

Response: We thank the commenters for their feedback and encourage them to reach out to measure developers/stewards to develop additional CKD measures that may fill the gap areas for submission to the Call for Measures for possible future implementation. The intent of measure First Year Standardized Waitlist Ratio (FYSWR) is to track the initial patient placement on the kidney or kidney-pancreas transplantation waitlist, or receipt of a living donor transplant, within the first year after dialysis initiation, with the intended objective of timely inclusion on the waitlist, improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. The intent of measure Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) is to assess monthly wait listing in active status of patients, as well as evaluate and encourage maintenance of patients on the waitlist over the entirety of the patient's time on the waitlist. This measure is a single assessment during a defined timeframe, whereas the PPPW and aPPPW measure follows the patient throughout their dialysis journey.

Comment: One commenter did not support this measure because it was not endorsed by the CBE Renal Standing Committee, citing concerns regarding exclusions and attribution. In particular, the CBE Renal Standing Committee raised concerns about how the measure developer identified the physician caring for the patient. The CBE Consensus Standards Approval Committee upheld the decisions of the Renal Standing Committee during their review and voted not to reconsider this measure during the appeals process.

Response: While we agree CBE endorsement is preferred, this measure should nonetheless be added to MIPS, as it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. There is a significant association between the clinician activities described in this measure and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved health outcomes associated with kidney transplant. See the studies cited in the rationale, above. Additionally, this measure would be implemented at the practitioner group level and not the individual clinician level.

We appreciate the public comments on this proposed new measure. However, due to potential implementation challenges within MIPS regarding timing and application of the risk adjustment methodology, we are not finalizing the *First Year Standardized Waitlist Ratio (FYSWR)* measure as proposed for the CY 2024 performance period/2026 MIPS payment year to allow further refinement and streamlining of the measure analytic for future MIPS implementation.

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25. Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351-357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x.*
26. Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871-2877. *https://doi.org/10.1681/ASN.2013121298.*

A.5. Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	N/A
Description:	The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Percentage of Prevalent Patients Waitlisted (PPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year. Numerator 2: Percentage of Prevalent Patients Waitlisted in Active (aPPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist in an active status as of the last day of each month during the reporting year.
Denominator:	Denominator 1 and 2: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner or practitioner group practice according to each patient's treatment history on the last day of each reporting month during the performance year. If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Exclusions:	Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month. Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to the CMS-2728 form. Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period. Patients with dementia at any time prior to or during the month.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We proposed this measure because it will address a CMS priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures *(https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease*). While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant (*https://pubmed.ncbi.nlm.nih.gov/34783494/*). This measure captures the adjusted count of patient months on the kidney and kidney-pancreas transplant waitlist for all dialysis patients in a dialysis practitioner or group practice by assessing patient status on the last day of each month during the reporting year and those on the transplant waitlist in active status as of the last day of the month during the reporting year. This process measure is directly linked to driving positive outcomes and measure data indicated a performance gap. Most ESRD patients have to wait to eventually access a deceased donor transplant (national median of roughly 4 years).[27] Maintenance of 'active status' on the transplant list requires ongoing collaboration between dialysis practitioners, transplant centers, and transplant networks, thereby ensuring sustained suitability for a transplant while optimizing the health of patients.[28] This maintenance process is associated with higher transplantation rates and lowered mortality rates while on the waitlist.[28] In addition, the maintenance of 'active status' is an important health equity issue. Research has found disparities in access to kidney transplant by race.[29] Race-neutral efforts by clinicians to encourage maintenance of patients on the waitlist may reduce such disparities while improving their performance on this measure.[29] This measure assesses monthly wait listing in active status of patients. It also evaluates and encourages maintenance of patients on the waitlist. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. In contrast to this measure, the First Year Standardized Waitlist Ratio measure found under Table A.4 of this Appendix focuses solely on new wait listings and living donor kidney transplants to incentivize early action, rather than ongoing maintenance on the waitlist, which this measure assesses. The MAP conditionally supported this measure for rulemaking pending an update of the measure's specifications to include only the PPPW (CBE 3695) rate that was recommended for endorsement by the CBE's Renal Standing Committee. While we agree that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CBE recommended endorsement for the PPPW subset of this measure. It is important to include the aPPPW rate in this measure as well to capture patients in active waitlist status and the full scope of the transplant list and the movement of patients between active and inactive status. The studies cited above provide the evidentiary basis for the adoption of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Category	Description
Comment: A few commenters supported the new Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure that will help ensure that clinicians are working with patients to help them access transplant waitlists. *Response:* We thank the commenters for supporting this new measure in MIPS. *Comment:* One commenter opposed this new measure and stated the measure was not endorsed by a CBE or the Renal Standing Committee. The commenter stated that while nephrologists have a role in referring patients for transplantation, they have nothing to do with the selection of patients from the waitlist and the measure is not an accurate reflection of the quality care provided by nephrologists. The commenter indicated there were also concerns with the testing data, which showed extreme variation in the transplant center practice. The commenter was concerned that two measures were combined into this measure with no evidence of review or testing, or feasibility and reliability, as a composite measure. *Response:* While we agree full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Maintenance of active status requires ongoing attention by dialysis practitioners to optimizing the health of patients, to ensure sustained suitability for transplant waitlisting. Maintenance of active status on the waitlist is additionally important given demonstrated disparities[29] and positive association with subsequent transplantation.[28] The CBE recommended endorsement for the PPPW subset of this measure. This measure assesses monthly wait listing in active status of patients, encouraging maintenance of patients to remain in active status. It also evaluates and encourages maintenance of patients on the waitlist. We acknowledged that patient selection from the waitlist for transplantation is not determined by the nephrologist and as such, this measure is not assessing this aspect of the transplant workflow. This is an important area to which dialysis practitioners can contribute by ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The testing provided by the measure steward was reviewed and demonstrated statistically sufficient results for the reliability and validity of each of the numerator actions, meeting requirements described within the CMS MMS Hub (*mmshub.cms.gov*) regarding quality measure testing. The measure will utilize two submission criteria to assess performance across dialysis clinician groups, creating a robust quality measure driving positive outcomes for ESRD patients. We appreciate the public comments on this proposed new measure. However, due to potential implementation challenges within MIPS regarding timing and application of the risk adjustment methodology, we are not finalizing the *Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)* measure as proposed for the CY 2024 performance period/2026 MIPS payment year to allow further refinement and streamlining of the measure analytic for future MIPS implementation.	

27. Johansen, K. L., Chertow, G. M., Foley, R. N., Gilbertson, D. T., Herzog, C. A., Ishani, A., ... & Wetmore, J. B. (2021). US Renal Data System 2020 Annual Data Report: Epidemiology of Kidney Disease in the United States. American Journal of Kidney Diseases, 77(4), A7-A8. *https://www.ajkd.org/article/S0272-6386(21)00024-X/fulltext.*
28. Grams, M. E., Massie, A. B., Schold, J. D., Chen, B. P., & Segev, D. L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. American Journal of Transplantation, 13(4), 1012-1018. *https://onlinelibrary.wiley.com/doi/pdf/10.1111/ajt.12143.*
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A.6. Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	497
Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization. Numerator 2: Patients who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine on or after their 19th birthday and before the end of the measurement period. Numerator 3: Women with one or more mammograms any time on or between October 1 two years prior to the measurement period and the end of the measurement period. Numerator 4: Patients with one or more screenings for colorectal cancer. Appropriate screenings are defined by any one of the following criteria: - Fecal occult blood test (FOBT) during the measurement period. – Flexible sigmoidoscopy during the measurement period or the four years prior to the measurement period. – Colonoscopy during the measurement period or the nine years prior to the measurement period. – Computed tomography (CT) colonography during the measurement period or the four years prior to the measurement period. – Stool DNA (sDNA) with Fecal immunochemical test (FIT) during the measurement period or the two years prior to the measurement period. Numerator 5: Patients with a documented BMI during the encounter or during the previous twelve months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the encounter. Numerator 6: - Patients who were screened for tobacco use at least once within the measurement period. – Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. – Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Numerator 7: Patient visits where patients were screened for high blood pressure AND have a recommended follow-up plan documented, as indicated, if the blood pressure is elevated or hypertensive.
Denominator:	Denominator 1: All patients aged 6 months and older seen for a visit during the measurement period. Denominator 2: Patients 65 years of age and older with a visit during the measurement period. Denominator 3: Women 41 – 74 years of age with a visit during the measurement period. Denominator 4: Patients 45-75 years of age with a visit during the measurement period. Denominator 5: All patients aged 18 and older on the date of the encounter with at least one qualifying encounter during the measurement period. Denominator 6: - All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit who were screened for tobacco use during the measurement period and identified as a tobacco user. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. Denominator 7: All patient visits for patients aged 18 years and older at the beginning of the measurement period.
Exclusions:	Denominator Exclusion Population 1: - Hospice services provided to patient any time during the measurement period. - Anaphylaxis due to the vaccine on or before the date of the encounter. Denominator Exclusion Population 2: - Patient received hospice services any time during the measurement period. - Patient had anaphylaxis due to the pneumococcal vaccine any time during or before the measurement period. Denominator Exclusion Population 3: - Women who had a bilateral mastectomy or who have a history of a bilateral mastectomy or for whom there is evidence of a right and a left unilateral mastectomy. - Hospice services used by patient any time during the measurement period. – Palliative care services used by patient any time during the measurement period. - Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long term care with POS code 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. Denominator Exclusion Population 4: - Patients with a diagnosis or past history of total colectomy or colorectal cancer. – Patient was provided hospice services any time during the measurement period. – Patient was provided palliative care services any time during the measurement period. - Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.

Category	Description
	Denominator Exclusion Population 5: - Documentation stating the patient has received or is currently receiving palliative or hospice care. – Documentation of patient pregnancy anytime during the measurement period prior to and including the current encounter. Denominator Exclusion Population 6: - Hospice services provided to patient any time during the measurement period (applicable to each of the 3 performance rates). Denominator Exclusion Population 7: - Patient not eligible due to active diagnosis of hypertension.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this composite measure, which combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services, to create a robust, broadly encompassing preventive care assessment. The measure developer submitted data demonstrating a performance gap for the composite measure. In testing, the developer identified a performance gap, where median performance on the combined measure was 52.7 percent, with a standard deviation of 11.2 percent. Initially, this measure will be implemented as a weighted average analytic, representing performance for quality actions linked to positive patient outcomes. This measure will set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we will gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/*). This measure consists of seven preventive care and screening processes that are consistent with guidelines from the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the American Association of Clinical Endocrinology (AACE), and the American College of Endocrinology (ACE). The seven screening processes are influenza immunization, pneumococcal immunization, breast and colorectal cancer screening, body mass index screening, tobacco use screening and cessation intervention, and screening for high blood pressure with follow-up. Each process received a recommendation of at least "Strong" or an equivalent rating from the corresponding body identified above.[30] The basis for each constituent measure was previously described in our prior rulemaking under the 2013 Physician Quality Reporting System (PQRS) in the CY 2012 PFS final rule (77 FR 69215 through 69267: Table 95 and 77 FR 69269 through 69271: Table 96), and each measure was retained with the implementation of MIPS (81 FR 77558 through 77675). With the addition of this measure, we also finalized to remove measures Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from traditional MIPS, while retaining those three measures for use in relevant MVPs as discussed under Table Group CC of this Appendix. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The preventive care and wellness composite measure is supported based upon the evidence discussed and cited within the respective rules in which each constituent measure was proposed and finalized as indicated previously in the rationale. A study of preventive services covered under the Affordable Care Act examined the extent to which lives could be saved if adults over 18 received them, including some addressed by this measure. The authors found preventive services ameliorate 9 of the 10 leading causes of death in America and could save at least 100,000 lives,[31] providing support for this composite measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: Several commenters supported the new Preventive Care and Wellness (composite) measure in MIPS. Specifically, one commenter stated this measure will set a higher performance standard for primary and family physicians by requiring that a comprehensive set of preventive care tests, immunizations and screenings be completed for each patient. The commenters agreed with CMS that adoption of the new composite measure will increase overall utilization of preventive measures and provide a better overall picture of preventive care practices.

Another commenter stated this measure sets a more stringent performance standard and helps ensure more all-inclusive preventive care. The commenter agreed with the numerator/ denominator criteria 5, 6, and 7. The commenter supported the inclusion of BMI screening (population 5), the tobacco screening and cessation intervention (population 6), and the use of blood pressures screening (population 7) as part of the composite measure. Another commenter stated this measure will promote more efficient preventive care improvements at the primary care level.

Response: We thank the commenters for supporting this new measure in MIPS.

Category	Description
	Comment: One commenter supported this new measure and encouraged CMS to add measure Q493: Adult Immunization Status (AIS) measure as a numerator in the Preventive Care and Wellness (composite) measure. The commenter stated that the proposal to use the standalone pneumococcal and influenza measures for the composite measure is not consistent with CMS goal of promoting alignment across measure sets. Instead of the influenza and pneumococcal standalone measures, the commenter encouraged the use of the AIS measure in the composite measure to include influenza, pneumococcal, zoster, and Td/Tdap vaccines. *Response:* We thank the commenter for supporting this composite measure's addition to MIPS. Although we appreciate the suggestion to combine composite measures, we note these two measures have different focuses. Measure Q493 provides a comprehensive adult immunization focus. This provides clinicians with an additional option to report a measure within MIPS that may be relevant to their practice. The Preventive Care and Wellness (composite) measure encourages engagement between the patient and clinician as a preventive health option. *Comment:* One commenter, in supporting the removal of measure Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan, suggested CMS align quality measures as part of the Universal Foundation and recommended these quality measures extend to Medicare Advantage plans, Managed Care Organizations, state Medicaid programs, and applicable waivers. A few commenters indicated the current Universal Foundation set of measures does not include an obesity measure. *Response:* This measure combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services to create a robust, broadly encompassing preventive care assessment. Measure Q128 is available for both the MIPS CQM and eCQM collection type and therefore utilizes all-payer data for reporting. Many of the individual components within this composite are included in the Universal Foundation or are considered core measure concepts that align with the Core Quality Measure Collaborative (CQMC) core measure set(s), and thus have been determined to be an important part of patient health and support healthy outcomes. *Comment:* One commenter supported the inclusion of the concepts from measure Q113: Colorectal Cancer Screening in this composite measure to help ensure all patients receive appropriate screening. The commenter indicated that new modalities of testing, such as blood-based screening, have the potential to overcome many of the access barriers associated with current methods by incorporating screening into routine medical care. The commenter encouraged CMS to work with the National Committee for Quality Assurance (NCQA) and other parties, as appropriate, to update quality measures for colorectal cancer (CRC) screening and the new composite measure, if finalized, to include blood-based CRC screening tests. *Response:* We thank the commenter for their support of including measure Q113 in this composite measure. Quality measures undergo annual review and updates. Guideline updates may be incorporated by the measure developer at that time. The version reviewed by the MAP did not include blood-based CRC screening tests. We thank the commenter for their feedback and will take it into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. *Comment:* One commenter expressed concern about the complexity of the composite measure with seven numerators, denominators, and exclusions/exceptions. The commenter also opposed the removal of seven individual measures if this composite is implemented in MIPS. The commenter stated that individual measures address important preventive care activities, and the proposal would eliminate the ability of some specialties to select a subset of the measures such as those vaccinations on which they may be able to report. *Response:* We recognize this measure sets a more stringent performance standard within primary care, than the component measures by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we will gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/)*. Additionally, clinicians have the flexibility to choose which measures to report and performance is not based solely on the reporting outcome of a single measure. We maintained two of the component measures, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, in select specialty measure sets due to the importance of those clinical concepts to specialties where the composite measure would not be applicable, and we maintained measure Q493: Adult Immunization Status for use within traditional MIPS. *Comment:* One commenter noted that the composite includes measure Q128: Preventive Care and Screening Body Mass Index (BMI) Screening and Follow-up Plan, which the commenter stated is outdated and is longer CBE endorsed and may not be appropriate for elderly patients. The commenter noted they believed these same interoperability challenges could also prevent primary care physicians from reliably receiving data on patients' screening mammograms, which could negatively impact performance on the composite measure. *Response:* Many of the individual components within this composite are included in the Universal Foundation or are considered core measure concepts that align with the CQMC core measure set(s) and have been determined to be an important part of patient health and support healthy outcomes. This includes documenting a patient's BMI and a follow-up plan when the BMI is outside of normal parameters as BMI correlates with health outcomes and cause-specific mortality (*https://pubmed.ncbi.nlm.nih.gov/35308730/*); however, we recognize that there are clinical limitations of BMI and, as such, it should not be used as a diagnostic tool but rather as an initial screening (*https://www.cdc.gov/healthyweight/assessing/bmi/index.html*). As it relates to concerns with system interoperability, the composite measure allows clinicians to capture this information via patient reported outcomes for some components. For example, patient reported mammograms, when recorded in the medical record, are acceptable for meeting the numerator. *Comment:* A couple of commenters opposed the addition of this new measure, stating that combining the current preventive care measures into one composite measure would hurt their current MIPS workflow and likely cause a disruption to patients as they would have to pull staff to learn and train all new workflows. *Response:* We acknowledged the measure will set a more stringent performance standard by requiring assessment of multiple immunization, and preventive care and wellness quality actions in one multi-performance measure and thus may be accompanied by system and workflow updates. However, this measure provides a comprehensive preventive care and wellness assessment for each patient to drive positive health

Category	Description
	outcomes by utilizing component measures for which many clinicians already have workflows in place. Clinician choice is still allowed for quality measures, and we encourage clinicians to choose measures that are meaningful and applicable to their scope of care and practice. *Comment:* A couple of commenters indicated that removing the component measures and combining into one composite measure would impact specialty practices that are limited to their EHR's quality measure selection, and they would not be able to meet the 6 measures required under traditional MIPS. Another commenter expressed that topping out specialty-agnostic quality measures, removing individual wellness and screening measures, and combining the current seven wellness and screening measures that all specialties commonly use into a composite measure will be detrimental to practices that already have limited quality measure selection. *Response:* We acknowledged the commenters' concerns related to limited quality measure selection and specialties' use of the composite measure. However, this is a more robust measure to drive quality care and ensure a focused Preventive Care and Wellness (composite), as compared to the individual measures alone. This measure is intended for use by primary care clinicians during annual wellness visits. We reviewed all specialties to ensure a sufficient number of measures are included in each specialty set as available that would still allow for clinician choice even with removal of the component measures in this composite. However, in some cases certain component measures were maintained in order to continue to assess important clinical concepts within specialties where the new Preventive Care and Wellness (composite) measure is not appropriate. Additionally, clinicians continue to have the flexibility to choose measures to report, and we encourage clinicians to choose measures that are meaningful and applicable to their scope of care and practice. We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measure steward to the Call for Measures. We encourage the commenters to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years. *Comment:* One commenter stated that composite measures should be a complement to individual measures when creating incentives for improvement, but composite measures should not be used alone. Each of the individual measures assesses important aspects of prevention and detection of disease. The commenter was pleased to see that the composite measure specifications have been improved since previous versions of the measure and now include the use of a denominator-weighted score. However, the commenter stated it is unclear if the results of the seven components will be made available to those reporting on the measure as CMS has not done so in the past with multi-component/composite measures. *Response:* This measure's performance is based on a weighted average of the included components. This measure provides a more comprehensive assessment of preventive care and wellness quality clinical assessments that should be received by each patient. While the MIPS benchmark will be based upon the weighted average for the Preventive Care and Wellness (composite), more granular performance data may be found through Medicare Care Compare or third-party intermediaries. *Comment:* A few commenters expressed that reporting burden would increase under the composite. One commenter indicated that combining the component measures into one composite measure would require the same amount of work and yield less results that would positively impact performance scores. One commenter did not support this new measure because it includes measures that have been removed from MIPS in prior rule making, resulting in process improvement efforts shifting to other areas of concern. The commenter stated a composite measure will add additional burden and non-specialty specific focus, thus may not be feasible for small practices. Another commenter similarly opposed addition of this measure and subsequent removal of the component measures citing there are few quality measures for gastroenterology that are specialty specific and due to human and financial limitations, small practices need to focus on two to three process improvements at a time. *Response:* We acknowledged the composite measure will set a more stringent performance standard by requiring a set of adult immunizations and preventive care and wellness measures in one multi-performance measure compared to the prior framework, under which each quality action was reported through a separate quality measure. Since all of the component measures have been available for reporting in MIPS, clinicians are familiar with the component requirements and systems should in place to capture the data; therefore, we expect reporting burden should be minimal. We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures within a specialty measure set will be applicable or appropriate to all clinicians within that specialty set umbrella. However, no measures within traditional MIPS are required. We allow for clinician choice to account for these nuances, while ensuring clinicians are able to choose measures that are most meaningful to their scope of care and patient case-mix. The goal is to ensure we have a comprehensive set of measures that drive positive health outcomes as well as allow flexibility in clinician choice when determining the appropriateness of each measure. We review all specialty sets to ensure adequate numbers of measures to allow for clinician choice as possible even with removal of the component measures in this composite. We did maintain two of the component measures, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, in select specialty measure sets due to the importance of those clinical concepts to specialties where the composite measure would not be applicable, and we maintained measure Q493: Adult Immunization Status for use within traditional MIPS. This measure's performance is based on a weighted average of those measures, and this measure provides a comprehensive preventive care and wellness measure. MIPS measures collect data on all payer sources; therefore, this measure will capture a more robust representation of performance than the individual components. *Comment:* One commenter was concerned about the exclusions of those receiving palliative care services under this measure. While those with an end-stage serious illness receiving palliative care would not benefit from these services, others earlier in an illness receiving palliative care might. Another commenter supported this new measure but also expressed concern about the exclusion of patients receiving palliative care or patients with advanced illness. Palliative services are not always connected to hospice services and, therefore, patients who are early in their diagnosis and could benefit from these services would be excluded. The commenter recommended removal of palliative care services from the exclusions for this measure. *Response:* We agree that palliative care is appropriate at any point in a serious illness and can be provided with any curative, disease modifying treatment. Palliative care is generally provided by an interdisciplinary medical team and focuses on the patient. We encourage clinicians to provide care as they determine best supports all patients during their healthcare journey, even if the patient population is not included within the target denominator of a given specification. For this composite measure, each individual measure contains individualized exceptions/exclusions specific to that measure, so that those patients who may not be appropriate for the quality action will be removed from

Category	Description
	measure performance. We will take the commenters' feedback into consideration during the annual MIPS quality measure revisions cycle. We encourage the commenters to reach out to the measure steward of current measures to discuss revisions for possible implementation in future years. *Comment:* Several commenters opposed this proposed measure as a CQM and the subsequent removal of three existing eCQMs under Table Group CC of this Appendix because they did not want the loss of eCQM measures. Another commenter also did not agree with the change of collection type from eCQM to CQM only and recommended that CMS not finalize the composite measure and retain the applicable original component measures in traditional MIPS, including retaining the eCQM collection type. Another commenter similarly expressed concern that the composite measure will not be available as an eCQM and that the options to collect CQM data are comparatively expensive, burdensome, and inefficient as CQMs are not automatically aggregated within certified electronic health record technology (CEHRT). Another commenter was concerned about having to pay for a registry to report measures they have always been able to report directly. *Response:* We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measure steward to the Call for Measures, which was a MIPS CQM. We acknowledged the commenters' concerns; however, this measure is being proposed as a MIPS CQM and may be supported by Qualified Registries or QCDRs, meaning that the data for calculation of this measure may be abstracted from multiple medical resources which contributes to the flexibilities in reporting this measure. We acknowledge that the removal of measures available for the eCQM collection type may be an inconvenience; however, continuing to drive quality care through the implementation of more robust, meaningful measures is critically important to continued improvement in quality care provided. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in future years. This is a more robust measure to drive quality care and ensure a comprehensive, focused preventive care and wellness assessment, as compared to the individual measures. We did maintain two of the component measures, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, in select specialty measure sets due to the importance of those clinical concepts to specialties where the composite measure would not be applicable. Both of these retained measures include the eCQM collection type. *Comment:* One commenter requested CMS clarify how the composite measure will be implemented, stating it is unclear whether a clinician will need to report on all parts of the measure to satisfy the requirements, or if they can report on only the parts that are relevant to their practice. If the measure relies on complete measure reporting to be satisfied, then the commenter did not support the removal of measure Q402: Tobacco Use and Help with Quitting Amongst Adolescents (see Table C.11 of this Appendix). *Response:* The Preventive Care and Wellness (composite) measure combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services, to create a robust, broadly encompassing preventive care assessment. Because this measure's performance is based on a weighted average of all component measures, the composite provides a comprehensive wellness and prevention measure. As a multiple performance rate measure, it is required for all reporting rates of the measure to be submitted, as many components allow for patient reported quality actions in addition to being appropriate for all patient's preventive health and continued wellness. Any missing data may negatively impact data completeness and/or performance. MIPS measures collect data on all payer sources; therefore, the composite will capture a more robust representation of performance than the individual components. While we acknowledged the commenters' concerns, the Preventive Care and Wellness (composite) measure provides a comprehensive multi-performance measure that utilizes components of measures that have been previously implemented in MIPS, at the individual clinician and group level. Therefore, the composite measure can be successfully implemented in MIPS. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52775 through 52777), we are finalizing the *Preventive Care and Wellness (composite)* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

30. Component 1: Grohskopf, L. A., Alyanak, E., Ferdinands, J. M., Broder, K. R., Blanton, L. H., Talbot, H. K., & Fry, A. M. (2021). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recommendations and Reports, 70(5), 1. *http://dx.doi.org/10.15585/mmwr.rr7005a1*.
Component 2: Kobayashi, M., Farrar, J. L., Gierke, R., Britton, A., Childs, L., Leidner, A. J., ... & Pilishvili, T. (2022). Use of 15-valent Pneumococcal Conjugate Vaccine and 20-valent Pneumococcal Conjugate Vaccine Among US Adults: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022. Morbidity and Mortality Weekly Report, 71(4), 109-117. *https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7104a1-H.pdf*.
Component 3: Siu, A. L., & US Preventive Services Task Force. (2016). Screening for Breast Cancer: US Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine, 164(4), 279-296. *https://www.acpjournals.org/doi/10.7326/M15-2886*.
Component 4: Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA, 325(19), 1965-1977. *https://doi.org/10.1001/jama.2021.6238*.
Component 5: Garvey, W. T., Mechanick, J. I., Brett, E. M., Garber, A. J., Hurley, D. L., Jastreboff, A. M., Nadolsky, K., Pessah-Pollack, R., Plodkowski, R., & Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines (2016). American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists, 22 Suppl 3, 1–203. *https://doi.org/10.4158/EP161365.GL*.
Component 6: Krist, A. H., Davidson, K. W., Mangione, C. M., Barry, M. J., Cabana, M., Caughey, A. B., ... & US Preventive Services Task Force. (2021). Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. JAMA, 325(3), 265-279. *https://doi.org/10.1001/jama.2020.25019*.
Component 7: Krist, A. H., Davidson, K. W., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Hypertension in Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. JAMA, 325(16), 1650-1656. *https://doi.org/10.1001/jama.2021.4987*.
31. Fox, J.B., & F.E. Shaw. (2015). Clinical Preventive Services Coverage and the Affordable Care Act. American Journal of Public Health, 105(1), e7-e10.

A.7. Connection to Community Service Provider

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	498
Description:	Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Measure Steward:	Oregon Community Health Information Network (OCHIN)
Numerator:	Patients who had contact with a CSP for at least one of their HRSNs within 60 days after screening.
Denominator:	Patients aged 18 or older who screened positive for at least 1 of the 5 HRSNs domains (food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety) during the measurement period.
Exclusions:	Patients who are counseled on connection with a CSP and explicitly opt-out.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will address five social and economic determinants we have identified as both a measurement priority and performance gap. Addressing this gap is a central part of our Health Equity strategic plan pillar, as discussed in the 2023 PFS final rule (87 FR 70253 through 70259) for previously finalized measure Q487: Screening for Social Drivers of Health. This measure assesses patients who screen positive for one or more of the five HRSNs for contact with a CSP for at least one of their HRSNs within 60 days of the screening. The five HRSNs are food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety. A CSP is defined as any independent, for-profit, non-profit, state, territorial, or local agency capable of addressing core or supplemental HRSNs. This measure excludes patients who opt out of contact with a CSP. Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health (*https://doi.org/10.7326/M17-2441*). Thus, systematically screening patients for social drivers of health and referring them to community-based resources as needed can result in improved health outcomes (*https://doi.org/10.7326/M17-2441*). Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being (*https://doi.org/10.31478/201705b*). As an example, early findings from the CMMI Accountable Health Communities (AHC) Model shows those patients within the "Assistance Track" (the intervention group offering navigation assistance to connect patients with the community services they need) had 9 percent fewer emergency department visits as compared to their control group counterparts who did not receive navigation assistance during the first year following screening (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). The USPSTF also recently released a technical brief on screening and interventions for social risk factors, which noted that social risk factors are mentioned in two-thirds of USPSTF recommendation statements, and six other professional medical organizations explicitly promote clinician engagement in social risk screening and referrals.[32] The report highlighted that, in studies reporting these outcomes, there were few if any unintended consequences resulting from the implementation of social risk screening and intervention despite perceived barriers to implementation.[32] This measure leverages the data and experience from the AHC Model (*https://innovation.cms.gov/innovation-models/ahcm*), which has screened nearly one million beneficiaries for HRSNs. The AHC Model requires that all AHC-screened beneficiaries with unmet HRSNs receive community referral summaries tailored to their needs (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). This measure is consistent with our priority to advance health equity throughout our various programs. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive (*https://www.cms.gov/pillar/health-equity*). The MAP conditionally supported this measure for rulemaking pending testing indicating the measure is reliable, valid, and feasible, and endorsement by a CBE. While we agree that the full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies showed that social drivers of health contribute to poorer health. Referrals to CSPs provide a direct means through which clinicians can assist patients in overcoming social drivers of health. As we have previously stated, we requested that interested parties consider when submitting a quality measure for possible inclusion whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing" (83 FR 53636; 84 FR 62954). While we considered whether or not a measure is fully tested, it is not the only relevant standard. This measure builds upon measure Q487, collecting data on positive screening and subsequent connection to a CSP for assistance. Having both measures

Category	Description
	in MIPS allows for assessment of two critical steps in addressing health equity; first ensuring that screening is completed on all patients and the second connecting patients who are facing a HRSN with resources that can help address these needs. Addressing health equity is a pressing issue which deserves serious focus and rapid action. This measure is an important next step for use of drivers of health (DOH) data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Clinicians choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is vital to allow further testing and development of additional health equity outcome measures. While we will encourage submission of health equity related measures, MIPS does allow for clinician choice in quality measure selection and will not require submission of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: Several commenters supported the new Connection to Community Service Provider measure because referrals to CSPs provide a direct means through which clinicians can assist patients in addressing DOH. The commenters also requested that CMS include this measure in MVPs. Commenters noted that while screening for HRSNs is an important step, addressing the HRSNs through interventions is the next logical step and appreciated CMS including this option for providers. Another commenter indicated that the addition of this measure to MIPS can also be used as an incentive for collaboration between ACOs, area agencies on aging, or other community-based organizations.

Response: We thank the commenters for supporting this new measure in MIPS. We will take the recommendation to include this measure in MVPs under consideration.

Comment: One commenter supported this new measure because connecting patients with identified social needs to service providers in their community is an important step in promoting health equity and will move the currently available measures beyond merely screening for social needs. However, the commenter indicated that CMS should implement this measure cautiously and explore ways to address challenges such as regional variation in the availability of community service providers to ensure safety net providers are not unfairly penalized. The commenter also requested that CMS work with NCQA to harmonize this measure and measure Q487: Screening for Social Drivers of Health to ensure alignment across measures used at the provider and health plan levels to address patients' social needs.

Response: We understand the concerns provided within the comment. This measure is not mandatory for clinicians to report but provides an opportunity to review current workflows and determine if there are potential changes clinicians can make to positively assess the social needs of their patients. If clinicians can review workflows for potential changes to address identified social needs, patient health can benefit. The Joint Commission, for example, has noted that "correct diagnoses and treatment plans may not be safe and effective if patients cannot afford their medications, do not have a place to live, lack transportation to get to appointments, or have adverse drug reactions because they cannot afford food. Health care organizations should work to understand these needs to provide optimal care."[33] Clinicians may choose to report this measure if they can develop a workflow and process that successfully connects their patients with resources. The use of telehealth and virtual networking may support those clinicians that have limited access to CSP. Regarding harmonization with measure Q487, we will take this feedback into consideration during the public notice and comment cycle for possible implementation in future years.

Comment: One commenter supported this new measure and recommended shortening the 60-day standard to 7 days to support more responsive connections to care and measuring whether the associated need was resolved. The commenter indicated it is imperative that patients' DOH needs are addressed in a timely manner and in a way that resolves the need and are not just connected to service providers. For example, the measure could capture percent of referrals accepted within 7 days (connection completed) and percent of accepted referrals that are closed with an outcome of "need resolved" (resolution of needs).

Response: We will take the commenter's feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. Additionally, we encourage the commenters to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter was concerned that providers who serve disadvantaged populations or practice in rural or low socioeconomic status communities may be unfairly penalized by this measure. Providers treating disproportionate numbers of these patients ultimately require additional dedicated resources to implement such interventions. Due to these circumstances, this measure may be more appropriate if reported at a system or regional level and the commenter did not support the measure for use within MIPS at the provider-level.

Response: We acknowledge the concerns in providing a connection with a CSP for disadvantaged, low socioeconomic status, or rural patient populations. However, these patient populations the commenter describes would benefit most from a clinical workflow that assesses for and addresses positively identified social needs. Including this measure in MIPS encourages clinicians to explore relationships with CSP resources. The goal of this measure is to promote the assessment of patient HRSNs, incorporate information about their HRSNs into their treatment, and facilitate access to CSPs that may be able to ameliorate the HRSN in order to improve health outcomes. Having CSP involvement in the care process may improve health outcomes for those identified with social needs based on current assessment of the patient. Patients with social needs may not have the access to the care recommended by clinicians or the ability to comply with treatment plans, therefore, a CSP could provide the critical assistance needed to ensure health care delivery. "Correct diagnoses and treatment plans may not be safe and effective if patients cannot afford their medications, do not have a place to live, lack transportation to get to appointments, or have adverse drug reactions because they cannot afford food. Health care organizations should work to understand these needs to provide optimal care."33 We encourage clinicians to seek relationships that drive this innovation in wholistic patient care.

Comment: A few commenters supported the intent of this measure but did not believe that implementation was appropriate at the individual clinician or group level in MIPS, particularly due to the absence of any resources or tools that would be widely and readily available to clinicians and practices. Measures must be evidence-based and facilitate improvements in patient care. The commenters stated that the measure developer did not provide any evidence to support the five social needs, nor did they sufficiently justify the requirement to connect a patient with a community services provider on at least one need within 60 days. At a minimum, the measure should align with the work of the Health Level 7 Gravity Project and the USCDI. In addition, the measure itself is not yet tested to demonstrate reliability and validity since

Category	Description
	only data for two screening tools (which are not required) were provided and most of the information outlined is based on the CMMI Accountable Health Communities (AHC) Model (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*), which involved community health centers/health systems and therefore does not provide sufficient information on how this measure would perform at the individual clinician level. Furthermore, the commenters noted they believed that it is imperative that this measure has demonstrated links to directly improving patient outcome without any unintended consequence of creating patient harm. The measure has also not been endorsed by a CBE. *Response:* We acknowledge that due to nuances in clinician specialization, scope of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty set umbrella. However, no measures within traditional MIPS are required. We allow for clinician choice to account for these nuances, while ensuring clinicians can choose measures that are most meaningful to their scope of care and patient case-mix. The measure aligns with the key DOH domains in measures developed through the multi-stakeholder Gravity Project and adopted by the Office of the National Coordinator for Health Information Technology into the US Core Data for Interoperability (USCDI) (*https://www.healthit.gov/sites/default/files/facas/2021-04-08_Gravity_Project_Presentation.pdf*). During discussions at the MAP, the steward confirmed that the 60-day time frame was established as a reasonable timeframe in which to expect the connection to resources has taken place. Furthermore, by improving the clinicians understanding of the social obstacles their patients face beyond the clinical realm they can initiate the next steps to help alleviate these social stressors to improve their patients' mental and physical health. Measures selected for the MIPS quality performance category need not be endorsed by a CBE. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The 5-year Accountable Health Communities (AHC) Model provides evidence of the need for the HRSNs and the positive outcomes by connecting patients with CSPs (*https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt*). The AHC Model utilized both Medicare and Medicaid patients to determine if connecting beneficiaries to community resources positively correlated to health outcome improvement and cost of care reduction. Within the AHC Model, clinical delivery sites (CDSs) were involved as partners to engage beneficiaries by participating in screenings and referral summaries, in addition to assisting navigation-eligible beneficiaries connect with navigators who facilitate referrals to community services (*https://www.cms.gov/priorities/innovation/data-and-reports/2020/ahc-first-eval-rpt*). The AHC Model Evaluation: Second Evaluation Report (December 2020) (*https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt*) found that the fee-for-service (FFS) Medicare beneficiaries within the Assistance Track, there was an 8 percent decrease in emergency department (ED) visits over the first three years after screening, driven by a 9 percent decrease in avoidable ED visits. Also, for the FFS Medicare beneficiaries within the Model's Alignment Track, there was a statistically significant decrease in receiving treatment for respiratory illness. In the AHC Model Evaluation: Second Evaluation Report (December 2020), it was also noted that most CSPs reported an increase in community capacity since the beginning of the model, which is how this measure can aid as an important next step for use of drivers of health (DOH) data to allocate supportive resources to patients in an impactful manner while supporting the clinicians treating these patients. A key finding from the AHC Model evaluations was a high acceptance of navigation, supporting the notion that, once a framework for coordination with CSPs has been implemented, patients will be more accepting and receptive to interventions that involve a CSP. Separate from the AHC Model, the Commonwealth Fund completed a review of evidence supporting HRSNs interventions by type of social service need (*https://www.commonwealthfund.org/sites/default/files/2019-07/ROI-EVIDENCE-REVIEW-FINAL-VERSION.pdf*) and found strong evidence that providing supportive housing can significantly lower expensive forms of health care, while providing housing for the elderly can lead to reductions in hospitalizations and ED visits and large decreases in skilled nursing facility and long-term-care days, translating into significant cost savings to Medicare. Regarding food insecurity (nutrition), the review cited two studies based upon the Meals on Wheels program showed a reduction in hospitalizations, ED visits, and overall health care costs for Medicare beneficiaries. Moderate evidence was found to support an increase in the receipt of outpatient, preventive care for low-income people, with certain chronic conditions or dually eligible, that may prevent the necessity of requiring expensive forms of care. There is additional evidence that suggests coordinated efforts to both identify and meet the patient's social needs can lead to decreases in health care use and costs while leading to better outcomes in patients (*https://doi.org/10.1377/hlthaff.2012.0170*; *https://doi.org/10.1016/j.amepre.2022.03.011*). We find this to be significant evidence that clinician coordination with and referral to CSPs can improve health outcomes. Clinicians that participated in the AHC Model are analogous to MIPS eligible clinicians and therefore, this measure is appropriate for the MIPS quality performance category. One of the most common types of clinical delivery sites in the AHC Model was the primary care practice. We recognize that patient acceptance is essential to success on this measure. For that reason, the measure includes an exclusion in the instance of a patient explicitly opting out of being connected to a CSP. *Comment:* One commenter opposed this new measure, stating that this measure (along with measure Q487: Screening for Social Drivers of Health) is not well suited for non-patient facing providers who cannot ensure that the patient is being screened. The radiologist's performance is dependent upon the facility conducting the screening and establishing a data sharing process with the radiologist. For many imaging facilities, the radiologist is not even located at the point of patient imaging and the staff at the center are employed by a different organization, such as the affiliated hospital. While the commenter supported these measures' intent, they are impractical for many non-patient-facing providers, such as diagnostic radiologists. See related comment under Table B.10 Addition of this Appendix. *Response:* We agree this measure may not be appropriate for the diagnostic radiology clinician type and, as such, we will not be finalizing this measure for inclusion within that measure set. See Table B.10 for a list of the finalized measures. *Comment:* One commenter requested clarification of what "contact" with a CSP for at least 1 of their HRSNs within 60 days after screening means. The commenter stated the measure should focus on the provider's referral for appropriate services, not whether the patient chooses to complete the contact with the community service provider. *Response:* It is not uncommon for a measure to require patient action. Currently, measure Q374: Closing the Referral Loop: Receipt of Specialist Report, requires a patient to complete the encounter while other measures require adherence to medications, such as measure Q009: Anti-Depressant Medication Management. The measure steward defines contact as "engagement with CSP for the purpose of addressing at least one HRSN, either as reported by patient

Category	Description
	or acknowledged from CSP." Engagement, for the purposes of this measure, is not limited completion of all interactions, but could be an initial contact with the CSP to get on a resource waitlist or scheduling a meeting, both of which a clinician may be able to facilitate. Ensuring that there is contact is critically important to ensuring that needs are being addressed. The commonality of this measure with other measures that require patient action is that these measures emphasize patients engaging in their own care. Clinicians encouraging engagement with a CSP should support positive health outcomes by supporting identified social needs that impede access to critical health treatments. Therefore, clinicians should be incentivized to follow up with patients to ensure they contacted the CSP as it may support the treatments recommended by the clinician. This measure is process in nature and does not require resolution of the HRSN or any specific interaction between the patient, CSP, and clinician, only that the patient and CSP made contact within the 60 days following the positive screening. However, we will take the commenter's feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. *Comment:* One commenter supported the intent of this new measure but had concerns that access to CSPs remains extremely variable across the country, and it would be challenging to hold providers accountable for finding resources in communities that lack the full continuum of care. The commenter also stated that this measure does not make a distinction between social risk and social needs screening, which are performed very differently, and is not supported by evidence. *Response:* While we agree availability of resources may be a challenge in some areas, with the increase in telehealth and virtual networking, the CSP need not be in the general area to provide assistance. We acknowledge that "more rigorously designed studies are needed as the field moves forward to clarify cost-effective intervention approaches" (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9257553/*). However, we note there are numerous clinicians who already incorporate HRSN screenings and encouraging patients to contact CSPs for additional support. While it is the patients' choice to act upon the recommendation of connecting with a CSP, clinicians are encouraged to follow up as CSP support has been shown to have an impact patient health outcomes, as discussed above. Through different programs, CSPs can identify and work with the proper resources to reduce social stressors for patients and clinicians. We will take the commenter's feedback regarding the distinction between social risk and social needs screening into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52778 through 52779), we are finalizing the *Connection to Community Service Provider* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

32. Eder, M., Henninger, M., Durbin, S., Iacocca, M. O., Martin, A., Gottlieb, L. M., & Lin, J. S. (2021). Screening and Interventions for Social Risk Factors: Technical Brief to Support the US Preventive Services Task Force. JAMA, 326(14), 1416–1428. *https://doi.org/10.1001/jama.2021.12825.*
33. The Joint Commission. *https://www.jointcommission.org/our-priorities/health-care-equity/accreditation-resource-center/assess-health-related-social-needs/#t=_StrategiesTab&sort=%40created%20descending&numberOfResults=50.*

A.8. Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	499
Description:	Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.
Measure Steward:	American Society of Retina Specialists
Numerator:	Number of patients who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye listed in chart OR if the IOP was >25 mm Hg, a plan of care was documented.
Denominator:	Patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) with a patient encounter during the performance period.
Exclusions:	Patients with a diagnosis of hypotony.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this process measure because it will address the MIPS priority area of patient safety. Patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid-induced glaucoma and their quality of life may be negatively impacted due to visual impairments.[34] Ensuring that appropriate monitoring is conducted to detect and treat this complication is important to prevent significant visual morbidity. Researchers who completed a systemic review identified that 10.9 percent to 79.0 percent of patients will develop clinically significant IOP elevations and should have a follow-up within 7 weeks, based upon randomized controlled trials.[35] This measure will directly measure IOP after corticosteroid injections. The intent of this measure encourages clinicians to screen and treat patients identified with an elevated IOP in a timely manner. Currently there are no measures in MIPS that address the screening and plan of care for elevated IOP following intravitreal or periocular steroid therapy. This measure will also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Current clinical guidelines do not address the need to assess for elevated IOP following corticosteroid injection; however, data has demonstrated that patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid induced glaucoma, visual impairment, and overall poor quality of life.[36 37] Several randomized clinical trials and a systematic review identified that IOPs typically peak around 7 to 9 weeks.[35 38 39] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: One commenter supported the new Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy measure, stating that retina specialists frequently treat these conditions and use their specialized knowledge to manage these patients with the goal of preventing more serious complications, such as retinal detachment or steroid-induced glaucoma. This measure reflects a higher quality of care that ensures patients are receiving a comprehensive examination and appropriate follow-up. The measure also covers a gap in care for these conditions that will lead to meaningfully improved patient outcomes.

A couple of other commenters supported this new measure and the new measures under Tables A.9 and A.10 of this Appendix. One commenter stated these measures take important steps to better align MIPS quality performance with the evidence-based treatment guidelines established by the professional medical societies, which aim to reduce the likelihood of patients facing long-term problems like elevated intraocular pressure, steroid-induced glaucoma, retinal tears, retinal detachment, epiretinal membrane, and loss of vision. New quality measures are an important advancement to better reflect the quality of work of retinal specialists. The follow-up care that is a key part of these measures allows for the prompt identification and mitigation of risk for possible complications.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52780), we are finalizing the *Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

34. American Academy of Ophthalmology. (2022, March 29). Steroid-Induced Glaucoma. EyeWiki. *https://eyewiki.aao.org/Steroid-Induced_Glaucoma.*
35. Kiddee, W., Trope, G. E., Sheng, L., Beltran-Agullo, L., Smith, M., Strungaru, M. H., ... & Buys, Y. M. (2013). Intraocular Pressure Monitoring Post Intravitreal Steroids: A Systematic Review. Survey of Ophthalmology, 58(4), 291-310. *https://doi.org/10.1016/j.survophthal.2012.08.003.*

36. Breusegem, C., Vandewalle, E., Van Calster, J., Stalmans, I., & Zeyen, T. (2009). Predictive Value of a Topical Dexamethasone Provocative Test Before Intravitreal Triamcinolone Acetonide Injection. Investigative Ophthalmology & Visual Science, 50(2), 573–576. *https://doi.org/10.1167/iovs.08-2625*.
37. Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jiao, J., Li, X. Y., Whitcup, S. M., Ozurdex GENEVA Study Group, & Li, J. (2011). Dexamethasone Intravitreal Implant in Patients with Macular Edema Related to Branch or Central Retinal Vein Occlusion Twelve-Month Study Results. Ophthalmology, 118(12), 2453–2460. *https://doi.org/10.1016/j.ophtha.2011.05.014*.
38. Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jacques, M. L., Jiao, J., Li, X. Y., Whitcup, S. M., & OZURDEX GENEVA Study Group (2010). Randomized, Sham-Controlled Trial of Dexamethasone Intravitreal Implant in Patients with Macular Edema due to Retinal Vein Occlusion. Ophthalmology, 117(6), 1134–1146.e3. *https://doi.org/10.1016/j.ophtha.2010.03.032*.
39. Aref, A. A., Scott, I. U., Oden, N. L., Ip, M. S., Blodi, B. A., & Van Veldhuisen, P. C. (2015). Incidence, Risk Factors, and Timing of Elevated Intraocular Pressure After Intravitreal Triamcinolone Acetonide Injection for Macular Edema Secondary to Retinal Vein Occlusion SCORE Study Report 15. JAMA Ophthalmology, 133(9), 1022-1029. *https://doi.org/10.1001/jamaophthalmol.2015.1823*.

A.9. Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	500
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Denominator:	Patients with a diagnosis of acute PVD in either eye and eligible encounter during measurement period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 8 weeks after initial acute PVD encounter. - Patients with a diagnosis of acute vitreous hemorrhage.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this process measure because it will address the appropriate screening and follow-up for patients with PVD. PVD puts patients at an increased risk of retinal tears.[40] PVD complicated by retinal tear may result in retinal detachment or epiretinal membrane, causing loss of vision.[40] When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate initial exam and re-evaluation.[41] Prompt identification of complications will allow for expedient treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life.[41] Currently there are no measures in MIPS that address care improvement for patients at risk of retinal tearing due to PVD. This measure is intended to assess compliance with the current guidelines published by the American Academy of Ophthalmology on PVD and retinal breaks, which calls for re-evaluation of patients within eight weeks of their diagnosis of PVD.[41] Such re-evaluations are associated with prompt identification of complications which will allow for expedient onset of treatment, minimizing the potential for further complications, such as retinal detachment improving a patient's quality of life.[40] This measure will also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE, with a specific review of the validity of the measure specifications and performance gap of the measure. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As stated above, PVD is not preventable; however, with prompt evaluations, and expedited treatment, these complications may be lessened, supporting the need for this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: A couple of commenters supported the new Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up measure for reporting by retinal specialists. Full comments are included under Table A.8 of this Appendix.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52781), we are finalizing the *Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

40. American Society of Retinal Specialists. (2016). Retina Health Series: Posterior Vitreous Detachment. Available at: *https://www.asrs.org/content/documents/fact_sheet_1_posterior_vitreous_detachment_new.pdf.*
41. American Academy of Ophthalmology Retina/Vitreous Preferred Practice Pattern Panel. (2019). Preferred Practice Pattern® Guidelines. Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration PPP 2019. San Francisco, CA: American Academy of Ophthalmology. Available at *http://www.aao.org/ppp.*

A.10. Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	501
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Denominator:	Patients with a diagnosis of acute PVD and acute vitreous hemorrhage in either eye and eligible encounter during performance period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 2 weeks after initial acute PVD encounter.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will address appropriate screening and follow-up for patients with PVD and acute vitreous hemorrhage, due to the increased risk for complications such as retinal tears and subsequent retinal detachment in this population. This measure will address the MIPS priority area of patient safety by incentivizing physicians to see patients in a timely manner. It was found that two-thirds of PVD patients presenting with associated vitreous hemorrhage, had at least one retinal break and therefore, require a more expedient follow-up evaluation. This measure will also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate evaluation. Prompt identification of complications will allow for expedient onset of treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life. The current guideline published by the American Academy of Ophthalmology on posterior vitreous detachment (PVD) and retinal breaks supports this measure. The guideline states, "selected patients, particularly those with any degree of vitreous pigment, vitreous or retinal hemorrhage, or visible vitreoretinal traction, should be asked to return for a second examination promptly if they have new symptoms or within 6 weeks following the onset of PVD symptoms."[41] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: A couple of commenters supported the new Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up measure for reporting by retinal specialists. Full comments are included under Table A.8 of this Appendix.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52782), we are finalizing the *Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

A.11. Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	502
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated improvement or maintenance of functioning, as demonstrated by results of follow-up assessment using the 12-item WHODAS 2.0 or Sheehan Disability Scale 30 to 180 days after the index assessment during the performance period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder and an encounter with an index assessment completed using the 12-item WHODAS 2.0 or Sheehan Disability Scale (SDS) during the denominator identification period.
Exclusions:	Patient situations, at any point during the denominator identification period, where the patient's functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools, such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders, - Patients who died during the performance period.
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will address a high priority specialty area and a high priority clinical topic, mental health and substance use disorders, and is not duplicative of any existing measure within MIPS. The mental and substance use disorders captured by this measure are among the 25 leading causes of years lived with disabilities as well as contributing significantly to the global burden of disease.[42] Twenty-two percent of U.S. adults (57.8 million individuals aged 18 and older) have a mental illness diagnosis and 17.3 percent (44 million individuals aged 18 and older) have a substance use disorder diagnosis (*https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases#annual-national-report*). Individuals with mental disorders are more likely to report severe impairment in functioning when compared to patients with chronic medical conditions.[43] Improvement or maintaining functioning is strongly predictive of a positive outcome.[43] Patients afflicted with mental disorders showed increased rates of morbidity from general medical conditions in addition to a higher risk of premature mortality.[43] Considering these factors and the contribution of mental health disorders to the global burden of disease, gaps persist in healthcare. This necessitates improvement in the overall quality of mental health care.[43 44] Outcome measures are critical to evaluating patient improvements based on current patient care, assisting clinicians in planning, monitoring, and adjusting care plans and treatment options.[45] This measure is comprehensive and broadly inclusive of mental health and substance use disorders. It uses a measurement-based care framework for implementation across various settings and populations to assess the outcome of care for patients with mental health and substance use disorders. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. A measure focused on functioning is linked to a decrease in negative symptoms and a reduction in resources utilized, making it have the potential to reduce economic burden. Using a screening tool will allow clinicians to better assess patient functioning over time and adjustment treatment accordingly. Measurement-based care with the use of a valid and reliable tool provides valuable information about functioning.[44] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: Several commenters supported the new Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder measure. One commenter stated that the increased adoption of measurement-based care and use of patient-reported outcomes in behavioral health measurement is critical to improving care in this area. Another commenter supported the new behavioral health measures and appreciated their proposal in relevant MVPs.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter supported this new measure and stated the measure is currently limited to the WHODAS 2 or Sheehan Disability Scale for assessing improvements in functional status. The commenter encouraged CMS to monitor the landscape and consider including additional assessment tools/models that may be found to be more conducive to assessment of certain populations, as evidence becomes available.

Response: We thank the commenter for supporting this new measure in MIPS and will take their feedback it into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. Additionally, we encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

Category	Description
	After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52783), we are finalizing the *Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

42. The U.S. Burden of Disease Collaborators. (2018). The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. Journal of the American Medical Association, 319(14), 1444–1472. *https://doi.org/10.1001/jama.2018.0158*.
43. Druss, B. G., Hwang, I., Petukhova, M., Sampson, N. A., Wang, P. S., & Kessler, R. C. (2009). Impairment in Role Functioning in Mental and Chronic Medical Disorders in the United States: Results from the National Comorbidity Survey Replication. Molecular Psychiatry, 14(7), 728-737. *https://doi.org/10.1038/mp.2008.13*.
44. Scott, K., & Lewis, C. C. (2015). Using Measurement-Based Care to Enhance Any Treatment. Cognitive and Behavioral Practice, 22(1), 49–59. *https://doi.org/10.1016/j.cbpra.2014.01.010*.
45. Kilbourne, A. M., Beck, K., Spaeth-Rublee, B., Ramanuj, P., O'Brien, R. W., Tomoyasu, N., & Pincus, H. A. (2018). Measuring and Improving Quality of Mental Health Care: A Global Perspective. World Psychiatry, 17(1), 30-38. *https://doi.org/10.1002/wps.20482*.

A.12. Gains in Patient Activation Measure (PAM®) Scores at 12 Months

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	503
Description:	The Patient Activation Measure® (PAM®) is a 10 or 13 item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
Numerator:	Numerator 1: Patients with a Baseline PAM® score and then a second score taken within 12 months of the baseline (but not less than 6 months). Numerator 2: Percentage of eligible patients who achieved a net increase in PAM® score of at least 3 points in a 6 to 12 month period (passing). Numerator 3: Percentage of eligible patients who achieved a net increase in PAM® score of at least 6 points in a 6 to 12 month period (excellent). Numerator 4: The average change (net difference) for all eligible patients between the baseline PAM® score and the second score taken within 12 months of the baseline (but not less than 6 months).
Denominator:	Denominator 1: Patients aged 14 and older with a qualifying visit at least once during the performance period. Denominator 2, 3 and 4: Patients aged 14 years and older with Performance Met for Submission Criteria 1 who had a baseline PAM® score and a second score within 6 to 12 month of baseline PAM® score and who were seen for a qualifying visit at least once during the performance period.
Exclusions:	Denominator 1, 2, 3: Diagnosis of Dementia; Diagnosis of Huntington's disease; Diagnosis of Cognitive Impairment or Alzheimer's disease Denominator 4: None
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	1.Clinicians must have collected a follow-up PAM® survey on at least 50 percent of all eligible patients during the performance period 2.Clinicians must have administered a follow-up PAM® survey to a minimum of 50 unique patients
Rationale:	We proposed this measure because this measure, while disease agnostic, will address chronic conditions and patient reported outcomes, both of which are high priority areas for measure consideration for MIPS. This PRO-PM provides a standardized method for clinicians to assess patient activation through the continuum of care. The PAM® survey[46] collects information directly from patients regarding their knowledge, skill, and confidence in managing their health and healthcare. This measure has been used with a wide variety of chronic conditions, as well as with people with no medical diagnosis. The intent of the PAM® is to assess an individual's ability to manage their own health and health care. According to the measure developer, the PAM® is predictive of most health outcomes, including such diverse outcomes as how a patient fares after orthopedic surgery; remission of depression over time; the likelihood of hospital re-admission or ambulatory care sensitive (ACS) utilization; the trajectory of a chronic disease over time; and even the likelihood of a new chronic disease diagnosis in the coming year.[47 48 49 50] The PAM® surveys the knowledge, skill, and confidence necessary for self-management on a 0-100 point scale that can be broken down into four levels from low activation to high activation. The 13 (or 10) item survey has strong measurement properties and is predictive of most health behaviors and many clinical outcomes.[51] PAM® scores are also predictive of health care costs, with lower scores predictive of higher costs.[46] The PAM® is in use both in the U.S. and internationally in research as well as clinical settings and has been translated into more than 30 languages.[46] The measure developer validated the instrument in populations of different racial and ethnic backgrounds and socio-economic levels, owing to the widespread utilization of PAM® by researchers all over the world.[46 51] A version of this measure, as well as the PAM® survey, is used in a number of federal quality and payment programs.[46] Additionally, it is currently a required assessment in the CMMI Kidney Care Choices (KCC) *(https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model*) and Maternal Opioid Misuse (*https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model*) alternative payment models. This measure received support for rulemaking from the MAP. The MAP discussed concerns regarding the potential proprietary nature of the assessment, costs to integrate the measure into EHRs, and the licensing for integration into EHRs. The measure developer clarified the measure will be available without licensing costs for implementation. MAP also raised concerns regarding the specificity of the denominator definition/population. However, this measure is currently implemented in other Federal quality and payment programs. The measure is also aligned with the CBE endorsed measure CBE 2483: Gains in Patient Activation (PAM®) Scores at 12 Months, which is applicable to the "Group/Practice" level of analysis. Overall, the MAP agreed this measure contributes to patient-centered care and supported the measure as a PRO-PM. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*
Comment: A few commenters supported the new Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure. One commenter noted that nurses are critical to the success and administration of this measure due to their expertise in patient education and care coordination. Another commenter stated that PAM® scores predict most health-related behaviors, regardless of health status or conditions, and interventions designed to increase activation also result in decreased costs and improved clinician burden. The commenter indicated the importance of including the PAM®-PM along with measure Q487: Screening for Social Drivers of Health to improve patient outcomes in populations disproportionately impacted by chronic conditions. The commenter also stated that clinicians should enable patients and arm them	

Category	Description
	with the tools they need to be more active in their care and develop healthy behaviors. Another commenter supported this new measure, stating that the PAM®-PM has been successful as part of the Kidney Care Choices model. *Response:* We thank the commenters for supporting this new measure in MIPS. We also appreciate the critical role nurses contribute to the healthcare system. *Comment*: One commenter supported this new measure for use in specialty sets and MVPs. In addition, the measure is already in use by orthopedic surgeons. Given this measure's value, the commenter requested that CMS consider it for inclusion in the Universal Foundation. Several commenters supported this measure in the End-Stage Renal Prospective Payment System Quality Incentive Program and the Universal Foundation. *Response:* We thank the commenter for supporting this new measure in MIPS. We will take feedback into consideration regarding inclusion of this measure in the Universal Foundation. *Comment:* One commenter supported this new measure and encouraged CMS to use the performance rate: "percent of patients age 14 years and older who achieved a net increase in PAM® score of at least 3 points in a 6–12-month period" as the benchmarking strata. The commenter noted they believed this stratum would be the most clinically relevant threshold based on existing data and expert clinical feedback. The commenter also recommended that CMS raise the threshold of the minimum number of patients receiving a second PAM® survey from 40 to 50. This threshold has been shown to be the minimum volume necessary for the performance measure to be empirically reliable and valid in its most recent testing. *Response:* We thank the commenter for their feedback and agree to make these updates requested by the measure steward to this measure for CY 2024. Under the Measure-Specific Case Minimum/Performance Period row, we have updated the text to read "2. Clinicians must have administered a follow-up PAM® survey to a minimum of 50 unique patients." This update does not change the nature of the measure as proposed and clarifies the expected number of surveys required to meet the threshold for reporting the measure. Other requested changes will occur in the measure specifications. *Comment:* One commenter indicated that while this measure can provide a good assessment of patients who actively participate in their healthcare, it fails to account for socioeconomic status, healthcare access, and comorbidities. Given the challenges in this population, it is highly unlikely that anyone with health-related social needs will be an active participant in their healthcare. Challenges exist with a survey-based tool, such as the possibility of response bias, and time and resource constraints on administration. While the measure can offer valuable insights into self-management in cardiology patients, the commenter noted they believed it should be used in conjunction with other clinical assessments and considerations to provide a more comprehensive evaluation of a patient's cardiac health and overall well-being. *Response:* The reliability and validity of the PAM® survey has been demonstrated across patient populations, sociodemographic segments, mode of administration, and across multiple languages. Across all patient populations, lower activation has been shown to be predictive of poor self-management, higher healthcare utilization, and higher costs. The evidence suggests factors such as education, income, ethnicity, and gender account for less than 5 percent of the variance in PAM® scores. Providers are not penalized for having a large percentage of patients with low activation scores, as those patients have the most room for gains. Providers are assessed for increasing activation in patients based upon the completion of an initial and follow-up PAM® survey, which is indicative of patient experience as opposed to healthcare access, as activation is addressing a patient's ability to understand and be an active part of their healthcare journey. Furthermore, evidence shows that all patients can improve in activation and when appropriately supported, patients at the lower levels of activation improve more quickly than other patients. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation. *Comment:* One commenter had concerns about the broad applicability of the measure and the feasibility and implementation burden the measure would pose. The commenter stated that it was positive that the measure looks at a change score and excludes patients who would not be eligible for the measure. However, the commenter noted they believed the measure should be applied to a narrower set of patients and that the measure does not account for patient preference and where a patient may not need activation. The measure may be burdensome to operationalize for practices that do not already have a system to support patient engagement and patient activation. In addition, the measure developer stated that PAM® scores are higher for patients who have good to excellent health. The measure developer also acknowledged lower scores for a vast majority of patients that make up an internal medicine physician's patient population, causing performance scores to likely skew lower for this specialty. *Response:* The addition of this measure enhances clinician choice when they select measures to report. The PAM® is a disease-agnostic measure meant to provide meaningful information about changes in activation across many patient populations and aligns with CMS health priorities of capturing the patient voice, ensuring patients can be partners in healthcare decisions with their clinicians. This will be a valuable tool for all patients within a clinician's scope of practice. Patients with an initial maximum score of four at baseline are addressed within the measure specification, such that this patient population should not inadvertently inflate performance. The evidence suggests factors such as education, income, ethnicity, and gender account for less than 5 percent of the variance in PAM® scores. Furthermore, patients at the lower levels of activation improve more quickly than other patients.[52 53] Evidence shows when patients are appropriately supported by their clinical teams, they typically gain in their ability to self-manage. Research shows that when the least activated (measuring at levels 1 or 2) are provided appropriate support, they will typically gain 6-9 points on the 0-100 scale within 6 months. This level of change in PAM® scores is significant in terms of changing patients' clinical trajectory, as well as their cost trajectory. In a follow up study, it was found that the PAM®-PM was significantly linked with clinician behaviors with regard to supporting the patient role and clinician beliefs about the importance of the patient role in the care process. *Comment:* One commenter supported measures that encourage physicians and practices to focus on ensuring that patients are equipped to manage their health and health care but questioned whether this measure had been tested for reliability and validity at the individual clinician level. The data provided during the MAP focused on the reliability and validity of the tool. In addition, the measure has not been reviewed for CBE endorsement for at least 7 years. New data on performance, feasibility of data collection and reporting burden should be available, as well as testing information. Therefore, the commenter stated that the measure must be re-evaluated for continued endorsement prior to inclusion of this measure in MIPS and placed within specialty measure sets.

Category	Description
	Response: The steward provided sufficient reliability and validity testing at the clinician level to determine that the measure can be reliably implemented within MIPS. While this measure aligns with the CBE endorsed measure CBE 2483: Gains in Patient Activation (PAM®) Scores at 12 Months, which is applicable to the "Group/Practice" level of analysis, it currently does not have CBE endorsement. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. At this point, there are a sufficient number of studies in the literature for multiple systematic reviews to have been published based on existing PAM® studies. For example, a recent systematic review examined utilization among patients with a chronic illness, including ten studies, and found that patients with low PAM® scores were more likely to seek care in an emergency department.[54] Another systematic review concluded that, along with the Health Related Quality of Live (HRQOL), patient activation is one of the most useful measures of self-management for clinicians.[55] *Comment:* One commenter expressed that Phreesia does not have a method for licensing the PAM® tool for other vendors to use. If a clinician is not using Phreesia, there is not a way to use the PAM® survey, and therefore they cannot participate in this measure. There are many activation patient-reported outcome measures (PROM) that are free, and others that while not free, have clear licensing processes and associated fee schedules, that allow clinicians to use whatever vendor they choose to administer the survey. The commenter suggested replacing the PAM® survey with an alternate activation survey that is accessible to any electronic PROM vendor/platform. *Response:* The PAM® survey will be made publicly available by the measure steward at no cost to clinicians. This will available after the 2024 Physician Fee Schedule final rule is released. The current MIPS quality measure inventory does not include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation. *Comment:* One commenter stated that gains in patient activation are important but had concerns that the measure specification only uses one qualifying encounter for clinician attribution. The commenter recommended that the measure steward include a requirement for at least two qualifying visits to illustrate a patient-clinician relationship. *Response:* We will take the commenter's feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52784 through 52785), we are finalizing the *Gains in Patient Activation Measure (PAM®) Scores at 12 Months* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

46. PAM Survey: *https://www.phreesia.com/patient-activation-measure/%20?utm_source=google&utm_%20medium=paid_%20search&utm_%20destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&utm_audience1=payer&utm_content=648172611574&utm_destinationco.*
47. Greene, J., Hibbard, J. H., Sacks, R., Overton, V., & Parrotta, C. D. (2015). When Patient Activation Levels Change, Health Outcomes and Costs Change Too. Health Affairs, 34(3), 431-437. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0452.*
48. Mitchell, S. E., Gardiner, P. M., Sadikova, E., Martin, J. M., Jack, B. W., Hibbard, J. H., & Paasche-Orlow, M. K. (2014). Patient Activation and 30-day Post-discharge Hospital Utilization. Journal of General Internal Medicine, 29(2), 349–355. *https://doi.org/10.1007/s11606-013-2647-2.*
49. Sacks, R. M., Greene, J., Hibbard, J. H., & Overton, V. (2014). How Well Do Patient Activation Scores Predict Depression Outcomes One Year Later? Journal of Affective Disorders, 169, 1-6. *https://doi.org/10.1016/j.jad.2014.07.030.*
50. Hibbard, J. H., Greene, J., Sacks, R. M., Overton, V., & Parrotta, C. (2017). Improving Population Health Management Strategies: Identifying Patients Who Are More Likely to Be Users of Avoidable Costly Care and Those More Likely to Develop a New Chronic Disease. Health Services Research, 52(4), 1297–1309. *https://doi.org/10.1111/1475-6773.12545.*
51. Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Services Research, 39(4 Pt 1), 1005–1026. *https://doi.org/10.1111/j.1475-6773.2004.00269.x.*
52. Lindsay, A., Hibbard, J. H., Boothroyd, D. B., Glaseroff, A., & Asch, S. M. (2018). Patient Activation Changes as a Potential Signal for Changes in Health Care Costs: Cohort Study of US High-Cost Patients. Journal of General Internal Medicine, 33(12), 2106–2112. *https://doi.org/10.1007/s11606-018-4657-6.*
53. Alvarez, C., Greene, J., Hibbard, J., & Overton, V. (2016). The Role of Primary Care Providers in Patient Activation and Engagement in Self-Management: A Cross-Sectional Analysis. BMC Health Services Research, 16, 85. *https://doi.org/10.1186/s12913-016-1328-3.*
54. Kinney, R. L., Lemon, S. C., Person, S. D., Pagoto, S. L., & Saczynski, J. S. (2015). The Association Between Patient Activation and Medication Adherence, Hospitalization, and Emergency Room Utilization in Patients with Chronic Illnesses: A Systematic Review. Patient Education and Counseling, 98(5), 545–552. *https://doi.org/10.1016/j.pec.2015.02.005.*
55. Newland, P., Lorenz, R., & Oliver, B. J. (2021). Patient Activation in Adults with Chronic Conditions: A Systematic Review. Journal of Health Psychology, 26(1), 103–114. *https://doi.org/10.1177/1359105320947790.*

A.13. Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	504
Description:	Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
Measure Steward:	American Psychiatric Association
Numerator:	Numerator 1: Patients for whom a completed suicide safety plan is initiated, reviewed, or updated in collaboration between the patient and their clinician at the time the suicidal ideation behavior or risk is identified (concurrent or within 24 hours of index clinical encounter), during the measurement period. Numerator 2: Patients for whom a suicide safety plan is initiated, reviewed, or updated in collaboration between the individual and their clinician at the time the suicidal ideation, behavior or risk is identified (concurrent or within 24 hours of clinical encounter) AND reviewed and updated within 120 days after the index clinical encounter after initiation.
Denominator:	Denominator 1 and 2: Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms or suicide risk at a clinical encounter during the denominator identification period.
Exclusions:	Denominator 1 and 2: Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it will focus on a process where initiating and reviewing a suicide safety plan with a patient at risk of suicide is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation; thereby, addressing behavioral health. Incorporating this measure into MIPS will encourage measure adoption, which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure represents a high priority area for MIPS due to its focus on improved outcomes in mental health. The use of standardized patient-reported outcome measures (PROMs) associated with suicide ideation and behavior and clinician-rated assessments of suicide risk, including the use of safety plans, varies within and across behavioral health specialties as well as primary care and emergency care settings, where suicidal persons often present for care. Currently, only hard-copy versions of safety planning documents have been used in most settings, with slow uptake of electronic versions.[56] Hard-copy safety plans provided to patients are prone to misplacement, creating a barrier to their use and follow-up.[56] Even with use of suicide safety plans at an index visit, research has found that less than 50 percent of suicidal persons had explicit evidence of ongoing review or utilization of the safety plan in ongoing treatments.[57] The implementation of this quality measure is intended to incentivize quality care that addresses the low rate of (re)assessment and poor outcomes. This quality measure will help to advance the Zero Suicide initiative set forth in the National Strategy for Suicide Prevention (*https://theactionalliance.org/our-strategy/national-strategy-suicide-prevention*) and ultimately improve the quality of care for patients with suicide ideation, behaviors, or suicide risk. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, this measure distinguishes itself from measure Q107 by focusing on a care process that is directly designed to mitigate suicide risk, as opposed to merely completely screening for it. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. While the PHQ-9, the assessment used in measure Q370[58], does include one question about self-harm, measure Q370 is specific to depression. This measure will include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This suicide prevention measure will be clinically useful for clinicians treating individuals at increased risk for suicide as it is associated with reduction in suicidal behaviors and may improve quality of care for at risk patients. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*
Comment: A couple of commenters supported the new Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk measure. One commenter stated that the increased adoption of measurement-based care and use of patient-reported outcomes in behavioral health measurement is critical to improving care in this area.	

Category	Description
Response: We thank the commenters for supporting this new measure in MIPS. *Comment:* One commenter supported this new measure and in the future encouraged CMS to require a specific and validated, stakeholder-supported screening tool as part of this measure such as the Columbia-Suicide Severity Rating Scale (C-SSRS). The C-SSRS is already incorporated in the proposed Reduction in Suicidal Ideation or Behavior Symptoms measure (See Table A.14 of this Appendix), and the commenter encouraged CMS to adopt this instrument for other suicide-focused measures, as it has been validated, is supported by industry, is available in the public domain, and requires no formal mental health training to administer. *Response:* We thank the commenter for their support and will take the commenter's feedback into consideration during the annual MIPS quality measure revisions cycle for possible implementation in future years. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. *Comment:* One commenter was concerned that this new measure is impractical for implementation because it would only be available as a CQM and CQMs are not automatically aggregated within CEHRT. The commenter noted that shifting from meaningful, validated, data-efficient eCQMs to costly CQMs is out of step with CMS' goals in the transition to digital quality measurement. *Response:* We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years, This is a robust measure to drive quality care and ensure suicide risk assessment and prevention. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52786), we are finalizing the *Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

56. Little, V., Neufeld, J., & Cole, A. R. (2018). Integrating Safety Plans for Suicidal Patients into Patient Portals: Challenges and Opportunities. Psychiatric services (Washington, D.C.), 69(6), 618–619. *https://doi.org/10.1176/appi.ps.201700458*.
57. Gamarra, J. M., Luciano, M. T., Gradus, J. L., & Wiltsey Stirman, S. (2015). Assessing Variability and Implementation Fidelity of Suicide Prevention Safety Planning in a Regional VA Healthcare System. Crisis, 36(6), 433–439. *https://doi.org/10.1027/0227-5910/a000345*.
58. See *https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf*.

A.14. Reduction in Suicidal Ideation or Behavior Symptoms

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	505
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated a reduction in suicidal ideation and/or behavior symptoms as demonstrated by results of a follow-up assessment using the C-SSRS within 120 days after the index assessment during the measurement period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms OR deemed a suicide risk based on their clinician's evaluation at an encounter with an index assessment completed using the C-SSRS during the denominator identification period.
Exclusions:	Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this PRO-PM because this measure focuses on mental health and substance use disorder (SUD), which are CMS high priority areas for MIPS measure consideration. This measure collects information related to a demonstrated reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' *(https://www.cms.gov/files/document/cssrs-screen-version-instrument.pdf)* versus 'Since Last Visit', taken within 120 days after an index assessment. Incorporating this measure into MIPS will encourage and support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure will represent another valuable PRO-PM measure for interested parties to report within MIPS, representing the continuum of care and improved health outcomes for individuals with suicidal ideation, behavior, or risk. This clinical outcome measure assesses reductions in suicidal ideation that are likely associated with reductions in suicides and suicide attempts. Suicide is a preventable cause of lost lives, yet each year over 40,000 Americans die by suicide (*https://www.cdc.gov/nchs/products/databriefs/db330.htm*). Safety planning, means reduction, and connecting suicidal persons to treatment are effective and critical elements in suicide prevention (*https://theactionalliance.org/sites/default/files/action_alliance_recommended_standard_care_final.pdf*), as discussed in the most updated clinical practice guidelines for assessment and treatment of suicidal persons (*https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf*). This measure, which focuses on the reduction of suicidal ideation, conceptually addresses behavioral health, and is a high priority area for MIPS. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, this measure distinguishes itself by focusing on the relevant clinical outcome. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. The instrument used to assess remission in measure Q370, the PHQ-9, does include one question about self-harm; however, measure Q370 is specific to depression. This measure will include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: A couple of commenters supported the new Reduction in Suicidal Ideation or Behavior Symptoms measure.

Response: We thank the commenters for supporting this new measure in MIPS

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52787), we are finalizing the *Reduction in Suicidal Ideation or Behavior Symptoms* measure as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Table Group B: Modifications to Previously Finalized Specialty Measures Sets Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

In the CY 2024 PFS proposed rule (88 FR 52788 through 53073), we proposed to modify the below previously finalized specialty measures sets based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures had proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. Further details of these types of measures are located in the CMS Measures Management System Hub (*mmshub.cms.gov*).

NOTE:

- Updates to measure titles and/or measure descriptions under Table Group B in this final rule may or may not be considered substantive in nature, therefore may not be proposed or updated under Table Group D. If the change was considered substantive in nature, it was finalized under Table Group D.
- Under Table Group B, we responded to comments related to new measures that were proposed for addition to measure sets, as well as measures proposed for removal. Any comments received on previously finalized measures that have no substantive changes are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and have been removed from the applicable Removal table. The reason for their retention was addressed under Table Group C.
- For each specialty set, measures in the Previously Finalized tables and any new measures finalized under applicable Addition tables will be available for reporting in CY 2024.

It should be noted for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any specialty set under Table Group B of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this final rule. For information regarding finalized changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

Note: The following specialty sets had no addition tables, no removal tables, and no substantive changes proposed for the CY 2024 performance period/2026 MIPS payment year: Anesthesiology, Electrophysiology Cardiac Specialist, and Pathology. The following specialty sets had no addition tables or removal tables but did have substantive changes as addressed under Table Group D: Dentistry and Radiation Oncology.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	338	CMS314v1	eCQM Specifications, MIPS CQMs Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Allergy/ Immunology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	NA / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Allergy/ Immunology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52791 through 52793), we are finalizing the above measure(s) for addition to the *Allergy/Immunology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52793), we are finalizing the above measure(s) for removal from the *Allergy/Immunology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set and this specialty set had no proposed changes.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	2152/ N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.3. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Audiology specialty set. We agreed with interested parties' feedback that adding this measure to this specialty set will help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the auditory system due to high blood pressure making this an important aspect of care for audiologists. Given the close correlation of adverse effects on the auditory system due to hypertension, interdisciplinary care is vital, and it should be the responsibility of all clinician types to address health promotion and wellness, and prevention, delay, or management of acute or chronic diseases and conditions. This measure will support the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule.

B.3. Audiology

MEASURES FINALIZED FOR ADDITION TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Audiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.3. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter supported the addition of measures Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented and the Connection to Community Service Provider to the Audiology specialty set. A second commenter supported the Connection to Community Service Provider measure.

Response: We thank the commenters for supporting the additional measures to this specialty set. As noted in the Table Group B Introduction, a commenter who requested additional quality measures be added to this specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these quality measures must be proposed through rulemaking.

Comment: A couple of commenters did not support adding measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented to the Audiology specialty set. Under current Medicare regulations, audiologists are not classified as "practitioners" (as are other allied health professionals) and thus are not recognized for patient care management. Should Medicare regulations change, the commenter would be pleased to submit further comments on patient management measures at that time. Audiologists are not able to manage and make recommendations to the patient regarding high blood pressure other than recommending the patient see a physician and cannot prescribe medications based on their scope of practice and licensing laws.

Response: Currently, the Audiology specialty set contains 10 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. While we understand that the treatment of hypertension would fall outside of the audiologist's scope of care, the measure does not require this for the purposes of meeting the quality action. Hypertension is a prevalent condition and a major risk factor for ischemic heart disease, stroke, and renal failure, among other conditions, with appropriate follow-up after blood pressure measurement being a pivotal component in the prevention of hypertension progression and subsequent development of heart disease. This was requested for inclusion via specialty set solicitation and we agree with the interested party's request to add this measure as it does not require audiologists to practice outside of their scope, as referral to a physician would suffice for performance.[59]

Comment: One commenter stated the new Connection to Community Service Provider measure was redundant to measure Q487: Screening for Social Drivers of Health: As result, the commenter requested that Q487 be removed from this set if the new measure is added.

Response: Measure Q487 is an important process measure for clinicians that supports the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Measure Q487 focuses on the completion of screening for DOH patient information. The Connection to Community Service Provider measure builds upon measure Q487, ensuring patients who screen positive for one or more of the health-related social needs (HRSNs) are then connected to community service providers that may assist, therefore closing the loop in addressing patients' HRSNs. Having both measures in MIPS allows for assessment of two critical steps in addressing health equity; first, ensuring that screening is completed on all patients, and second, connecting patients who are facing a HRSN with resources that can help address these needs.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52797 through 52798), we are finalizing the above measure(s) for addition to the *Audiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

59. Luehr, D., Woolley, T., Burke, R., Dohmen, F., Hayes, R., Johnson, M...., Schoenleber, M. (2012). Hypertension Diagnosis and Treatment; Institute for Clinical Systems Improvement Health Care Guideline. Updated November, 2012.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS13 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS14 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: ● Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And ● Most recent tobacco status is Tobacco Free – And ● Daily Aspirin or Other Antiplatelet Unless Contraindicated – And Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Cardiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Process	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months**: The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Cardiology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the addition of the Connection to Community Service Provider measure to the Cardiology specialty set to promote health equity and stated that every specialty should be rated on this metric. The commenter indicated that the Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure should be used in conjunction with other clinical assessments and considerations to provide a more comprehensive evaluation of a patient's cardiac health and overall well-being (see related comment under Table A.12 of this Appendix).

Response: We thank the commenter for supporting the additional measures to this specialty set and for their comment on the PAM® measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52803 through 52805), we are finalizing the above measure(s) for addition to the *Cardiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
Comment: One commenter supported the removal of measures Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients and Q402: Tobacco Use and Help with Quitting Among Adolescents. *Response:* We thank the commenter for supporting the removal of these measures from the Cardiology specialty set. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52806 through 52808), we are finalizing the above measure(s) for removal from the *Cardiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set and this specialty set had no proposed changes.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	475	CMS349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	496	N/A	MIPS CQMs Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We proposed to include this measure in the Certified Nurse Midwife specialty set as it will be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set will incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Certified Nurse Midwife specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual′s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Certified Nurse Midwife specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Certified Nurse Midwife specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Certified Nurse Midwife specialty set as it will be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty will reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52810 through 52815), we are finalizing the above measure(s) for addition to the *Certified Nurse Midwife Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.6. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Chiropractic Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52818), we are finalizing the above measure(s) for addition to the *Chiropractic Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	382	CMS177v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance	We proposed to include this measure in the Clinical Social Work specialty set as it will be clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure will be beneficial for clinical social workers to address the complex psychosocial challenges that accompany those with substance use disorders. Behavioral health clinicians, such as clinical social workers, are instrumental in ensuring that services address the needs of these individuals. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.7. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Clinical Social Work specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Clinical Social Work specialty set. We agreed with interested parties' feedback that this measure will be clinically relevant to this clinician type. Clinical social workers are vital in helping those with mental health and substance use disorders (SUD). Social work practice is in a unique position to influence the delivery of services by addressing the acute and chronic needs of clients with SUDs, including co-occurring disorders and polysubstance patterns. By developing and applying evidence-informed approaches that incorporate established interventions and evolving techniques based on emerging research findings, clinical social workers can markedly improve treatment services for clients and their families. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Clinical Social Work specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Clinical Social Work specialty set as it will be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty will reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52822 through 52828), we are finalizing the above measure(s) for addition to the *Clinical Social Work Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52829), we are finalizing the above measure(s) for removal from the *Clinical Social Work Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75 v12	eCQM Specifications	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS 74v13	eCQM Specifications	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	485	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	486	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Dermatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

MEASURES FINALIZED FOR ADDITION TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Dermatology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter did not support the addition of the Connection to Community Service Provider measure to the Dermatology specialty set, stating that the measure is similar to measure Q487: Screening for Social Drivers of Health. The commenter also did not support the addition of the Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure to this set as it is not relevant to the practice of dermatology.

*Response***:** Measure Q487 is an important process measure for clinicians that supports the process of collecting DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Measure Q487 focuses on the completion of screening for DOH patient information. The Connection to Community Service Provider measure builds upon measure Q487, ensuring patients who screen positive for one or more of the health-related social needs (HRSNs) are then connected to community service providers that may assist, therefore closing the loop in addressing patients' HRSNs. Having both measures in MIPS allows for assessment of two critical steps in addressing health equity; first, ensuring that screening is completed on all patients, and second, connecting patients who are facing a HRSN with resources that can help address these needs.

The PAM® survey will be made publicly available and free by the measure steward to clinicians. The MIPS quality measure inventory does not currently include a measure with an alternate activation survey, and, as such, we are including this measure to fill a gap in care within the Dermatology Specialty Measure Set. Because clinicians have the flexibility to choose which measures to report, the adoption of this measure is not a requirement for clinicians. Instead, the addition of this measure enhances clinician choice when they select which measures to report. The PAM® is a disease-agnostic measure meant to provide meaningful information about changes in activation across many patient populations and aligns with CMS health priorities of capturing the patient voice and ensuring the patients can be partners in healthcare decisions with their clinicians. This will be a valuable tool for all patients within a clinician's scope of practice.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52833 through 52834), we are finalizing the above measure(s) for addition to the *Dermatology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52834), we are finalizing the above measure(s) for removal from the *Dermatology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance

B.10. Diagnostic Radiology

MEASURES NOT FINALIZED FOR ADDITION TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3633e / N/A	494	CMS1056v1	eCQM Specifications	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical Indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)	We proposed to include this measure in the Diagnostic Radiology specialty set as it will be clinically relevant to this clinician type. This measure will provide radiologists with a clinically relevant outcome measure within MIPS and meets the high priority definition for MIPS reporting as an outcome and patient safety measure. It aligns with numerous consensus-based clinical recommendations and guidelines and is also consistent with the CMS emphasis on expanding digital quality measures with reduction in clinician burden. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.1 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.10. Diagnostic Radiology

MEASURES NOT FINALIZED FOR ADDITION TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Diagnostic Radiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter did not support the addition of the Connection to Community to Service Provider measure in the Diagnostic Radiology specialty set (along with previously finalized measure Q487: Screening for Social Drivers of Health) because the measure is not suited for a non-patient facing clinician who cannot ensure that the patient is being screened. If these new measures remain in the specialty set, there will be no opportunity to apply for a denominator reduction through the EMA (Eligible Measures Applicability) process. One commenter requested that CMS revise this specialty set to only include measures whose quality actions are within the radiologist's purview to influence.

Response: We agreed that the Connection to Community Service Provider measure may not be suited for non-patient facing clinicians and that the quality actions may not be feasible for the diagnostic radiologist. We also agree that measure Q487 is difficult for diagnostic radiologists to report.

After consideration of public comments, we are not finalizing measure Q498: Connection to Community Service Provider to the *Diagnostic Radiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year. In addition, we are removing measure Q487: Screening for Social Drivers of Health from the Previously Finalized table for this specialty set as indicated in the B.10 Diagnostic Radiology Removal table.

However, we are finalizing the implementation of measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) to this specialty set with a 1-year delay to the CY 2025 performance period/2027 MIPS payment year and future years as detailed in Table A.1 of this Appendix. As a result, measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques has been added back to the Previously Finalized table for this specialty set for one more year (see Table C.12 of this Appendix for further information).

Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED AND NOT FINALIZED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure is being removed from the Diagnostic Radiology specialty set under this final rule as we agree with concerns raised that this measure may not be applicable to non-patient facing clinicians.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52839), we are finalizing measure Q147: Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy for removal from the *Diagnostic Radiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

We are not finalizing removal of measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques for the CY 2024 performance period/2026 MIPS payment year and have added this measure back to the Previously Finalized Measures table for this specialty set. However, this measure is finalized for removal with a 1-year delay to the 2025 performance period/2027 MIPS payment year and future years due to the decision to delay the implementation of measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) as detailed in Table A.1 of this Appendix. We are also removing measure Q487 based upon applicability of this measure within a non-patient facing measure specialty set.

Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069/ N/A	065	CMS15 4v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS14 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQMs Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Emergency Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52842), we are finalizing the above measure(s) for addition to the *Emergency Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE EMERGENCY MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	107	CMS 161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52842 through 52843), we are finalizing the above measure(s) for removal from the *Emergency Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS34 7v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
	N/A / N/A	462	CMS64 5v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS95 1v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.12. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Endocrinology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.12. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Endocrinology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52847 through 52848), we are finalizing the above measure(s) for addition to the *Endocrinology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52849), we are finalizing the above measure(s) for removal from the *Endocrinology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0083 / 0083e	008	CMS144v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS128v12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS13 1v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124v12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	338	CMS314v1	eCQM Specifications, MIPS CQMs Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS90v13	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice.	The American Board of Family Medicine
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	488	CMS95 1v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	495	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. This patient-reported outcome measure will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	497	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this quality measure to this specialty set will reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure will set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure will help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Family Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical condition for MIPS. It is an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure will help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Family Medicine specialty set will reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty will reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: A few commenters noted that many of the seven measures proposed for addition to the Family Medicine specialty set come with good intent and solid clinical purpose and value, but the current health care landscape and fragmented health IT environment do not support easy, seamless reporting of the data elements. Therefore, most clinicians will choose not to report on these measures because the burden associated with reporting is too great (for example, Gains in Patient Activation Measure (PAM®) Scores at 12 Months).

Response: Currently, the Family Medicine specialty set includes 64 measures. After finalizing seven additional measures and removing eight measures in this final rule, there will be 63 measures available for CY 2024, many of which are broadly applicable. Given that family medicine physicians who participate in traditional MIPS must choose six of these 63 measures (including one outcome measure or high priority measure) there are many options from which to choose that would fall into a family medicine clinician's scope of care. This allows clinicians to select measures that are the most meaningful and impactful to the patients and communities they serve, while remaining feasible to report using their current health IT capabilities. Our goal is to continuously drive high quality care, which includes addition of new measures that fill current quality measure gaps in care or require more robust quality actions than current quality measures. However, we acknowledge challenges to the implementation and adoption of such measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52860 through 52867), we are finalizing the above measure(s) for addition to the *Family Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	107	CMS1 61v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
2372 / N/A	112	CMS1 25v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 40 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS1 30v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS6 9v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal from the Family Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.
N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from the Family Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52868 through 52871), we are finalizing the above measure(s) for removal from the *Family Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an Interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	NA / N/A	275	N/A	MIPS CQMs Specifications	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.14. Gastroenterology

MEASURES FINALIZED FOR ADDITION TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Gastroenterology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.14. Gastroenterology

MEASURES FINALIZED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Gastroenterology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52874 through 52875), we are finalizing the above measure(s) for addition to the *Gastroenterology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

Comment: One commenter did not support the removal of measure Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from the Gastroenterology specialty set because the measure continues to hold value for quality improvement across multiple specialties (also see comments under Table CC.3 of this Appendix).

Response: We acknowledged the concerns expressed by the commenters for the removal of measure Q128. However, this measure is duplicative of a component found within the new preventive care and wellness composite measure. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care, rather than offering duplicate measures. We strive to offer measures with more robust evaluation methods that will continue to drive quality patient outcomes though the clinical care provided.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52876), we are finalizing the above measure(s) for removal from the *Gastroenterology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.15. General Surgery

MEASURES FINALIZED FOR ADDITION TO THE GENERAL SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the General Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52879), we are finalizing the above measure(s) for addition to the *General Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GENERAL SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52880), we are finalizing the above measure(s) for removal from the *General Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771 v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	NA / N/A	497	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We proposed to include this measure in the Geriatrics specialty set as it will be clinically relevant to this clinician type. The addition of this quality measure to this specialty set will reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure will set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure will help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Geriatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52884 through 52885), we are finalizing the above measure(s) for addition to the *Geriatrics Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal from the Geriatrics specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

Comment: One commenter opposed removal of measure Q283: Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management from the Geriatrics specialty set and requested the measure be retained until another measure can be developed.

Response: We acknowledged the concerns expressed by the commenters. However, the data shows that the measure has reached the end of its topped-out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2023 Benchmark File.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52886), we are finalizing the above measure(s) for removal from the *Geriatrics Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	205	CMS1188v1	eCQM Specifications, MIPS CQMs Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12	National Committee for Quality Assurance

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
				Specifications, MIPS CQMs Specifications		years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	
* §	N/A / N/A	240	CMS117v12	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* § ! (Outcome)	NA / N/A	338	CMS314v1	eCQM Specifications, MIPS CQMs Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed	National Committee for Quality Assurance

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	
* §	N/A / N/A	475	CMS349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Infectious Disease specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52890), we are finalizing the above measure(s) for addition to the *Infectious Disease Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0083 / 0083e	008	CMS 144v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS 128v 12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS 131v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS 2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS 165v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS 156v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
! (Opioid)	N/A / N/A	305	CMS 137v 12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS 124v 12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS 139v 12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	338	CMS 314v 1	eCQM Specifications, MIPS CQMs Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS 159v 12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A / N/A	374	CMS 50v1 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS 90v1 3	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS 347v 7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients–- all considered at high risk of cardiovascular events–- who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS 249v 6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS 349v 6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS 771v 5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice.	The American Board of Family Medicine

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS 951v 2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	495	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. This patient-reported outcome measure will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES FINALIZED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	497	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this quality measure to this specialty set will reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure will set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure will help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Internal Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

MEASURES FINALIZED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical condition for the MIPS. It is an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure will help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Internal Medicine specialty set will reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10– or 13– item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52900 through 52909), we are finalizing the above measure(s) for addition to the *Internal Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS2 2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52910 through 52914), we are finalizing the above measure(s) for removal from the *Internal Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Interventional Radiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52916), we are finalizing the above measure(s) for addition to the *Interventional Radiology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications , eCQM Specifications , MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
* §	N/A / N/A	366	CMS13 6v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0710 / 0710e	370	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / N/A	382	CMS177v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR ADDITION TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it will be clinically relevant to this clinician type. This measure addresses a high priority specialty and high priority clinical condition for the MIPS. It is an important comprehensive PRO- PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure will help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Mental/ Behavioral Health specialty set will reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR ADDITION TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Mental/ Behavioral Health and Psychiatry specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES FINALIZED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it will be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty will reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52920 through 52925), we are finalizing the above measure(s) for addition to the *Mental/Behavioral Health and Psychiatry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	107	CMS 161v 12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS 69v1 2	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52926 through 52927), we are finalizing the above measure(s) for removal from the *Mental/Behavioral Health and Psychiatry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS95 1v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.22. Nephrology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	N/A	N/A	MIPS CQMs Specifications	Process	**First Year Standardized Waitlist Ratio (FYSWR):** The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as it will be clinically relevant to this clinician type. The measure's intended objective consists of improving the overall health of patients on dialysis, with Nephrologists at the forefront of caring for this patient population. Clinicians within this specialty are responsible for the education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.4 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	N/A	N/A	MIPS CQMs Specifications	Process	**Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):** The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as will be clinically relevant to this clinician type. The maintenance of end stage renal disease patients on active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent transplantation. These practices are important for Nephrologists who are at the forefront of caring for this patient population. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Nephrology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Nephrology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: A few commenters supported the inclusion of the First Year Standardized Waitlist Ratio (FYSWR) and Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measures in the Nephrology specialty set.

Response: We thank the commenters for supporting the additional measures to this specialty set. However, due to potential implementation challenges within MIPS regarding timing and application of the risk adjustment methodology, we are not finalizing the First Year Standardized Waitlist Ratio (FYSWR) and Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measures for addition to the *Nephrology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year to allow further refinement and streamlining of the measures' analytic for future MIPS implementation.

We are finalizing measures Q498: Connection to Community Service Provider and Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months for the reasons stated above and in the proposed rule (88 FR 52930 through 52933) for addition to the *Nephrology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression)	American Academy of Neurology
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.23. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Neurology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMS Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Neurology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the measures proposed for addition to this specialty set.

Response: We thank the commenter for supporting the additional measures to this specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52937 through 52938), we are finalizing the above measure(s) for addition to the *Neurology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

Comment: One commenter supported the measures proposed for removal from this specialty set.

Response: We thank the commenter for supporting the removal of measures from this specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52939), we are finalizing the above measure(s) for removal from the *Neurology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumba Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.24. Neurosurgical

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROSURGICAL SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Neurosurgical specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52942), we are finalizing the above measure(s) for addition to the *Neurosurgical Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS1 55v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. ● Percentage of patients with height, weight, and body mass index (BMI) percentile documentation ● Percentage of patients with counseling for nutrition ● Percentage of patients with counseling for physical activity	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	NA / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nutrition/ Dietician specialty set. We agreed with interested parties' feedback that depression continues to be a major public health concern and all Medicare clinicians should be doing their part to address the issue. Screening for depression is often a routine part of the comprehensive nutrition assessment performed by Registered Dieticians/ Nutritionists (RDNs) as nutrition status is closely linked to mental health. Optimizing the nutrition status of an individual with mental illness has been shown to improve both cognitive and emotional functioning. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Nutrition/Dietician specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52994 through 52945), we are finalizing the above measure(s) for addition to the *Nutrition/Dietician Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NUTRITION/DIETICIAN SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52945), we are finalizing the above measure(s) for removal from the *Nutrition/Dietician Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS 165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS 124v12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS 153v12	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§ ! (Appropriate Use)	N/A / 3475e	472	CMS 249v6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS 349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	496	N/A	MIPS CQMs Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it will be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set will incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	497	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We proposed to include this measure in the Obstetrics/ Gynecology specialty set as it will be clinically relevant to this clinician type. The addition of this quality measure to this specialty set will reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure will set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure will help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Obstetrics/Gynecology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	504	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it will be clinically relevant to this clinician type. The incorporation of this measure in this specialty set will help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR ADDITION TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it will be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set will encourage measure adoption which will support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. The addition of this quality measure for this specialty will reinforce our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter did not support the addition of the Preventive Care and Wellness (composite) to the Obstetrics/Gynecology specialty set. The commenter expressed concern that the complexity of the measure would make it difficult for clinicians to report and indicated that maintaining separate measures that are meaningful and useful for relevant specialties will lead to higher rates of reporting and utilization across MIPS. The commenter also noted there is no discussion of risk stratification or adjustment within the composite measure as proposed, in order to further extrapolate the impact of measurement on targeted groups.

Response: We understand some of these screening and wellness services may not be relevant to, or administered in, certain clinical settings; however, it is important for all clinicians to be actively engaging in activities that address preventive care and wellness. Since all of the component measures have been available for reporting in MIPS, clinicians are familiar with the component requirements and systems should be in place to capture the data. Therefore, we expect reporting burden should be minimal. In addition, many of the components allow for patient reported receipt to meet the numerator. We acknowledge that the removal of component measures may be an inconvenience, however, continuing to drive quality care through the implementation of more robust, meaningful measures is critically important to continued improvement in quality care provided. Currently the Obstetrics/Gynecology specialty set contains 22 measures allowing clinicians to choose to submit those measures that are meaningful to their scope of care. This measure does not require risk adjustment as all of the processes being assessed for are appropriate for each component's denominator eligible patient population, with exclusions removing patients from components of the measure who would not be appropriate for the quality action. While each component of the measure will have a performance rate, the overall score for the purposes of MIPS will be based upon a weighted average.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52949 through 52957), we are finalizing the above measure(s) for addition to the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
2372 / N/A	112	CMS125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 40 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal from the Obstetrics/Gynecology specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.
N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from the Obstetrics/Gynecology specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52957 through 52959), we are finalizing the above measure(s) for removal from the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0384 / 0384e	143	CMS157v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	490	N/A	MIPS CQMs Specifications	Process	**Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	495	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type. This patient-reported outcome measure will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Oncology/ Hematology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52964 through 52968), we are finalizing the above measure(s) for addition to the *Oncology/Hematology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52967), we are finalizing the above measure(s) for removal from the *Oncology/Hematology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS 129v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0384 / 0384e	143	CMS 157v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	N/A / N/A	226	CMS 138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology/Optometry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Ophthalmology/Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 0086e	012	CMS143v12	eCQM Specifications	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS13 3v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.28. Ophthalmology/Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Ophthalmology/ Optometry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	499	N/A	MIPS CQMs Specifications	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists	We proposed to include this measure in the Ophthalmology/ Optometry specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure addresses the MIPS priority area of patient safety. This measure will help to incentivize timely initiation of the appropriate screening for these patients and ensure there is a plan of care for elevated IOP following intravitreal or periocular steroid therapy. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.8 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES FINALIZED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	500	N/A	MIPS CQMs Specifications	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.	American Society of Retina Specialists	We proposed to include this measure in the Ophthalmology/Optometry specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure is guideline based and addresses the MIPS priority area of patient safety. It is also linked to health outcomes by appropriate care for acute PVD, which can prevent retinal tears. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.9 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
	N/A / N/A	501	N/A	MIPS CQMs Specifications	Process	**Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.	American Society of Retina Specialists	We proposed to include this measure in the Ophthalmology/Optometry specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. In addition, enhancing our ophthalmology related measure inventory could help to ensure retinal specialty coverage by having measures available that are robust and clinically relevant to clinicians within this sub specialization. This measure is guideline based and will help to improve patient safety by incentivizing physicians to see patients in a timely manner. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.10 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52972 through 52976), we are finalizing the above measure(s) for addition to the *Ophthalmology/Optometry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52976), we are finalizing the above measure(s) for removal from the *Ophthalmology/Optometry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v12	eCQM Specifications	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers** of **Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

MEASURES FINALIZED FOR ADDITION TO THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Orthopedic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52984), we are finalizing the above measure(s) for addition to the *Orthopedic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

Comment: One commenter opposed removal of measure Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from the Orthopedic Surgery specialty set and expressed that this BMI measure is relevant to many specialties in which there is no MVP and removing this measure is limiting choice for specialists.

Response: We acknowledged the concerns expressed by the commenters for the removal of measure Q128. However, this measure is duplicative of a component found within the new preventive care and wellness composite measure. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care, rather than offering duplicate measures. We strive to offer measures with more robust evaluation methods that will continue to drive quality patient outcomes though the clinical care provided.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 52985), we are finalizing the above measure(s) for removal from the *Orthopedic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS14 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.30. Otolaryngology

MEASURES FINALIZED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Otolaryngology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52989), we are finalizing the above measure(s) for addition to the *Otolaryngology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52990 through 52991), we are finalizing the above measure(s) for removal from the *Otolaryngology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set and this specialty set had no proposed changes.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQMs Specifications	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma:** Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both	College of American Pathologists

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	205	CMS1188v1	eCQM Specifications, MIPS CQMs Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117v12	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	310	CMS153v12	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	366	CMS136v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / N/A	382	CMS177v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk	Mathematica
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.32. Pediatrics

MEASURES FINALIZED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We proposed to include this measure in the Pediatrics specialty set. Updates were proposed to measure Q226 to now include patients 12 years of age and older. Therefore, screening for tobacco use and cessation intervention will be an important measure for the pediatric clinician type to utilize. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.32. Pediatrics

MEASURES FINALIZED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Pediatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 52996 through 52997), we are finalizing the above measure(s) for addition to the *Pediatrics Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PEDIATRICS SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PEDIATRICS SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 52998 through 52999), we are finalizing the above measure(s) for removal from the *Pediatrics Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS 138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS 22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Physical Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53002), we are finalizing the above measure(s) for addition to the *Physical Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53003), we are finalizing the above measure(s) for removal from the *Physical Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set. We agreed with interested parties' feedback that this measure will be clinically relevant to this clinician type. Occupational therapy services enable clients to participate in their everyday life occupations in their desired roles, contexts, and life situations through evaluation and treatment related to basic activities of daily living and instrumental activities of daily living. Occupational therapy practitioners use their knowledge and skills to help clients conduct or resume daily life occupations that support function and health throughout the lifespan, including patients with dementia and their caregivers. The addition of this quality measure in this specialty set will make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it will be clinically relevant to this clinician type. We agreed with interested parties' feedback that this measure will help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. In addition, Occupational therapy practitioners provide services to people across the lifespan who experience a range of mental health and ill health based on genetic predisposition and/or life stressors (for example, disability, injury, trauma). Occupational therapy is used to help support people with mental illness in skill development, activity engagement, and with meeting individual recovery goals under an OT Plan of Care. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the addition of the new measures to the Physical Therapy/Occupational Therapy specialty set.

Response: We thank the commenter for supporting the addition of new measures to the Physical Therapy/Occupational Therapy specialty set. For the commenter's request to add CPT codes to a previously finalized measure, we encourage the commenter to reach out to the measure stewards to communicate possible revisions to be considered for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53009 through 53013), we are finalizing the above measure(s) for addition to the *Physical Therapy/Occupational Therapy Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure was proposed for removal from the Physical Therapy/Occupational Therapy specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. PT/OT applicable coding has not been added to this measure, so we proposed to remove this measure from this specialty set.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
Comment: One commenter opposed removal of measure Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from the Physical Therapy/Occupational Therapy specialty set, stating that it is inconsistent and illogical to remove the measure from the set but retain it for the Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Table A.5). The commenter stated that BMI is a well utilized and impactful measure among physical therapists regardless of whether they submit MIPS data or MVP data and that physical therapists submitting MIPS data will continue to report measure Q128 because they have denominator eligible instances for the measure. Removing measure Q128 from MIPS will confuse participants and create inconsistencies between MIPS and future MVPs. In addition, QCDR burden increases having to field inquiries from clinicians/groups wondering why the measure was removed from the Physical Therapy/Occupational Therapy specialty set. Several other commenters opposed the removal of measure Q128 from this set with similar concerns that physical therapists can have a significant effect by increasing the patient's ability to move to control BMI. *See* Table CC.3 of this Appendix for additional comments on removing measure Q128 from traditional MIPS and retaining the measure for use in MVPs. *Response:* We acknowledged the concerns expressed by the commenters for the removal of measure Q128. This measure is included as a component of the finalized Preventive Cared and Wellness (composite) measure. The Preventive Care and Wellness (composite) measure combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services, to create a robust, broadly encompassing preventive care assessment. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53014), we are finalizing the above measure(s) for removal from the *Physical Therapy/Occupational Therapy Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.35. Plastic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Plastic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53017, we are finalizing the above measure(s) for addition to the *Plastic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PLASTIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53018), we are finalizing the above measure(s) for removal from the *Plastic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	N/A / N/A	226	CMS 138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS 139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Podiatry specialty set as it will be clinically relevant to this clinician type. The addition of this measure will provide this specialty the opportunity to report on an important PRO-PM that will align with their scope of care consisting of the treatment of the lower extremity. Functional deficits are common in the general population and are costly to the individual, their family and society, and improving functional status has been associated with greater quality of life, self-efficacy, improved financial well-being and lower future medical costs (*https://fotoinc.com/science-of-foto/nqf-measure-specifications/*). Predictive modeling allows for patient-level predictions to help guide treatment decision making and expectations for recovery.

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS 22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Podiatry specialty set. The addition of this measure to this specialty set will help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the circulatory system due to high blood pressure making this an important aspect of care for podiatrists. Hypertension is often related to atherosclerosis and this buildup of plaque in blood vessels can lead to decreased circulation and peripheral arterial disease (PAD) (*https://www.apma.org/hypertension*). Patients with decreased circulation in their lower extremities may develop ulcerations that can lead to amputations. Given the close correlation of hypertension and decreased circulation in lower extremities, interdisciplinary care is vital and should be the responsibility of all clinician types. The addition of this measure to the Podiatry specialty set will help to encourage the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population.

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons	We proposed to include this measure in the Podiatry specialty set as it will be clinically relevant to this clinician type. Patients undergoing podiatric surgery should receive a thorough perioperative evaluation. Medical "clearance" is no longer sufficient; rather, formal risk assessment should be performed, and risk-reducing strategies communicated. A collaborative, multidisciplinary approach is generally most appropriate, however, expertise and training in this critical dimension of clinical practice varies. Thus, podiatrists should develop independent competence in perioperative evaluation to ensure optimal care for their patients. In preparation for elective foot and ankle surgery, the podiatric surgeon often will refer the patient for a preoperative evaluation. Surgeons rely on the input of that consultant to provide a determination as to the operative risk for the patient (*https://pubmed.ncbi.nlm.nih.gov/12776978/*).

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Podiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10- or 13-item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Podiatry specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.36. Podiatry

MEASURES FINALIZED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter supported the addition of measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented to the Podiatry specialty set, stating there is a close correlation between hypertension and decreased circulation in the lower extremities. Adding this quality measure to this specialty set should lead to higher screening rates for hypertension and increased identification of patients with high blood pressure at risk for peripheral artery disease (PAD) and associated lower extremity amputation. The commenter also requested that CMS develop a new quality measure that would assess rates of lower extremity diabetes-related amputations for at-risk patients. *Response:* We thank the commenter for supporting the addition of measure Q317 to this specialty set. We encourage the commenter to reach out to measure developers/stewards to develop the new quality measure recommended for submission to the Call for Measures for possible future implementation. *Comment:* One commenter supported adding Q219: Functional Status Change for Patients with Lower Leg, Foot, or Ankle Impairments to the Podiatry specialty set as this measure reinforces patient-reported outcome measures (PROMs) for foot care. The commenter also suggested considering the Foot Health Status Questionnaire (FHSQ), which a systematic review provides that this measure is the most fitting PROM for patients with diabetes with foot and ankle pathologies. The commenter supported adding Q317 because podiatrists already screen for high blood pressure. The commenter supported adding Q358: Patient Centered Surgical Risk Assessment and Communication because this measure is already included for orthopedic surgery and general surgery specialties. The commenter supported adding the new Connection to Community Service Provider measure to specialty sets, except for hospitalists. The commenter supported the new Gains in Patient Activation Measure (PAM®) Scores at 12 Months as a validated tool that measures patient activation and helps guide clinicians in assisting their patients to become more self-sufficient. *Response:* We thank the commenter for supporting the additional measures to this specialty set. For the commenter's request to add the Foot Health Status Questionnaire (FHSQ), to a previously finalized measure, we encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Alternatively, we encourage the commenter to reach out to measure developers/stewards to develop new FHSQ measures for submission to the Call for Measures for possible future implementation. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53020 through 53024), we are finalizing the above measure(s) for addition to the *Podiatry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PODIATRY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53025), we are finalizing the above measure(s) for removal from the *Podiatry Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS 122v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS 2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS 347v 7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS 349v 6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS 951v 2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.37. Preventive Medicine

MEASURES FINALIZED FOR ADDITION TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	497	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We proposed to include this measure in the Preventive Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this quality measure to this specialty set will reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure will set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure will help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES FINALIZED FOR ADDITION TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Preventive Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Preventive Medicine specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53030 through 53032), we are finalizing the above measure(s) for addition to the *Preventive Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
2372 / N/A	112	CMS125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 40 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS130v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal from the Preventive Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set will be duplicative.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	317	CMS2 2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from the Preventive Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53033 through 53035), we are finalizing the above measure(s) for removal from the *Preventive Medicine Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic and were prescribed a long-acting inhaled bronchodilator	American Thoracic Society
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Pulmonology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Pulmonology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53038 through 53039), we are finalizing the above measure(s) for addition to the *Pulmonology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PULMONOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53040), we are finalizing the above measure(s) for removal from the *Pulmonology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance

B.39. Rheumatology

MEASURES FINALIZED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Rheumatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES FINALIZED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Rheumatology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES FINALIZED FOR ADDITION TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

Comment: One commenter did not support the addition of the Connection to Community Service Provider measure to the Rheumatology specialty set, stating that the numerator actions are outside the scope of a specialty clinician's care. Although extremely meaningful for individual patients, addressing and linking to these services is not achievable in a standard office visit where a focus on evaluation and diagnosis or management of chronic, complex conditions is provided. This is especially true for rheumatology practices in rural areas with significant rheumatology access issues and a lack of community resources. The commenter noted they believed the measure should initially focus on primary and inpatient care.

Response: The Connection to Community Service Provider measure builds upon measure Q487, ensuring patients who screen positive for one or more of the health-related social needs (HRSNs) are then connected to community service providers that may assist, therefore closing the loop in addressing patients' HRSNs. Having both measures in MIPS allows for assessment of two critical steps in addressing health equity; first, ensuring that screening is completed on all patients, and the second, connecting patients who are facing a HRSN with resources that can help address these needs. Clinicians maintain the flexibility to choose those quality measures that are most meaningful and appropriate to their practice. This is an important next step in addressing HRSNs and are including it allows clinicians the opportunity to report the measure. The American College of Rheumatology (ACR) has made identifying and addressing racial and socioeconomic health disparities a core part of their meeting agendas, highlighting the importance of this topic within this specialty.[60] Studies have shown links and adverse interactions between socioeconomic status (SES) and RA disease activity.[61] We understand that not all measures within the set will be applicable to every clinician's scope of care, which is why we allow choice in which quality measures a clinician may submit, but given the link between SES and some rheumatic conditions, it is important to encourage implementation of clinical workflows to include assessment of HRSNs to positively effect a patient's health outcome. Some rheumatology specialists are advocating for this and providing insight, such as team based approaches, for overcoming roadblocks to enacting this quality action. [62] [63]

Comment: One commenter did not support the addition of the Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure to this specialty set given the costs associated with licensing the tool required to implement this measure. The commenter cited the cost of the tool for small and solo practices that participate in their QCDR. As there is a low likelihood of adoption across rheumatology practices, the commenter did not support including the measure in this specialty set.

Response: We thank the commenter for their feedback. The PAM® survey will be made publicly available and free by the measure steward to clinicians. The MIPS quality measure inventory does not currently include a measure with an alternate activation survey and as such, we are including this measure to fill a gap in care within the Rheumatology Specialty Measure Set. We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures within a specialty measure set will be applicable or appropriate to all clinicians within that specialty set umbrella. However, no measures within traditional MIPS are required. We allow for clinician choice to account for these nuances, while ensuring clinicians are able to choose measures that are most meaningful to their scope of care and patient case-mix. The goal is to ensure we have a comprehensive set of measures that drive positive health outcomes as well as allow flexibility in clinician choice when determining the appropriateness of each measure. encourage the commenter to reach out to measure developers/stewards to develop additional measures ensuring alternate activations surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53043 through 53044), we are finalizing the above measure(s) for addition to the *Rheumatology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

60. ACR 2021: 9 Important Insights About Health Disparities in Rheumatology. *https://creakyjoints.org/advocacy/acr-2021-health-disparities/*.
61. Dey, M., Busby, A., Elwell, H., Lempp, H., Pratt, A., Young, A., Isaacs, J., & Nikiphorou, E. (2022). Association Between Social Deprivation and Disease Activity in Rheumatoid Arthritis: A Systematic Literature Review. RMD Open, 8(1), e002058. *https://doi.org/10.1136/rmdopen-2021-002058*.
62. Volansky, R. (2023). 'We are not asking the right questions': Social Health Determinants Key in Rheumatology. *https://www.healio.com/news/rheumatology/20230805/we-are-not-asking-the-right-questions-social-health-determinants-key-in-rheumatology*.
63. Navarro-Millan, I. (2021). Beyond Race and Ethnicity: Social Determinants of Health and Disparities in Rheumatology. *https://news.hss.edu/beyond-race-and-ethnicity-social-determinants-of-health-and-disparities-in-rheumatology/*.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

Comment: One commenter supported removing measure Q402: Tobacco Use and Health with Quitting Among Adolescents from the Rheumatology specialty set.

Response: We thank the commenter for supporting the removal of this measure from this specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53045), we are finalizing the above measure(s) for removal from the *Rheumatology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

MEASURES FINALIZED FOR ADDITION TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Skilled Nursing Facility specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53048), we are finalizing the above measure(s) for addition to the *Skilled Nursing Facility Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.41. Speech Language Pathology

MEASURES FINALIZED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology	We proposed to include this measure in the Speech Language Pathology specialty set. We agreed with interested parties' feedback that SLPs are keenly interested in a measure set that includes quality measures that are more reflective of the types of clinical conditions they treat. While the diagnosis of Parkinson's disease is made by a medical team, SLPs are trained to assess cognitive-communication deficits related to this condition, and to identify cultural, linguistic, and environmental influences that have an impact on functioning. The services provided by SLPs contribute to improving the safety and well-being of the individual. Therefore, it will be important to consider SLPs as an integral member of the clinical care team working with patients diagnosed with Parkinson's and include this measure in the speech-language pathology specialty measure set. The addition of this quality measure in this specialty set will make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Speech Language Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. We agreed with interested parties' feedback that SLPs are committed to addressing health equity and play a key role in screening individuals for social risks. When factors are identified, SLPs consider them when establishing a care plan and modifications are made to create achievable, sustainable, and functional goals that are patient-centered. In response to the interested parties' feedback, we proposed to add this measure to this specialty set if all proposed measures for the specialty set are finalized. This is a screening data collection measure and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the SLP specialty set will contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that will work best for their scope of practice and clinical workflow. The measure being added to this specialty set will be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES FINALIZED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Speech Language Pathology specialty set. We agreed with interested parties' feedback that this measure will be clinically relevant to this clinician type as this profession has historically addressed social needs through screening and evaluation, providing referrals, and connecting patients to community services and falls within their scope of care. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is a screening measure requiring a connection to the CSP, and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the Speech Language Pathology specialty set will contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that will work best for their scope of practice and clinical workflow. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.41. Speech Language Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter was supportive of adding measures to the Speech Language Pathology specialty set that address DOH. The commenter also appreciated the addition of measure Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease to this set. *Response:* We thank the commenters for supporting the additional measures to this specialty set. The Call for Measures process can be used to request measures for future consideration to this specialty set as suggested by the commenter. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53050 through 53052), we are finalizing the above measure(s) for addition to the *Speech Language Pathology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS 138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.42. Thoracic Surgery

MEASURES FINALIZED FOR ADDITION TO THE THORACIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Thoracic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

Comment: One commenter supported the addition of the Connection to Community Service measure to the Thoracic Surgery specialty set as long as clinicians continue to be able to choose the measures relevant to their practice.

Response: We thank the commenter for supporting the addition of this measure to this specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53055), we are finalizing the above measure(s) for addition to the *Thoracic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE THORACIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53056), we are finalizing the above measure(s) for removal from the *Thoracic Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

MEASURES FINALIZED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Urgent Care specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53059), we are finalizing the above measure(s) for addition to the *Urgent Care Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE URGENT CARE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53060), we are finalizing the above measure(s) for removal from the *Urgent Care Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Centers for Medicare & Medicaid Services
*	N/A / N/A	104	N/A	MIPS CQMs Specifications	Process	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022/ N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQMs Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216/ N/A	457	N/A	MIPS CQMs Specifications	Outcome	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
! (Outcome)	N/A / N/A	476	CMS771v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A/ N/A	481	CMS646v 4	eCQM Specifications	Process	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951v 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Urology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	503	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Urology specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53066 through 53067), we are finalizing the above measure(s) for addition to the *Urology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.44. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53068), we are finalizing the above measure(s) for removal from the *Urology Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.							

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS 138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS 165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A / N/A	317	CMS 22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS 50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.45. Vascular Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	498	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We proposed to include this measure in the Vascular Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure will allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set will be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (88 FR 53072), we are finalizing the above measure(s) for addition to the *Vascular Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.								

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the finalized Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore finalized for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (88 FR 53073), we are finalizing the above measure(s) for removal from the *Vascular Surgery Specialty Set* as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS. See Table Group CC of this Appendix for any comments and responses pertaining to measures finalized for partial removal from traditional MIPS but retained for use in relevant MVPs.

Table Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

In this final rule, we are removing 11 of the 12 proposed previously finalized MIPS quality measures from MIPS for the CY 2024 performance period/2026 MIPS payment year and future years as well as removing one previously finalized measure with a 1-year delay to the CY 2025 performance period/2027 MIPS payment year. These measures are discussed in detail below. The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures.

Under our measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.*
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

Under Table Group CC, we finalize to partially remove three additional measures from traditional MIPS and to retain these three measures for MVP use and retain two of these measures for purposes of Shared Savings Program ACOs reporting through the APP.

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion that we use for the removal of measures includes extremely topped out measures, which means measures are topped out with an average (mean) performance rate between 98-100 percent.

For a measure that is finalized for removal due to criteria relating to the benchmark and performance data, further information regarding MIPS benchmarking data can be located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.

NOTE: Since publication of the measures in Table Group C in the CY 2024 PFS proposed rule (88 FR 53074 through 53080), we have determined the following measure will be retained in the CY 2024 performance period/2026 MIPS payment year: Q436 as detailed under Table C.12 of this Appendix. However, measure Q436 is finalized for removal starting in the CY 2025 performance period/2027 MIPS payment year.

As noted in the introduction to Table Group B, measures that were not finalized for removal under Table Group C have been added back to the Previously Finalized tables, where applicable, and removed from the Removal tables, under the appropriate specialty set in Table Group B.

C.1. Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
CBE # / eCQM CBE #:	0087 / N/A
Quality #:	014
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter expressed concern about CMS systematically removing relevant measures related to AMD and diabetic retinopathy based on topped out measure policies. Without retina-specific measures, retina specialists are frequently reporting on measures related to vaccine status or documentation of current medications, often for several consecutive years. While these elements are clinically important, they do nothing to assist a patient who has just been diagnosed with a potentially blinding disease select the right physician for treatment.

Response: We acknowledged the concerns expressed by the commenter; however, the data shows that measure Q014: Age-Related Macular Degeneration (AMD): Dilated Macular Examination has reached the end of its topped-out life cycle, which does not allow a meaningful benchmark. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2023 Benchmark File. We encourage the commenter to reach out to measure developers/stewards to develop additional retina-specific quality measures for submission to the Call for Measures for possible future implementation. Additionally, we are finalizing the addition of three new measures applicable to retinal specialists.

Comment: One commenter opposed removal of this measure, stating that it is reported by a substantial number of ophthalmologists and its removal could have negative consequences on patient care. While the measure is currently topped out, the measure is still an important part of high-quality care. An ophthalmologist doing a dilated macular examination can detect multiple sight-threatening conditions, and when these exams are not supported, these conditions may not be caught and the opportunity for early intervention is lost.

Response: We agree that performing a dilated macular examination is an important barometer of identifying and addressing the severity of AMD; however, as noted above, the data shows that the measure has reached the end of its topped-out life cycle which does not allow a meaningful benchmark. We acknowledge removal of this measure decreases the number of available measures for ophthalmology; however, there are policies in place to account for this when working to meet MIPS quality performance category requirements.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53075), we are finalizing the removal of measure Q014 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.2. Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0654 / N/A
Quality #:	093
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter supported removal of measure Q093: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use and agreed that the measure is topped out. The commenter also agreed that quality measures have a certain shelf life, and as clinicians perform better on these measures, they move towards higher benchmarks and topping out.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter opposed removal of this measure and disagreed with its topped-out status, stating that pediatricians still see too many clinicians giving systemic antibiotics every time a parent asks for an antibiotic for ear pain. The commenter stated there is still the opportunity to improve clinical outcomes with this quality measure. Another commenter did not support removal of this measure and encouraged CMS to consider the repercussions of antimicrobial use. Overtreatment with antibiotics may increase patient harm and can lead to antibiotic resistance. In addition, newly eligible clinicians lose access to these important process measures within a specialty due when topped out measures are removed.

Response: We acknowledge the commenters' concerns and agree overtreatment with antibiotics can lead to resistance; however, the data shows the measure has reached the end of its topped-out life cycle which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2023 Benchmark File.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53075), we are finalizing the removal of measure Q093 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.3. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	107
CMS eCQM ID:	CMS161v12
Collection Type:	eCQM Specifications
Measure Description:	Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.
Measure Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk measure being finalized in Table A.13 of this Appendix. Measure Q107 is specific to major depressive disorder whereas the new measure will include patients with other behavioral health conditions who are at risk of suicide. Furthermore, the new measure represents a high priority area for MIPS: mental health. It focuses on a care process that is directly designed to mitigate suicide risk, as opposed to just completing the screening. Studies have shown that clinical interventions aimed at suicide prevention, such as initiating and reviewing a suicide safety plan with a patient at risk of suicide, is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation (*https://pubmed.ncbi.nlm.nih.gov/29998307/*).
In the Circumstance the Measure Was Retained	If the measure was not finalized for removal in the CY 2024 PFS final rule, we proposed to apply the following substantive change to the measure specifications: 1) the measure description, initial patient population and guidance will be updated so that the age description in the narrative matches the Clinical Quality Language (CQL) logic of capturing patients who are 17 years and older. This proposal would have ensured the measure was implemented as specified, and the correct patient population was being captured. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix. The substantive changes outlined above would have been applied to the measure specifications.

Comment: Several commenters did not support the removal of measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (with a repeat comment for other eCQM measures proposed for removal under Tables C.4, C.5, CC.1, CC.2, and CC.3 of this Appendix) because they noted the CQM collection type of the measure does not serve as an appropriate replacement for an eCQM collection type. Commenters stated that replacing an eCQM with a CQM does not advance the use of digital tools for quality measurement and does not support CMS' objective of moving to digital quality measurement. The use of CQMs as the collection type also does not support the interoperable exchange of quality measurement data. Commenters stated that CMS should prioritize the adoption and use of eCQMs for quality measures to promote greater adoption of interoperable health IT, reduce burden, and improve consistency in quality measurement. Another commenter stated that not all clinicians are willing to pay for use of a registry.

A few additional commenters stated that organizations that predominantly report via the eCQM collection type need to have their efforts acknowledged and valued and removing this measure (as well as Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults) could overshadow the hard work improving these crucial areas of patient care.

Response: The new measure, Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk, is more robust and will include patients with other behavioral health conditions who are at risk of suicide. Measure Q107 only focuses on major depressive disorders rather than providing a comprehensive behavioral health evaluation to mitigate suicide risk. More broadly, we encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include different collection types within our quality measure inventory to allow flexibility in reporting. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter did not support removal of measure Q107 because the measure is evidence-based, methodologically sound, and clinically meaningful. Another commenter opposed the removal of this measure because it plays a significant role in assessing healthcare quality and patient safety.

Response: As noted above, the new measure, Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk, is more robust, includes patients with other behavioral health conditions who are at risk of suicide, and represents a high priority area for MIPS. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care, rather than offering duplicate measures. Offering measures with more robust evaluation methods will continue to drive quality patient outcomes though the clinical care provided.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53076), we are finalizing the removal of measure Q107 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.4. Preventive Care and Screening: Influenza Immunization

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	110
CMS eCQM ID:	CMS147v13
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being finalized as a replacement for those MVPs that contain measure Q110. This measure will remain for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure Was Retained	If the measure was not finalized for removal in the CY 2024 PFS final rule, we proposed to apply the following substantive change to the measure specifications: 1) denominator exclusion for all collection types will be updated to include anaphylaxis due to the vaccine as there is new coding available to capture this data. It is clinically appropriate and prudent to refrain from administering the vaccine to patients who experienced anaphylaxis with a previous vaccine administration. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix. The substantive changes outlined above would have been applied to the measure specifications.

Comment: One commenter stated that clinicians should still have the flexibility to report measure Q110: Preventive Care and Screening: Influenza Immunization individually (same comment for measure Q111 under Table C.5 of this Appendix). Measure Q493, which currently includes these individual measure rates, calculates a combined rate of vaccination, making it difficult to determine where improvement opportunities may be available at the individual vaccination measure level. Another commenter stated that measure Q110 is evidence-based, methodologically sound, and clinically meaningful.

Response: The removal of measure Q110 (and measure Q111) from traditional MIPS was finalized beginning with the CY2023 performance period/2025 MIPS payment year but retained for use in relevant MVPs. This measure's clinical concept is included in measure Q493 and despite this measure representing four different submission criteria, the calculated weighted average allows for a comprehensive evaluation based on multiple recommended age-appropriate immunizations that promote well-being.

Comment: One commenter opposed removal of this measure from the Quality inventory (as well as measure Q111), stating that measure Q493 is burdensome and not all vaccination statuses will be of value to clinicians, especially specialists.

Response: We understand some of these immunizations may not be relevant to, or administered in, certain fields; however, patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. Despite this measure representing four different submission criteria, the measure is calculated using a weighted average. This means all performance data from the four different submission criteria will be used to provide an overall performance rate for the measure. This allows for a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53076), we are finalizing the removal of measure Q110 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.5. Pneumococcal Vaccination Status for Older Adults

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	111
CMS eCQM ID:	CMS127v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q111 only focuses on the administration of the pneumococcal immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being finalized as a replacement for those MVPs that contain measure Q111.
In the Circumstance the Measure Was Retained	If the measure was not finalized for removal in the CY 2024 PFS final rule, we proposed to apply the following substantive changes to the measure specifications: 1) for the eCQM Specifications collection type, the denominator exclusion will be updated to include anaphylaxis any time before the end of the measurement period due to new coding availability to capture this data; 2) for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types, the denominator exclusions for active chemotherapy, bone marrow transplant and history of immunocompromising conditions will be removed; and 3) for all collection types, the initial patient population will be changed from 66 years of age and older to 65 years of age and older while the numerator criteria lookback period will be extended to the 19th birthday for pneumococcal vaccination. These updates would have lent to better alignment with the most recent ACIP guidelines *(https://www.cdc.gov/vaccines/vpd/pneumo/hcp/recommendations.html*). If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix. The substantive changes outlined above would have been applied to the measure specifications.

Comment: One commenter supported removal of measure Q111: Pneumococcal Vaccination Status for Older Adults, stating that it had concerns with the reliability and validity of this measure.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter indicated that measure Q111 is one of its most popular measures and there is value in retaining this measure until care teams gain more experience in implementing measure Q493 and until CMS incentivizes the adoption of the new, more complex measures.

Response: As mentioned in the response above, measure Q493: Adult Immunization Status, is more robust and will help improve complete vaccination rates for patients. As a result, measure Q111 is being removed as it will be duplicative to measure Q493.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53077), we are finalizing the removal of measure Q111 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.6. Melanoma: Coordination of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	138
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter opposed removal of measure Q138: Melanoma: Coordination of Care, stating that sudden removals of quality measures could disrupt the progress made in addressing melanoma care coordination. Removing a topped-out measure without allowing time for proper adjustments might overwhelm healthcare clinicians further and divert their focus from responding to urgent patient needs. The commenter requested that measure Q138 be phased out over a defined period to enable clinicians to adjust their care coordination processes and integrate alternative quality measures effectively.

Another commenter opposed removal of this measure as it is an important facet of care coordination. While the commenter understood that this measure has reached the end of its topped-out lifecycle, the commenter has seen how CMS' efforts to incentivize care coordination in other measures can meaningfully impact the priorities of practices. Another commenter did not support removal of this measure because measure Q138 is critical as a companion to measure Q397: Melanoma Reporting, to ensure appropriate diagnosis, treatment, and follow-up for patients with melanoma.

Response: The data shows the measure has reached the end of its topped-out life cycle which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2023 Benchmark File. While we agree the concept is important to quality care, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. As such, current clinically appropriate workflows should remain in place regardless of the MIPS measure inventory. Additionally, this measure has been in MIPS since the onset of the program, driving care coordination for seven years with continued high performance.

Comment: One commenter opposed removal of measure Q138, stating that elevated performance rates do not imply that a measure lacks significance in assessing quality of care, thereby justifying its discontinuation from reporting. The commenter stated that CMS should recognize and provide credit to those clinicians sustaining high-quality performance and stated that this measure could be used in a future MVP for dermatology.

Response: We strive to ensure all measures align with MIPS goals and priorities, including the removal of measures that are at the end of the topped-out lifecycle. We utilize MIPS data to determine the measure's year over year performance and utilize it as a criterion for measure removal, both allowing clinicians to maximize their quality score and to drive submission of measures that are able to produce meaningful benchmarks as applicable.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53077), we are finalizing the removal of measure Q138 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.7. Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	147
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.
Measure Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: A couple of commenters stated that although measure Q147: Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy is topped out, removal of this measure would make it difficult for nuclear medicine clinicians to participate successfully in MIPS due to a lack of applicable measures. Another commenter indicated that the measure remains meaningful given that bone scans are commonly used clinical tools for the detection bone metastasis, evaluation of fractures/trauma, as well as bony infections. Bone scans are also a cost-effective study for the diagnosis and management of bone metastases in a wide range of cancer types.

Response: As mentioned, the data shows the measure has reached the end of its topped-out life cycle which does not allow a meaningful benchmark. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2023 Benchmark File. We acknowledged removal of this measure decreases the number of available measures for nuclear medicine; however, there are policies in place to account for this when working to meet MIPS quality performance category requirements.

Comment: One commenter requested CMS delay removing measure Q147 (and removing measures Q324 and Q436 under Tables C.9 and C.12 of this Appendix) until sufficient replacement measures can be developed and tested. The commenter indicated that the removal of measures would leave most diagnostic radiology groups with only six MIPS measures to report by traditional registry or claims-based reporting. Another commenter opposed removal of measure Q147 because it is difficult to earn an incentive as a diagnostic radiologist in the quality performance category based on the 7-point cap and given that these clinicians are not patient facing.

Response: As stated above, the data shows the measure has reached the end of its topped-out life cycle which does not allow a meaningful benchmark. We acknowledged that removal of this measure decreases the number of available measures for diagnostic radiologists; however, there are policies in place to account for this when working to meet MIPS quality performance category requirements. Additionally, the removal of measure Q436 is being delayed for 1-year based upon public comments.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53078), we are finalizing the removal of measure Q147 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.8. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	283
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter opposed removal of measure Q238: Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management, stating that while the measure is topped out, the effectiveness of the interventions has not been examined. The commenter noted this is an opportunity to gauge what type of dementia-associated interventions and measures could replace this topped out measure to continue to encourage evidence-based care that supports patients with dementia remaining in the community, avoiding institutionalization, and receiving appropriate palliation as their disease progresses. The commenter requested that this measure remain in MIPS until a new measure may be developed.

Response: We acknowledged the commenter's concerns; however, the data shows the measure has reached the end of its topped-out life cycle which does not allow a meaningful benchmark. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2023 Benchmark File. We encourage the commenter to reach out to measure developers/stewards to develop new dementia specific measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53078), we are finalizing the removal of measure Q283 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.9. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	324
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the quality action being measured is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 0.81 percent for the MIPS CQMs Specifications collection type. As such, the MIPS CQMs Specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: A few commenters supported removal of measure Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients. Commenters agreed that the measure is a standard of care and extremely topped out and had concerns with the measure's reliability and validity. One commenter indicated that retirement of a measure with high and unvarying performance is an acceptable common practice and it seemed appropriate to remove this measure.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53079), we are finalizing the removal of measure Q324 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.10. Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
CBE # / eCQM CBE #:	0576 / N/A
Quality #:	391
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because we received feedback from interested parties that it is analytically challenging to implement this measure at the clinician level. The quality action of this measure is to ensure that patients discharged from an acute setting have outpatient follow ups. However, clinicians have provided feedback that patients who receive inpatient care, and are denominator eligible for this measure, may not always seek follow-up care within the inpatient clinician's health system which limits the clinician's or group's ability to document adequate follow up to outpatient encounters. This limitation makes it difficult to attribute the required numerator actions back to the accountable clinician, creating undue burden for MIPS eligible clinicians.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter supported removal of measure Q391: Follow-Up After Hospitalization for Mental Illness (FUH) because they had concerns with the reliability and validity of this measure.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter opposed removal of measure Q391 because the measure is used in several clinician and payer performance programs, including CMS' pediatric Universal Foundation, CMS' Quality Rating System, NCQA health plan ratings, and the Medicaid and Children's Health Insurance Program (CHIP) core sets. In addition, multiple states that require clinicians and/or payers to submit measure data have expressed that this measure is valuable to their work. Another commenter did not support removal of this measure because there are a limited number of behavioral health measures available, and the measure is in HEDIS, the CQMC Core sets, the Universal Foundation, and is commonly included in plan contracts.

Response: While we endeavor to align across CMS programs when feasible and possible, we strive to ensure all measures align with MIPS goals and priorities, including the removal of measures that may be difficult to implement. Ensuring patients discharged from acute care settings have outpatient follow up is a challenge at the clinician-level as patients in the denominator may not always seek follow-up care with clinicians associated with the healthcare system that provided the inpatient care. This makes it difficult to attribute the required numerator actions to the accountable clinician, thereby creating undue burden for MIPS eligible clinicians. Additionally, this measure continues to lack a benchmark due to an insufficient volume of data being submitted, further supporting removal of this measure from MIPS, as implementation for the measure as currently specified is more applicable at the plan-level of analysis.

Comment: One commenter did not support removal of measure Q391, citing that the lack of continuity of care is a major problem for behavioral healthcare. The commenter noted that although the hospital may not be in the same health system as the community provider, there are many ways that an inpatient setting can facilitate follow-up, such as reaching out through telephone contact. Discharge planners can take more time to ensure that the individual has transportation and has made some contact with the community provider prior to discharge.

Response: We acknowledged continuity of care is a vital component of quality healthcare outcomes; however, ensuring patients discharged from acute care settings have outpatient follow up is a challenge at the clinician level as patients in the denominator may not always seek follow-up care with clinicians associated with the healthcare system that provided the inpatient care. This makes it difficult to attribute the required numerator actions to the accountable clinician, thereby creating undue burden for MIPS eligible clinicians. As noted above, this measure continues to lack a benchmark due to an insufficient volume of data being submitted, further supporting removal of this measure from MIPS, as implementation for the measure as currently specified is more applicable at the plan-level of analysis.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53079), we are finalizing the removal of measure Q391 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.11. Tobacco Use and Help with Quitting Among Adolescents

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	402
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. We are finalizing in Table D.22 of this Appendix substantive changes to measure Q226 that will broaden the denominator by lowering the age to 12 years old and will therefore capture the denominator-eligible patient population for this measure.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter supported removal of measure Q402: Tobacco Use and Help with Quitting Among Adolescents as duplicative to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. Another commenter supported the proposed changes to this measure to streamline tobacco screening by bringing the age for screening down to 12.

Response: We thank the commenters for supporting removal of this measure from MIPS.

Comment: One commenter stated that while measure Q402 is similar to measure Q226, measure Q402 captures patients 12 to 20 years of age and is widely applicable for pediatric clinicians. By contrast, measure Q226 captures screening only among patients 18 years and older, making it of limited utility for clinicians providing care in the pediatric setting. Given the importance of tobacco cessation to both lowering the cancer burden and to improving cancer treatment outcomes for patients in active cancer treatment, the commenter urged CMS to retain measure Q402.

Response: As mentioned, substantive changes have been finalized to measure Q226 under Table D.22 of this Appendix. One of the substantive changes is lowering the age of denominator eligible patients to 12 years old. This change is beneficial to ensuring optimal care outcomes for the pediatric population.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53080), we are finalizing the removal of measure Q402 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

C.12. Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	436
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.
Measure Steward:	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the measure Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) being finalized with a 1-year delay in implementation in Table A.1 of this Appendix. This new measure is an outcome and digital measure which supports MIPS' focus on quality measures that assess outcomes and reduce clinician burden. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which may increase the risk of cancer. This new measure is more robust than measure Q436 which represents a process measure.
In the Circumstance the Measure Was Retained	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2024 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

Comment: One commenter opposed removal of measure Q436: Radiation Consideration for Adult CT: Utilization of Dose-Lowering Techniques measure, stating that the measure is not duplicative of new measure Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) proposed in Table A.1 of this Appendix because the new measure was proposed as an eCQM. The commenter indicated that the proposed measure does not measure a quality action that can be attributed to a diagnostic radiologist who has little control over the radiation dose used during a CT exam that is more within the purview of the radiologic technologist and the medical physicist. On the other hand, measure Q436 directly examines whether the radiology report is adequately communicating to referring clinicians and patients whether dose-lowering techniques were used during the CT. While these measures both encourage the use of dose-lowering techniques in CT, only measure Q436 includes a quality action which can be directly attributable to the radiologist and the removal of measure Q436 will negatively affect radiologists who may have difficulty adopting the new measure.

Response: As mentioned earlier, the proposed new measure, Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level), is more robust than measure Q436 which represents a clinical process. The new measure would support radiologists with a clinically relevant outcome measure within MIPS and meet the high priority definition for MIPS reporting as an outcome and patient safety measure. In addition, the Excessive Radiation Dose measure is a digital measure which supports MIPS' focus on quality measures that assess outcomes and reduce clinician burden. The focus of the new measure is to reduce radiation doses from computerized tomography (CT) scans, which may increase the risk of cancer. Also, it will enhance the accessibility of data contained in electronic clinical data systems for increased efficiency, which could decrease clinician burden. Using electronic and standardized data already collected as part of routine clinical care, this new measure assesses the radiation dose for every exam with complete information and assessment of imaging quality to ensure that efforts to reduce radiation dose do not result in poor image quality. However, to foster clinician/system readiness to report the new Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) measure and align it with implementation timelines across other CMS programs, implementation of the new measure will be delayed for 1-year and measure Q436 will be retained for the CY 2024 performance year/2026 MIPS payment year.

After consideration of public comments, we are not finalizing the removal of measure Q436 as proposed for the CY 2024 performance period/2026 MIPS payment year due to the 1-year delay in implementation of measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) as discussed in Table A.1 of this Appendix. Measure Q436, however, is finalized for removal starting with the CY 2025 performance year/2027 MIPS payment year and future years.

Table Group CC: Finalized Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Finalized Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

Beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we proposed to maintain 3 quality measures: Q112: Breast Cancer Screening; Q113: Colorectal Cancer Screening; and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan for MVP development and implementation (and maintain quality measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP). The clinical concepts represented by these MIPS quality measures will support some specialties in a more targeted approach rather than the broader clinical concept of preventive screenings represented within the finalized Preventive Care and Wellness (composite) measure finalized under Table A.6 of Appendix 1: MIPS Quality Measures. The tables within this section offer the rationale for the decision to partially remove quality measures Q112, Q113, and Q128, in which such quality measures are finalized for removal from traditional MIPS but retained for use in MVPs.

Therefore, we are finalizing to remove the three aforementioned previously finalized quality measures from traditional MIPS due to finalizing the addition of the Preventive Care and Wellness (composite) measure in Table A.6 of Appendix 1: MIPS Quality Measures, which includes the concepts of quality measures Q112, Q113, and Q128 as part of the finalized composite Preventive Care and Wellness (composite), and retain measures Q112, Q113, and Q128 for use in MVPs (and retain measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this final rule; see Table Group E of this Appendix for the finalized changes to quality measures Q112 and Q113 available within the CMS Web Interface collection type).

Furthermore, measure Q112 is finalized as an available measure within the Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1).

Measure Q128 is finalized for removal from traditional MIPS with retention in MVPs under Table CC.3 of this Appendix. It is noted that measure Q128 is being finalized as an available measure within the following two finalized MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Quality measure Q128 is currently an available measure within the following two previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8).

We solicited comments on this proposal.

CC.1. Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we proposed a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q112 only focuses on a single clinical concept of women who have had a mammogram screening for breast cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q112 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap within the quality performance category of these MVPs. Therefore, we proposed the removal of this measure from traditional MIPS but proposed retention of this measure for use in relevant MVPs. Measure Q112 had already been finalized in the Promoting Wellness MVP but is finalized for removal from that MVP due to the finalization of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and finalization of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). Measure Q112 is currently finalized as a quality measure within the finalized Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1). It is also part of the CQMC, Adult Universal Core Set, and in alignment across multiple CMS quality reporting programs. This measure will remain for purposes of the CMS Web Interface collection type available to Share Savings Program ACOs reporting through the APP.
In the Circumstance the Measure Was Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix was not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would have retained measure Q112 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes finalized for this measure.

Comment: One commenter stated that organizations that predominantly report via the eCQM collection type need to have their efforts acknowledged and valued and did not support the removal of measure Q112: Breast Cancer Screening (in addition to not supporting the removal of the measures in Tables CC.2 and CC.3 of this Appendix). Another commenter opposed removal of this measure, stating that while more comprehensive registry-reported measures are available, clinicians are unlikely to transition from EHR-based reporting to registry-based reporting solely to maintain reporting of those measures. The commenter stated the cost and inconvenience associated with using a registry would force clinicians to opt for less impactful or desirable eCQM measures to fulfill reporting requirements and removing eCQMs in favor of MIPS CQMs or QCDR measures is not a sound approach. A few commenters did not support the removal of this measure as an eCQM and keeping it as a CQM under the Preventive Care and Wellness (composite) measure.

Response: A more robust and comprehensive measure, Preventive Care and Wellness (composite) has been finalized to replace measure Q112, which only focuses on a single clinical concept of women who have had a mammogram screening for breast cancer. The mammogram screening for breast cancer is included as one of the components of the composite measure. More broadly, we encourage the development of eCQMs as part of our strategy toward transition to digital quality measures; however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include different collection types within our quality measure inventory to allow flexibility in reporting. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: Congruent with several commenters' recommendation not to finalize the Preventive Care and Wellness (composite) measure, the commenters recommended that CMS retain this individual measure in MIPS (in addition to retaining the measures in Tables CC.2 and CC.3 of this Appendix). One commenter opposed removal of this measure (and measure Q113 in Table CC.2 of this Appendix) because combining multiple rates into one composite measure make it difficult to pinpoint improvement opportunities, and both measures are part of the adult Universal Foundation. The commenter stated that CMS' measure alignment goals should continue to apply, even in traditional MIPS reporting.

Category	Description
	Response: We recognize the new Preventive Care and Wellness (composite) measure sets a more stringent performance standard than the component measures by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we will gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/*). Additionally, clinicians have the flexibility to choose measures to report and performance is not based solely on the reporting outcome of a single measure. While the MIPS benchmark will be based upon the weighted average for the Preventive Care and Wellness (composite), more granular performance data may be found through Medicare Care Compare or third-party intermediaries. *Comment:* One commenter did not support removal of this measure (in addition to not supporting removal of Q113 in Table CC.2) because these measures are in HEDIS, CQMC core sets, Universal Foundation, and are commonly used in plan contracts. *Response:* While we endeavor to align across CMS programs when feasible and possible, we strive to ensure all measures align with MIPS goals and priorities. The measure will still be available for use within applicable MVPs and the clinical quality action is also still be assessed for within the new composite measure. *Comment:* One commenter appreciated the value of a composite measure in the primary care setting but noted the individual cancer screening measures continue to have value for clinicians specializing in oncology. Ensuring adherence to routine cancer screening is an important component of oncology care for individuals in active cancer treatment, as well as for cancer survivorship. Another commenter did not support the removal of measure Q112 because there are very few relevant breast cancer quality measures available within the MIPS measure inventory and there is still value in measuring the individual components of the proposed composite measure. *Response:* We acknowledged the commenters' concerns; however, it is important to ensure duplicative measures/concepts are removed from MIPS to develop a system of quality measures that drive value-based care. Offering measures with more robust evaluation methods will continue to drive quality patient outcomes though the clinical care provided. The measure will still be available for use within applicable MVPs. We encourage the commenter to reach out to measure developers/stewards to develop new oncology related measures for submission to the Call for Measures for possible future implementation. *Comment:* One commenter requested that the three measures under Table Group CC not be removed until CY 2025 because the timeframe does not provide large practices enough time to be ready by January 1, 2024. Another commenter requested that CMS provide a longer timeframe to sunset these individual measures to allow adequate time to move toward composite measures that are reflective of whole person care rather than individual screening components. The commenter indicated that this same logic should apply to the future development of composite measures. Another commenter stated that removal of measures has made it more difficult to meet the quality performance category and clinicians cannot switch measures at the frequency with which CMS is changing them. The commenter indicated that many specialties use this measure because of their core value to patient wellness. *Response:* While we acknowledged the commenters' concerns, the use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, will gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/).* This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/*). We thank the commenter for their feedback regarding delaying implementation, however, the current structure of the composite measure still breaks down each component measure to be a separate submission criterion and does not require an 'all or none' analytic. This measure will still be available for use in applicable MVPs. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53082), we are finalizing the partial removal of measure Q112 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

CC.2. Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034/ N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we proposed a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q113 only focuses on a single clinical concept of patients who have had an appropriate screening for colorectal cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q113 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we proposed the removal of this measure from traditional MIPS but proposed retention of this measure for use in relevant MVPs. This measure had previously been finalized in the Promoting Wellness MVP but is finalized for removal from that MVP due to the finalization of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and finalization of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). This measure will remain available for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure Was Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix was not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would have retained measure Q113 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes finalized for this measure.

Comment: One commenter opposed removal of measure Q113: Colorectal Cancer Screening (in addition to not supporting the removal of measure Q128 under Table CC.3 of this Appendix), stating that while more comprehensive registry-reported measures are available, clinicians are unlikely to transition from EHR-based reporting to registry-based reporting solely to maintain reporting of those measures. The commenter indicated the costs of using a registry would force clinicians to opt for less impactful or desirable eCQM measures to fulfill reporting requirements, and removing eCQMs in favor of CQMs or QCDR measures is not a sound approach.

Response: A more robust and comprehensive measure, Preventive Care and Wellness (composite) has been finalized to replace measure Q113 which only focuses on a single clinical concept of patients who have had an appropriate screening for colorectal cancer. This clinical concept is included as one of the components of the composite measure. We also encourage the development of eCQMs as part of our strategy toward transition to digital quality measures, however, not all measures are submitted for the eCQM collection type as this is not currently a requirement. We endeavor to include different collection types within our quality measure inventory to allow flexibility in reporting. While the MIPS benchmark will be based upon the weighted average for the Preventive Care and Wellness (composite), more granular performance data may be found through Medicare Care Compare or third-party intermediaries.

Comment: One commenter did not support the removal of measure Q113 from traditional MIPS because although this measure has been combined into the new Preventive Care and Wellness (composite) geared toward primary care clinicians, measure Q113 continues to hold value for quality improvement across multiple specialties. The commenter was also concerned that the composite measure will produce a single score and based on the current design of this new composite, performance on the individual indicators will not be available.

Response: As indicated above, the clinical concept from measure Q113 is included as one of the components of the composite measure. It is important to ensure duplicative measures/concepts are removed from MIPS to develop an ecosystem of quality measures that drive value-based care, rather than offering duplicate measures. Offering measures with more robust evaluation methods will continue to drive quality patient outcomes though the clinical care provided.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53083), we are finalizing the partial removal of measure Q113 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

CC.3. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	128
CMS eCQM ID:	CMS69v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we proposed a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q128 only focuses on the clinical concept of a documented BMI and follow-up plan if the BMI was outside of normal parameters, rather than a comprehensive preventive care and wellness approach. However, the clinical quality action assessed within measure Q128 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we proposed the removal of this measure from traditional MIPS but proposed retention of this measure for use in relevant MVPs. Measure Q128 is also being finalized as a quality measure for use within two finalized MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Measure Q128 is available within two previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8). This measure had previously been finalized in the Promoting Wellness MVP but is finalized for removal from that MVP due to the finalization of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and finalization of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11).
In the Circumstance the Measure Was Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix was not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would have retained measure Q128 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes finalized for this measure.

Comment: One commenter supported removal of measure 128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan because the processes and populations addressed in these measures will be evaluated as part of the newly proposed Preventive Care and Wellness (composite). The commenter supported removing the measure from specialty sets and/or MVPs as it is replaced by the new composite measure.

Response: We thank the commenter for supporting the removal of this measure from traditional MIPS with retention for use in MVPs.

Comment: One commenter supported removal of measure Q128, indicating that for some specialties, the BMI measure would be replaced by the new Preventive Care and Wellness (composite) measure, which aggregates multiple services into one score. This score allows for a more statistically sound measure, though the commenter sought clarity if a clinician receives partial credit if some of the wellness checks are completed. Research has shown the importance of patients receiving a diagnosis of obesity to be an important factor in patients seeking treatment for their chronic disease. Of individuals who would be identified as having obesity, only 55 percent report being diagnosed with the disease.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: Per comments under Table B.34 Removal Table of this Appendix, several commenters did not support removing this measure from traditional MIPS but retaining the measure for use in the Rehabilitative Support for Musculoskeletal Care MVP.

Response: We acknowledged the concerns expressed by the commenters for the removal of measure Q128. However, this measure is duplicative of a component found within the new preventive care and wellness composite measure. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care, rather than offering duplicate measures. Offering measures with more robust evaluation methods will continue to drive quality patient outcomes though the clinical care provided. The Preventive Care and Wellness (composite) measure, which is more robust and comprehensive, has been finalized to replace measure Q128, which only focuses on a documented BMI and follow-up plan if the BMI was outside of normal parameters. This clinical concept is included as one of the components of the new composite measure. The clinical quality action assessed within measure Q128 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, it is being removed from traditional MIPS but being retained for use in relevant MVPs.

Comment: As indicated under Table A.6 of this Appendix, one commenter requested that if CMS finalizes the new Preventive Care and Wellness (composite) measure, that it retain measure Q128 as a standalone measure to retain available to specialists, especially those who

Category	Description
may have limited measures to report. The commenter indicated that its members report that the BMI measure is important as it encourages them to talk to their patients about obesity; spine health and risk of surgery, weight loss strategies, and encourages patients to follow up with their primary care physicians. A couple of commenters stated that the BMI measure is relevant to many specialties and removing the measure is limiting choice for specialists. Other commenters representing rheumatology, interventional cardiology, and psychiatry opposed removal of measure Q128. There were also concerns that clinicians may be penalized for not performing/referring for breast and colon cancer screening or giving influenza and pneumococcal immunizations under the proposed composite structure. In addition, this measure was not proposed for retention in the Quality Care in Mental Health and Substance Use Disorder MVP (See Appendix 3, Table A.4). *Response:* The clinical concept of this measure is included in the new Preventive Care and Wellness (composite) measure, which is more robust and comprehensive. Besides, the historical benchmark data shows that the measure has reached the end of its topped-out life cycle which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2023 Benchmark File. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53084), we are finalizing the partial removal of measure Q128 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

Table Group D: Previously Finalized Quality Measures with Substantive Changes Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #. In section IV.A.4.f.(1)(b) and section III.G.2. of this final rule, we are finalizing the proposal to establish the following new collection type, Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). To operationalize the implementation of Medicare CQMs, specifically the capability to distinguish between the submission of data for a Medicare CQM and a MIPS CQM to CMS, we created an identifier that reflects the Quality number associated with a quality measure (i.e., Q001, Q134, and Q236) followed by the letters "SSP." For the reporting of Medicare CQMs, the identifiers are as follows: 001SSP, 134SSP, and 236SSP. Such Medicare CQM identifiers must be included in the submission files.

The D Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2024. The changes made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2024 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature but are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 quality measure specifications, in the form of an 'Instructions Note' to clarify telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible will the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the finalized substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any table under Table Group D of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this final rule. For information regarding finalized changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE # / eCQM CBE #:	0059/ N/A
Quality #:	001
CMS eCQM ID:	CMS122v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with the intent of the measure to exclude patients with this condition from the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53085), we are finalizing the changes to measure Q001 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
CBE # / eCQM CBE #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) in order to be recognized through electronic capture.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53086), we are finalizing the changes to measure Q005 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	**Description**
CBE # / eCQM CBE #:	0067 / N/A
Quality #:	006
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator exception: Removed:** Documentation of system reason(s) for not prescribing aspirin or clopidogrel (e.g., lack of drug availability, other reasons attributable to the health care system). **Updated denominator criteria: Removed:** coding for subsequent myocardial infarction.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This will also create alignment within the denominator exceptions across all American Heart Association (AHA) measures. We proposed to remove patients with subsequent myocardial infarction (MI) from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI will already have a diagnosis of CAD from the initial MI. Therefore, these patients will already be correctly included in the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53086), we are finalizing the changes to measure Q006 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe." **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Removed:** For submission criteria 2: coding for subsequent myocardial infarction For all submission criteria: endoscopic procedures on the heart and pericardium. **Updated denominator exception: For all collection types: Removed:** For all submission criteria: Documentation of system reason(s) for not prescribing beta-blocker therapy (e.g., other reasons attributable to the health care system).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronic capture. We proposed to remove patients with subsequent MI from the denominator criteria for the MIPS CQMs Specifications collection type as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI will already have a diagnosis of CAD from the initial MI. Therefore, these patients will already be correctly included in the denominator eligible patient population. Additionally, we proposed to remove coding for endoscopic procedures of the heart and pericardium for the MIPS CQMs Specifications collection type as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action. We proposed to remove the denominator exception for all collection types for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of beta-blocker therapy. This will also create alignment within the denominator exceptions across all AHA measures.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53087), we are finalizing the changes to measure Q007 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
CBE # / eCQM CBE #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronic capture.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53087), we are finalizing the changes to measure Q008 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.6 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	019
CMS eCQM ID:	CMS142v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**The measure description is revised to read: For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period. **For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the measurement period. **The measure numerator is revised to read: For the MIPS CQMs Specifications collection type:** Patients with documentation, at least once within the performance period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care. **For the eCQM Specifications collection type:** Patients with documentation, at least once within the measurement period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description and numerator to clarify that the "reporting period" is the 12-month performance period of January 1st – December 31st and to maintain consistency across measures in MIPS.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53088), we are finalizing the changes to measure Q019 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.7 Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for initial encounters for age-related osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add coding for initial encounters for age-related or other osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints to align with codes in the Healthcare Effectiveness Data and Information Set (HEDIS) Fractures Value Set and create consistency in implementation while ensuring the appropriate patient population is identified for numerator compliance assessment.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53088), we are finalizing the changes to measure Q024 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.8 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for physical and occupational therapy clinician types.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add coding for physical and occupational therapy clinician types as the measure is appropriate and it will be within their scope of care to complete this assessment.
Comment: One commenter supported the addition of occupational therapy (OT) coding proposed for measure Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older to reflect services provided by OT practitioners to these patient populations. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53088), we are finalizing the changes to measure Q048 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.9 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
CBE # / eCQM CBE #:	0102 / N/A
Quality #:	052
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.
Substantive Change:	**The measure title is revised from 'Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy' to:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic, and were prescribed a long-acting inhaled bronchodilator. **Update instructions: Added:** **This measure will be calculated with 2 performance rates:** (1) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry. (2) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting inhaled bronchodilator. A simple average, which is the sum of the performance rates divided by the number of performance rates will be used for performance. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1. Patients diagnosed with COPD with who have documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry in the medical record. 2. Patients diagnosed with COPD who have documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting bronchodilator. This measure contains two submission criteria which together ensure that the proper evaluation and treatment is provided for patients with COPD and that patients without COPD are not provided inappropriate therapy. Submission Criteria 1 evaluates whether spirometry was performed for patients diagnosed with COPD and results confirming airflow obstruction are documented. Submission Criteria 2 evaluates whether a long-acting inhaled bronchodilator was prescribed for COPD patients who have symptoms. NOTE: Submission of the two performance rates is required for this measure. A simple average, which is the sum of the performance rates divided by the number of the performance rates, will be used to calculate performance. **Updated denominator: Added:** DENOMINATOR (SUBMISSION CRITERIA 1): All patients aged 18 and older with a diagnosis of COPD. **Revised:** DENOMINATOR (SUBMISSION CRITERIA 2): All patients aged 18 years and older with a diagnosis of COPD with spirometry results documented (FEV1/FVC < 70%), and have symptoms (e.g., dyspnea, cough/sputum, wheezing). **Updated denominator criteria: Added:** For Submission Criteria 1: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Patient encounter during the performance period WITHOUT Telehealth Modifier **Revised:** For Submission Criteria 2**:** Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Spirometry results documented (FEV1/FVC < 70%) AND Patient encounter during the performance period WITHOUT Telehealth Modifier AND Patient has COPD symptoms (e.g., dyspnea, cough/sputum, wheezing) **Updated numerator: Added: For** Submission Criteria 1: Patients with documented spirometry and confirmed airflow obstruction (FEV1/FVC < 70%).

Category	Description
	Revised: For Submission Criteria 2: Symptomatic COPD patients who were prescribed a long-acting inhaled bronchodilator. **Updated numerator instructions: Added:** For Submission Criteria 1: Documentation of spirometry results of (FEV1/FVC < 70%) can take place before the performance period. The intent of Submission Criteria 1 is to ensure accurate diagnosis of COPD in patients with respiratory symptoms such as dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease is appropriate by having documentation of spirometry results of FEV1/FVC < 70%, which is required to make the COPD diagnosis. **Updated numerator note: Added:** For Submission Criteria 1: Denominator Exception(s) are determined on the date of the denominator eligible encounter. If there is a diagnosis of COPD, but there is no documented spirometry within five years of the date of the encounter, and the current spirometry result is ≥70%, an exception may be reported. **Updated numerator options: Added:** For Submission Criteria 1: **Performance Met:** Spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) documented and reviewed. **Denominator Exception:** Documentation of medical reason(s) for not documenting and reviewing spirometry results (e.g., patients with dementia or tracheostomy). **Denominator Exception:** No history of spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) and present spirometry is ≥ 70%. **Denominator Exception:** Documentation of system reason(s) for not documenting and reviewing spirometry results (e.g., spirometry equipment not available at the time of the encounter). **Performance Not Met:** No spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%)documented and/or no spirometry performed with results documented during the encounter. **Revised:** For Submission Criteria 2: **Denominator Exception:** Documentation of medical reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., patient intolerance or history of side effects). **Denominator Exception:** Documentation of system reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., cost of treatment or lack of insurance). **Removed:** For Submission Criteria 2: Denominator Exception for patient reason(s).
Measure Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise this measure to add a submission criteria and performance rate so all patients are assessed for spirometry evaluation to ensure that the proper evaluation and subsequent treatment is provided for the patients with COPD. We proposed to add submission criteria one to evaluate whether spirometry was performed and if there were results confirming airflow obstruction. Submission criteria 2 will evaluate whether a long-acting bronchodilator was prescribed for the COPD patient meeting evaluation criteria and having symptoms. The inclusion of submission criteria one "allows potentially wide application of testing to improve recognition and diagnosis of COPD" which is then complimented in submission criteria 2 with the appropriate care of patients diagnosed with COPD.[64] Additionally, we proposed to revise the denominator exceptions for submission criteria two to clarify implementation by giving examples of scenarios that meet the denominator exception intent. We proposed to remove the denominator exception for patient reason(s) as it is incumbent upon the clinician to educate the patient on the importance of treatment. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53089 through 53090), we are finalizing the changes to measure Q052 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

64. Johns, D. P., Walters, J. A., & Walters, E. H. (2014). Diagnosis and Early Detection of COPD Using Spirometry. Journal of Thoracic Disease, 6(11), 1557–1569. *https://pubmed.ncbi.nlm.nih.gov/25478197/.*

D.10 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
CBE # / eCQM CBE #:	0069 / N/A
Quality #:	065
CMS eCQM ID:	CMS154v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the "Comorbid Conditions for Respiratory Conditions" value set, and aggressive periodontitis to the "Competing Conditions for Respiratory Conditions" value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient visits, telephone visits, online assessments (i.e., e-visit or virtual check-in), observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) from January 1 to December 28 for patients 3 months of age and older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Added:** An episode is defined as each eligible encounter for patients aged 3 months of age and older with a diagnosis of upper respiratory infection during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Added:** Aminoglycosides: Amikacin, Gentamicin, Streptomycin, Tobramycin To Beta-lactamase inhibitors: Ampicillin-sulbactam, Piperacillin-tazobactam Fourth-generation cephalosporins: Cefepime To Lincomycin derivatives: Lincomycin Miscellaneous antibiotics: Aztreonam, Chloramphenicol, Dalfopristin-quinupristin, Daptomycin, Linezolid, Metronidazole, Vancomycin To Natural penicillins: Penicillin G benzathine, Penicillin G benzathine procaine, Penicillin G procaine To Penicillinase-resistant penicillins: Nafcillin, Oxacillin To Quinolones: Gemifloxacin Rifamycin derivatives: Rifampin To Second generation cephalosporins: Cefotetan, Cefoxitin To Sulfonamides: Sulfadiazine To Third generation cephalosporins: Cefotaxime, Ceftazidime Urinary anti-infectives: Fosfomycin, Nitrofurantoin, Nitrofuantoin macrocrystals-monohydrate, Trimethoprim **Removed:** Folate antagonist From Macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We proposed to remove the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion will align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We proposed to update the value set/coding for the eCQM Specifications collection type by adding coding for 'Aggressive periodontitis' to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1017)" value set and coding for 'Neoplasms' to the "Comorbid Conditions for Respiratory Conditions ((2.16.840.1.113883.3.464.1003.102.12.1017)" value set, which will allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it will create alignment with the NCQA's HEDIS measure. We proposed to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this will align with the numerator timeframe of 'on or within 3 days of the eligible encounter'. We proposed to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53091), we are finalizing the changes to measure Q065 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.11 Appropriate Testing for Pharyngitis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	066
CMS eCQM ID:	CMS146v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the 'Competing Conditions for Respiratory Conditions' value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient, telephone, online assessment (i.e., e-visit or virtual check-in), observation, or emergency department (ED) visits with a diagnosis of pharyngitis or tonsilitis from January 1 to December 28 and an antibiotic order on or within 3 days after the episode date among patients 3 years or older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Revised:** An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Removed:** From macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate Penicillinase resistant penicillins From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We proposed removal of the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion will align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We proposed to update the value set/coding for the eCQM Specifications collection type by adding coding for malignant neoplasms to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1025)" value set which will allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it creates alignment with NCQA's HEDIS measure. We proposed to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this will align with the numerator timeframe of 'through 3 days after the eligible encounter'. We proposed to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53092), we are finalizing the changes to measure Q066 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.12 Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	104
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.
Substantive Change:	**The denominator definition is revised to read:** **Risk Strata – Very Low, Low, Intermediate, High, or Very High –** **Very Low Risk –** PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1c; AND presence of disease in fewer than 3 biopsy cores; AND ≤ 50% prostate cancer involvement in each fragment/core; AND PSA density < 0.15 ng/mL/g. **Low Risk –** PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1 to T2a. **Intermediate Risk –** PSA 10 to 20 ng/mL; OR Gleason score 7/Gleason grade group 2-3; OR clinical stage T2b to T2c; AND no high-risk group or very-high-risk group features. **High Risk –** Has one of the following: PSA > 20 ng/mL; OR Gleason score 8 to 10/Gleason grade group 4-5; OR clinically localized stage T3a, without any very-high-risk group features. **Very High Risk –** At least one of the following: Clinical stage T3b to T4; OR primary Gleason pattern 5; OR more than 4 cores with Gleason score 8 to 10/Gleason grade group 4-5 OR 2-3 high-risk features. (NCCN, 2022) **External beam radiotherapy –** "External beam radiotherapy" refers to 3D conformal radiation therapy (3D- CRT), intensity modulated radiation therapy (IMRT), stereotactic body radiotherapy (SBRT), and proton beam therapy.
Measure Steward:	American Urological Association Education and Research
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator definition to better classify risk category for patients receiving treatment for prostate cancer in accordance with revised NCCN guidelines.[65]
Comment: One commenter supported the substantive changes proposed to measure Q104: Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer and provided additional edits to fully align with NCCN guidelines. *Response:* We thank the commenter for supporting the substantive changes to this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53093), we are finalizing the changes to measure Q104 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

65. Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part I: Introduction, Risk Assessment, Staging, and Risk-Based Management. The Journal of Urology, 208(1), 10–18. *https://doi.org/10.1097/JU.0000000000002757.*
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Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline. Part III: Principles of Radiation and Future Directions. The Journal of Urology, 208(1), 26–33. *https://pubmed.ncbi.nlm.nih.gov/35536141/.*

D.13 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
CBE # / eCQM CBE #:	0058 / N/A
Quality #:	116
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) services. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion and numerator components: **Removed:** Ketolides From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to include coding for FQHC services to standardize codes in the value sets and align with the HEDIS version of this measure (*https://www.ncqa.org/hedis/measures/avoidance-of-antibiotic-treatment-for-acute-bronchitis-bronchiolitis/*). We proposed to update the list of antibiotic medications, found in Table 1 – Antibiotic Medications, used to determine patients who are appropriate for the denominator exclusion and numerator compliance. This update will ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is assessed appropriately by removing antibiotics that may not fully align with the measure intent and standardizing medication names to maintain alignment with the HEDIS measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53094), we are finalizing the changes to measure Q116 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.14 Diabetes: Eye Exam

Category	**Description**
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For the** MIPS CQMs Specifications collection type**: Added:** Dementia combinations: Donepezil-memantine **to** list of dementia exclusion medications. **Updated numerator note: For the MIPS CQMs Specifications collection type: Added:** reporting of CPT 92229 meets the intent of the quality action for performance met.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion for the MIPS CQMs Specifications collection type to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally for the MIPS CQMs Specifications collection type, we proposed to update the numerator note to indicate that denominator eligible patients who receive services under CPT code 92229 will meet the intent of the measure and should be included in the appropriate performance met numerator option, based on retinopathy findings.
Comment: A couple of commenters indicated that clinicians who participate in MIPS have been required to make manual updates to EHR systems to document measure performance, which could prevent access to this vision saving technology for people with diabetes. An update to the CQMs file to include CPT 92229 will ensure consistency with the CY 2022 PFS and the technical specifications published by the measure steward for the Diabetes: Eye Exam measure (NCQA, HEDIS MY 2023 Vol 2 Value Set). The commenters supported the substantive change proposed to measure Q117: Diabetes: Eye Exam to add the following numerator note: "For the MIPS CQMs Specifications collection type: reporting of CPT 92229 meets the intent of the quality action for performance met." Another commenter also supported the update to include CPT 92229 and CMS' support in including the use of artificial intelligence in this measure. *Response:* The inclusion of CPT 92229 within the denominator of the measure will bias the measure analytic and prevent it from performing as intended since the code is a direct correlation to numerator compliance. However, after discussion with the measure steward, NCQA, we have provided clarification within the numerator of the measure that allows clinicians to achieve numerator compliance if this code is documented within the medical record. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53094), we are finalizing the changes to measure Q117 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.15 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0066 / N/A
Quality #:	118
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**Updated denominator criteria: Removed:** For all submission criteria: coding for subsequent myocardial infarction. **Updated denominator exception: Removed:** For all submission criteria: other reasons attributable to the health care system.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove patients with subsequent MI from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI will already have a diagnosis of CAD from the initial MI. Therefore, these patients will already be correctly included in the denominator eligible patient population. We proposed to remove documentation of system reason(s) from the denominator exception as this option is not recommended for this measure due to wide-spread availability of these medications. This will also create alignment within the denominator exceptions across all AHA measures.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53095), we are finalizing the changes to measure Q118 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.16 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	134
CMS eCQM ID:	CMS2v13
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated guidance: For the eCQM Specifications collection type: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder. Patients who have ever been diagnosed with bipolar disorder prior to the qualifying encounter used to evaluate the **numerator** will be excluded from the measure regardless of whether the diagnosis is active or not. **Updated denominator exclusion: For all collection types: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator note: For the MIPS CQMs Specifications and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator note. **Updated denominator definition: For the MIPS CQMs Specifications and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator exclusion definition. **Updated denominator criteria: For all collection types: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We proposed to revise the guidance for the eCQM Specifications collection type to reflect inclusion of patients with a previous inactive (or resolved) diagnosis of depression as it is important to identify patients who have been treated for depression in the past but may have re-emerging symptoms. We also proposed to revise the denominator exclusion to remove a diagnosis of depression as an applicable exclusion, as patients with a history of depression may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We proposed to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.

Comment: One commenter supported the substantive changes proposed to measure Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, as removing the pre-existing depression from the exclusions supports measurement-based care.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: A couple of commenters did not support updating the denominator criteria to add qualifying encounters for nutritionists/dieticians (for all collection types). The commenters noted they did not believe it is clinically appropriate to routinely conduct depression screenings during these encounters and depression screening does not fall within the scope of practice for these clinicians. One commenter stated that patients are traditionally referred to these specialty services by a physician, physician assistant, or nurse practitioner. If the registered dietitian has concerns regarding the patient, they should assess the patient within their scope of practice and contact the referring clinician or follow their organizations guidelines for referral. Organizational processes should be followed regarding any emergency situations.

Response: We thank the commenters for their feedback. Because clinicians have the flexibility to choose which measures to report, the addition of this measure does not place additional burden on clinicians. We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures will be applicable or appropriate to all clinicians. However, no measures within traditional MIPS are required. We allow for clinician choice to account for these nuances, while ensuring clinicians can choose measures that are most meaningful to their scope of care and patient case-mix. The goal is to ensure we have a comprehensive set of measures that drive positive health outcomes as well as allow flexibility in clinician choice when determining the appropriateness of each measure.

Comment: One commenter did not support removal of a diagnosis of depression from the denominator exclusion. Patients who have an active diagnosis/active problem on problem list AND who are actively being treated for depression should NOT be screened for depression. The commenter recommended updating the denominator exclusion to state "patients who have current or an active diagnosis of depression during the current measurement period or the year prior to the measurement period."

Category	Description
Response: As noted above, patients with a previous inactive or resolved diagnosis of depression are included in the measure as it is important to identify patients who may have re-emerging symptoms. The measure does not include patients who have an active diagnosis of depression and who are actively being treated for depression. We encourage the commenter to reach out to the measure steward to discuss revisions to this measure for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53095), we are finalizing the changes to measure Q134 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.17 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality #:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**The measure title is revised from 'Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care ' to:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care. **The measure description is revised to read: For all collection types:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **The measure numerator is revised to read: For all collection types:** Patients whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **Updated definitions: For all collection types: Revised: Glaucoma Treatment Not Failed** – The most recent IOP was reduced by at least 20% in the affected eye or if both eyes were affected, the reduction of at least 20% occurred in both eyes from pre-intervention levels. **Updated numerator instructions: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels. **Updated numerator options: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise multiple components of this measure for all collection types to align with the latest scientific evidence that shows that 20 percent reduction in pre-intervention IOP optimizes patient outcomes by reducing the rate of worsening visual fields and is used as a benchmark for treatment outcomes. In a recent randomized clinical trial comparing phaco/Kahook Dual Blade to phaco/iStent, success was defined as at least a 20 percent reduction in IOP or reduction of one or more glaucoma medications from baseline.[66] In the only multicenter randomized clinical trial comparing minimally invasive glaucoma surgery standalone procedures, the COMPARE Study defined success as an unmedicated IOP reduction of at least 20 percent from baseline or unmedicated IOP less than or equal to 18 mmHg.[67]

Comment: One commenter had no concerns with the substantive changes proposed for measure Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care. The commenter regularly convenes panels of ophthalmologists with expertise in the guideline topic, a methodologist, and other experts to develop preferred practice patterns to guide practitioners based on the best available scientific evidence. For POAG treatment, its panel agreed with CMS' suggestion that a "… reasonable initial treatment goal in a POAG patient is to reduce IOP 20 percent to 30 percent below baseline and to adjust up or down as indicated by disease course and severity." The commenter supported CMS using the most up to date research and studies when working to adjust measures for MIPS.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53096), we are finalizing the changes to measure Q141 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

66. Falkenberry, S., Singh, I. P., Crane, C. J., Haider, M. A., Morgan, M. G., Grenier, C. P., ... & Dorairaj, S. (2020). Excisional Goniotomy vs. Trabecular Microbypass Stent Implantation: A Prospective Randomized Clinical Trial in Eyes with Mild to Moderate Open-Angle Glaucoma. Journal of Cataract & Refractive Surgery, 46(8), 1165-1171. *https://doi.org/10.1097/j.jcrs.0000000000000229*.
67. Ahmed, I. I. K., Fea, A., Au, L., Ang, R. E., Harasymowycz, P., Jampel, H. D., ... & COMPARE Investigators. (2020). A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma: The COMPARE Study. *Ophthalmology*, *127*(1), 52-61. *https://www.amedeolucente.it/public/A%20Prospective%20Randomized%20Trial%20Comparing.pdf.*

D.18 Functional Outcome Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	182
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.
Substantive Change:	**Updated numerator definition: Revised:** Functional Outcome Deficiencies – Impairment, loss of function, or difficulty with participation in daily activities related to physical (e.g., musculoskeletal, cardiovascular, pulmonary, integumentary), sensory, cognitive, behavioral, or visual/perceptual impairments. **Updated denominator criteria: Added:** coding for cognitive assessment.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator definition to describe assessment areas more accurately and completely for physical therapy and occupational therapy clinicians. We also proposed to add qualifying encounter coding utilized for cognitive assessment, as the quality action will be appropriate for this patient population.
Comment: One commenter supported the revisions to the numerator definition describing functional assessment areas as well as the addition of qualifying encounter coding utilized for cognitive assessment for measure Q182: Functional Outcome Assessment. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53097), we are finalizing the changes to measure Q182 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.19 Stroke and Stroke Rehabilitation: Thrombolytic Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	187
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.
Substantive Change:	**Updated denominator exception: Removed:** Tenecteplase (TNK) as an example of a denominator exception.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove Tenecteplase (TNK) as one of the examples for the denominator exception as the numerator action is looking at patients for whom IV thrombolytic therapy was initiated within 4.5 hours.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53097), we are finalizing the changes to measure Q187 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.20 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	**Description**
CBE # / eCQM CBE #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure surgeries on Sep 30 are included in the denominator.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the measure logic for the eCQM Specifications collection type to include cataract surgeries performed on September 30 to align with the measure intent of including all cataract surgeries performed between January 1st and September 30th of the measurement period.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53097), we are finalizing the changes to measure Q191 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.21 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	205
CMS eCQM ID:	CMS1188v1
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **The measure description is revised to read:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period. **Updated instructions: Removed:** Only patients who had at least two visits during the performance period, with at least 90 days between each visit will be counted in the denominator for this measure. **The denominator is revised to read:** All patients 13 years of age and older at the start of the performance period with a diagnosis of HIV before the end of the performance period with an eligible encounter during the performance period. **Updated denominator criteria: Revised:** age determined at start of the performance period. **Removed:** At Least Two Denominator Eligible Encounters During the Measurement Year, With at Least 90 days Between Each. **Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. **Updated denominator exclusion: Removed:** exclusion for patients receiving hospice services. **The numerator is revised to read:** Patients who were tested for each of the following at least once during the performance period: syphilis, gonorrhea, and chlamydia. **Updated denominator exception: Removed:** Chlamydia, gonorrhea, and syphilis screening results not documented (Patient refusal is the only allowed exception).
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We proposed to update the measure to reflect the clinical recommendations[68] [69] for annual sexually transmitted infections (STIs) screenings given the prevalence of sexually transmitted co-infections over the course of HIV disease. According to one literature review, the mean prevalence of STI co-infection was 16.3 percent with syphilis, gonorrhea, and chlamydia showing median rates of 9.5 percent, 9.5 percent, and 5 percent respectively.[70] A key takeaway from this review, continued high rates of co-occurring STIs in this patient population will hinder efforts in HIV transmission prevention. We proposed to update the instructions and denominator criteria to remove the requirement for at least two denominator eligible visits to ensure all patients who have been diagnosed with HIV receive appropriate testing. We proposed to revise the age anchor to be at the start of the performance period to reduce burden in implementation and add coding for preventive medicine encounters, nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and home or residence visits as it will be appropriate for patients at these encounters to be assessed for the quality action. We proposed to remove the denominator exclusion for patients who use hospice services as it may still be appropriate to screen for and subsequently treat these infections. Additionally, we proposed to remove the denominator exception for patient refusal as these sexually transmitted diseases can increase the risk for HIV infection through increases in the infectiousness and an individual's susceptibility.[71]
Comment: A couple of commenters supported the substantive changes proposed to measure Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis because they reflected recent updates to the USPSTF clinical guidelines for annual sexually transmitted infections screenings given the prevalence of sexually transmitted co-infections over the course of HIV disease. Additionally, lessening the measure's denominator criteria from two to one denominator-eligible encounter will ensure more patients are included in the measure population and will signal CMS' continued commitment to increase access to high-quality HIV care. *Response:* We thank the commenters for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53098), we are finalizing the changes to measure Q205 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

68. US Preventive Services Task Force, Mangione, C. M., Barry, M. J., Nicholson, W. K., Cabana, M., Chelmow, D., Coker, T. R., Davis, E. M., Donahue, K. E., Jaén, C. R., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Ruiz, J. M., Stevermer, J., & Wong, J. B. (2022). Screening for Syphilis Infection in Nonpregnant Adolescents and Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. *JAMA, 328*(12), 1243–1249. *https://doi.org/10.1001/jama.2022.15322.*
69. US Preventive Services Task Force, Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., Donahue, K. E., Doubeni, C. A., Krist, A. H., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Silverstein, M., Simon, M. A., Stevermer, J., Tseng, C. W., & Wong, J. B. (2021). Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement. *JAMA, 326*(10), 949–956. *https://doi.org/10.1001/jama.2021.14081.*

70. Kalichman, S. C., Pellowski, J., & Turner, C. (2011). Prevalence of Sexually Transmitted Co-infections in People Living with HIV/AIDS: Systematic Review with Implications for Using HIV Treatments for Prevention. *Sexually Transmitted Infections, 87*(3), 183–190. *https://doi.org/10.1136/sti.2010.047514.*

71. Hayes, R. J., Watson-Jones, D., Celum, C., van de Wijgert, J., & Wasserheit, J. (2010). Treatment of Sexually Transmitted Infections for HIV Prevention: End of the Road or New Beginning? *AIDS (London, England)*, *24*(0 4), S15–S26. *https://doi.org/10.1097/01.aids.0000390704.35642.47.*

D.22 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	226
CMS eCQM ID:	CMS138v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.
Substantive Change:	**Updated measure description: For all collection types: Revised:** Patient age to 12 years and older. **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 12 years and older. **Updated initial patient population: For the eCQM Specifications Collection type: Revised:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated measure analytic: For all collection types: Revised:** data completeness will be determined utilizing performance rate one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure for all collection types to combine the patient population within Q402: Tobacco Use and Help with Quitting Among Adolescents with that of Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure, by lowering the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Measure Q402 is finalized for removal under Table C.11 of this Appendix. We proposed to update the analytic of the measure to utilize performance rate one for the determination of data completeness to ensure a complete data set is submitted and inclusive of all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as tobacco users, the intent of the measure is to also ensure screening of all patients aged 12 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.

Comment: A couple of commenters supported the proposed denominator expansion to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, as it will promote adolescent tobacco screening and tobacco cessation.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53099), we are finalizing the changes to measure Q226 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.23 Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	236
CMS eCQM ID:	CMS165v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **The measure guidance is revised to read: For the eCQM Specifications collection type:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **The measure instructions note and numerator note are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-85 years of age by the end of the measurement period who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We proposed to revise the initial patient population for the eCQM Specifications collection type by specifying the patient visit must occur during the measurement period to clarify the encounter timing. We proposed to revise the measure guidance for the eCQM Specifications collection type and the instructions note and numerator note for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable. Additionally, we proposed to update the denominator exclusion for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.
Comment: One commenter requested for additional specific updates to the measure specifications for measure Q236: Controlling High Blood Pressure. The revised measure guidance states that it is the responsibility of each clinician to confirm the automated blood pressure monitor or device used to measure blood pressure is acceptable and reliable. However, it provides no guidance on how to determine if a device is accurate and reliable. Rather it puts the onus on the clinician to research and identify what device to use to ensure clinically accurate data. The commenter suggested that the measure only include blood pressure readings from devices on the United States Validated Device List	

Category	Description
(validateBP.org). The commenter agreed that the measure should include both an 'automated blood pressure monitor' and "device" but suggested the word 'device' may be confusing. The commenter suggested that "device" be replaced with "remote monitoring device." *Response:* We encourage the commenter to reach out to the measure steward, NCQA, to communicate potential revisions to this measure for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53100), we are finalizing the changes to measure Q236 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.24 Use of High-Risk Medications in Older Adults

Category	Description
CBE # / eCQM CBE #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** For Numerator (Submission Criteria 1): Definitions: Table 1 - High-Risk Medications at any dose or duration: **Revised:** Antithrombotics – Dipyridamole (oral, excluding extended release) Cardiovascular, other – Nifedipine (excluding extended release) Table 2 - High-Risk Medications With Days Supply Criteria **Removed:** From Anti-Infectives, other - Nitrofurantoin macrocrystals Table 3 - High-Risk Medications With Average Daily Dose Criteria **Added:** Description: Alpha agonists, central Description: Cardiovascular, other Description: Tertiary tricyclic antidepressants (TCAs) (as single agent or as part of combination products) **Removed:** Doxepin hydrochloride For Numerator (Submission Criteria 2): Definitions: Table 4 - High-Risk Medications **Added:** To Antipsychotics, first (conventional) and second (atypical) generation - Aripiprazole lauroxil **The measure numerator is revised to read: For the eCQM Specifications collection type:** Submission Criteria/Rate 2: Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines) on different days except for appropriate diagnoses. a. Patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. b. Patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator exclusion: For the eCQM Specifications collection type: Removed:** Rate 2: For patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. For patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator logic: For the eCQM Specifications collection type: Revised:** for medications ordered on the same day intended to start on different dates.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the medication tables for the MIPS CQMs Specifications collection type to align with the current guidelines and ensure appropriate high-risk medications are identified. This will align with the intent of the measure and ensure the appropriate patient population is being assessed for the quality action. We proposed to update the numerator for all collection types to clarify and ensure capture of the appropriate patient population. For the eCQM Specifications collection type, this was achieved by removing the standalone numerator exclusion and incorporating the exclusion language in the numerator criteria, to mitigate previous implementation concerns. Additionally, we proposed to add logic for medications ordered on the same day but intended to start on different dates.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53100 through 53101), we are finalizing the changes to measure Q238 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.25 Childhood Immunization Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	240
CMS eCQM ID:	CMS117v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**Updated numerator: Revised:** IPV, MMR, VZV, PCV, Hep A, and Flu: to allow for anaphylaxis due to the vaccine to count towards numerator compliance.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add language excluding patients with anaphylaxis due to vaccine administration to 6 of the 10 numerator criteria where applicable. A history of a severe allergic reaction to a vaccine should be considered a contraindication to additional doses of the same vaccine *(https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html)*.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53101), we are finalizing the changes to measure Q240 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.26 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
CBE # / eCQM CBE #:	0643 / N/A
Quality #:	243
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator criteria: Removed:** From 'Coronary Artery Bypass Graft Surgery' coding for endoscopic procedures on the heart and pericardium.
Measure Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove coding for endoscopic procedures of the heart and pericardium as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53102), we are finalizing the changes to measure Q243 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.27 Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	254
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Substantive Change:	**Updated denominator criteria:** **Revised:** Diagnosis of Other Current Condition in the Mother Classifiable Elsewhere but Complicating Pregnancy, Childbirth, or the Puerperium to Current Diagnosis of Pregnancy. **Added:** coding for other and unspecified abnormal uterine and vaginal bleeding and current diagnosis of pregnancy. **Updated denominator exception: Removed:** patient has visited the ED multiple times within 72 hours. **Updated measure instructions and numerator instructions: Revised:** submission frequency from each time to each visit.
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to include other and unspecified abnormal uterine and vaginal bleeding coding and revised the criteria for pregnancy to ensure all applicable patients are being included in the denominator eligible population and are being appropriately assessed. Additionally, we proposed to remove the exception for those patients that have visited the ED multiple times within 72 hours and revise the measure submission to each denominator eligible visit as it will be clinically appropriate for them to receive an ultrasound with pregnancy location determination at each visit.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53102), we are finalizing the changes to measure Q254 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.28 Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	275
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.
Substantive Change:	**The measure denominator is revised to read:** All patients, regardless of age, with a diagnosis of inflammatory bowel disease who initiated an anti-TNF agent during the performance period. **Updated denominator definition: Revised:** initiated an anti-TNF agent. **Updated denominator criteria: Revised:** initiated an anti-TNF agent.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add initiated an anti-TNF agent during the performance period in order to capture the intended patient population accurately. As the measure is currently written, it will allow patients who initiated treatment prior to the performance period and could inflate the intended population and possibly impact performance negatively with no clinician recourse.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53102), we are finalizing the changes to measure Q275 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.29 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	279
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.
Substantive Change:	**The measure title is revised from 'Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy' to:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy. **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **The measure denominator is revised to read:** All patients aged 18 years and older with obstructive sleep apnea who were prescribed an evidence-based therapy. **Updated denominator definition: Added:** Evidence-based Therapy – includes positive airway pressure, oral appliances, positional therapies, hypoglossal nerve stimulation, or other devices with monitoring capabilities. **Updated denominator criteria: Revised:** coding to reflect a diagnosis of obstructive sleep apnea. **Revised:** Evidence-based therapy was prescribed. **Updated numerator: Revised:** Patients with documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **Updated numerator definition: Added:** Documentation of adherence to therapy – includes a note documented in the patient's medical record that patient is adherent to the prescribed therapy for obstructive sleep apnea. Objective Informatics – a telemonitoring system that shows data demonstrating patient adherence to the prescribed therapy for obstructive sleep apnea (i.e., CPAP machines with SD cards that store data). Self-Reporting – patient and/or parent/caregiver attests to compliance with prescribed therapy for obstructive sleep apnea, which is documented in the medical record. Objective Reporting – data that are reported from an objective informatics or other data source and is not reported by the patient or parent/caregiver. **Removed:** Objectively Measured definition. **Updated numerator options: Revised:** Performance Met: Adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available, documented) Denominator Exception: Documentation of reason(s) for not objectively reporting adherence to evidence-based therapy (e.g., patients who have been diagnosed with a terminal or advanced disease with an expected life span of less than 6 months, patients who decline therapy, patients who do not return for follow-up at least annually, patients unable to access/afford therapy, patient's insurance will not cover therapy) Performance Not Met: Adherence to therapy was not assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available), reason not given.
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of this measure to reflect on the assessment of patients with obstructive sleep apnea (OSA) who were prescribed an evidence-based therapy by revising the denominator criteria to reflect this patient population. We proposed revisions to this measure to add flexibility in how the numerator is evaluated by allowing self-reporting for patients who do not have access to objective informatics systems or where resources may not be available. Additionally, we proposed to add definitions that will clarify the intended denominator eligible patient population and appropriate clinical action for numerator compliance.

Comment: One commenter supported the substantive changes proposed to measure Q279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53103), we are finalizing the changes to measure Q279 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.30 Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and occupational therapy clinician types.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add additional coding for speech language pathology and occupational therapy encounters. This will ensure a more complete denominator patient population is captured as it will be clinically appropriate for these clinician types to complete the quality action.
Comment: One commenter supported the addition of occupational therapy (OT) coding to measure Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease to reflect services provided by OT practitioners to these patient populations. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53104), we are finalizing the changes to measure Q291 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.31 Chlamydia Screening for Women

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	310
CMS eCQM ID:	CMS153v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** Women who are only eligible for the initial population due to a pregnancy test during the measurement period, and who had an order for an x-ray or for a specified medication on the date of the pregnancy test or the six days after the pregnancy test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion language to clarify the timing. The original measure language "within 7 days" is ambiguous as it can be interpreted as either "7 days after pregnancy test" or "on the day of pregnancy test and 6 days after". Therefore, clarifying the timeframe within the measure to evaluate a 7-day period better aligns with the measure intent of to include the day of the pregnancy test.
Comment: One commenter supported the substantive changes proposed to measure Q310: Chlamydia Screening for Women. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53104), we are finalizing the changes to measure Q310 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.32 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator: For all collection types: Added:** coding for audiology.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria for all collection types to include audiology codes within the denominator eligible encounter criteria as this measure is applicable to their scope of care. Patients with high blood pressure are at an increased risk of hearing loss as compared to those without hypertension, making this concept important for audiologists to assess.[72]
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53105), we are finalizing the changes to measure Q317 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

72. Agarwal, S., Mishra, A., Jagade, M., Kasbekar, V., & Nagle, S. K. (2013). Effects of Hypertension on Hearing. Indian Journal of Otolaryngology and Head and Neck Surgery: Official Publication of the Association of Otolaryngologists of India, 65(Suppl 3), 614–618. *https://doi.org/10.1007/s12070-013-0630-1.*

D.33 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	326
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator exception: Revised:** Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (e.g., present or planned atrial appendage occlusion or ligation or patient being currently enrolled in a clinical trial related to AF/atrial flutter treatment) **Removed:** documentation of system reasons exception.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exception to include patients currently being enrolled in a clinical trial related to AF/atrial flutter treatment as a medical reason for exception. Patients that are enrolled into a clinical trial related to AF/atrial flutter treatment may have contraindications for receiving FDA-approved oral anticoagulant drug therapy. Additionally, we proposed to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This will also create alignment within the denominator exceptions across all American Heart Association (AHA) measures.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53106), we are finalizing the changes to measure Q326 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.34 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	331
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated instructions: Added:** Each unique occurrence is defined as a 90-day period from onset of acute viral sinusitis symptoms. If multiple occurrences are documented within a 90-day period, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent instance.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure instructions to include additional clarifying language to remove ambiguity related to the definition of an occurrence of acute viral sinusitis. The revisions define a unique occurrence of acute viral sinusitis as a 90-day period from onset of acute viral sinusitis and include guidance in instances where multiple occurrences are documented.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53106), we are finalizing the changes to measure Q331 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.35 HIV Viral Load Suppression

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	338
CMS eCQM ID:	CMS314v1
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **Updated instructions: Revised:** timing for patient encounter to the first 240 days of the performance period. **The measure description is revised to read:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period. **The measure denominator is revised to read:** All patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period with at least one eligible encounter in the first 240 days of the performance period. **Updated denominator criteria: Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. Revised: timing for HIV diagnosis to be prior to or during the first 90 days of the performance period. Revised: timing for the denominator eligible encounter to occur during the first 240 days of the performance period.
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We proposed to revise the measure description and denominator to update the timing of the patient's HIV diagnosis and eligible encounter. Requiring the HIV diagnosis before or with the first 3 months of the performance period in conjunction with limiting the eligible encounter timeframe allows the MIPS eligible clinician time to treat the patient in an effort to achieve numerator compliance. A viral load less than 200 copies/mL is optimal for patients with HIV to stay healthy and reduce transmission to others (*https://www.cdc.gov/hiv/risk/art/index.html*). According to the Panel on Antiretroviral Guidelines for Adults and Adolescents, antiretroviral therapy (ART) should be initiated as soon as possible after HIV diagnosis (*https://www.ncbi.nlm.nih.gov/books/NBK586306/*). Furthermore, the Panel on Antiretroviral Guidelines for Adults and Adolescents states indicates that individuals who are adherent to their ARV regimen and do not harbor resistance mutations to the component drugs can generally achieve suppression 8 to 24 weeks after ART initiation; rarely, in some patients it may take longer. Additionally, we proposed to update the measure to include coding for telephone assessments with nonphysician/QHPs, residence services, and preventive medicine visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.

Comment: One commenter supported the proposed changes to measure Q338: HIV Viral Load Suppression. The commenter agreed that the proposed modifications, requiring the HIV diagnosis before or within the first 3 months of the performance period, allows the clinician the necessary time to treat the patient to achieve numerator compliance.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53107), we are finalizing the changes to measure Q338 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.36 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	366
CMS eCQM ID:	CMS136v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated definition: Added:** Treatment days (covered days): The actual number of calendar days covered with prescriptions during the 301-day period. Use the following steps to identify and calculate covered days. Step 1: For same medications that are prescribed on the same day or on different days with overlapping days' supply, the days' supply is summed. The start and end dates are then identified. The start date is the date of service of the earliest prescription event and the first covered day. The end date is the calendar day when the days' supply runs out. The start date through the end date are considered covered days. This rule assumes that the patient will take one prescription at a time (and start taking the next prescription after exhausting the previous prescription). For example: - If there are three 7-days' supply prescription events for the same medication on January 1, the start date is January 1 and the end date is January 21. Covered days include January 1–21. - If there are two 7-days' supply prescription events for the same medication on January 1 and January 5, the start date is January 1 and the end date is January 14. Covered days include January 1–14. - If there are three 7-days' supply prescription events for the same medication on January 1, a 7-days' supply prescription event on January 20 and a 7-days' supply prescription event on January 28, the start date is January 1 and the end date is February 4. Covered days include January 1–February 4. Step 2: For all other events (multiple prescriptions for the same medication on different days without overlap, multiple prescriptions for different medications on the same or different days, with or without overlap), the covered days are identified by the start and end dates for each prescription event individually. The start date through the end date are considered covered days. This rule assumes the member will take the different medications concurrently. Step 3: Each calendar day covered by one or more medications is considered one covered day. **The initial patient population is revised to read:** Initial Population 1: Children 6-12 years of age as of the Intake Period who had an IPSD and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Initiation Phase. Initial Population 2: Children 6-12 years of age as of the Intake Period who had an IPSD and remained on the medication for at least 210 treatment days during the 301-day period, beginning on the IPSD through 300 days after the IPSD, and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Continuation and Maintenance Phase. **The measure numerator is revised to read:** Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits on different dates of service during the 31-300 days after the IPSD.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure that will simplify the logic and create definitions to align with the HEDIS measure by identifying the index prescription start date (IPSD) with negative medication history. We also proposed to change the denominator qualifying encounter timeframe from during the measurement year to 6 months prior to the IPSD, which will enable the measure to attribute patients to clinicians who have a greater chance of interacting with the patient and/or prescribing the medication. Additionally, we proposed to revise the numerator to align with the measure intent by clarifying that the two follow-up visits must occur on different dates.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53108), we are finalizing the changes to measure Q366 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.37 Depression Remission at Twelve Months

Category	Description
CBE # / eCQM CBE #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v12

Category	Description
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update all collection types to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it is not a meaningful exclusion for the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53109), we are finalizing the changes to measure Q370 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.38 Functional Status Assessment for Total Hip Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery. **The measure denominator exclusions are revised to read:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients with severe cognitive impairment that starts before or in any part of the measurement period. 3. Exclude patients with one or more specific lower body fractures indicating trauma in the 24 hours before or at the start of the total hip arthroplasty. 4. Exclude patients with a partial hip arthroplasty procedure on the day of the total hip arthroplasty. 5. Exclude patients with a revision hip arthroplasty procedure, an implanted device/prosthesis removal procedure or a resurfacing/supplement procedure on the day of the total hip arthroplasty. 6. Exclude patients with a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm on the day of the total hip arthroplasty. 7. Exclude patients with a mechanical complication on the day of the total hip arthroplasty. 8. Exclude patients with a second total hip arthroplasty procedure 1 year before or after the original total hip arthroplasty procedure. 9. Exclude patients who die on the day of the total hip arthroplasty procedure or in the 300 days after. **The initial patient population is revised to read:** Patients 19 years of age and older who had a primary THA between November two years prior to the measurement period and October of the year prior to measurement period; and who had an outpatient encounter between November of the year prior to the measurement period and the end of the measurement period. **Updated numerator: Revised:** timeframe for follow-up assessment to 300 – 425 days after the THA procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to change the fracture exclusion from two fractures at the time of the procedure to one lower body fracture that will more accurately indicate a non-elective THA. We proposed to add denominator exclusions to remove patients who do not receive elective THA and will not be appropriate for quality action assessment. We also proposed to revise the initial patient population to push back the procedure timing and revise the numerator to extend the follow-up functional status assessment timing. This change harmonizes procedure and follow-up timing with other similar measures within the program reducing clinician burden when submitting similar measures across programs. This revision will also be reflected in the measure description.

Comment: One commenter supported adjusting the timeframe for follow-up assessment and the exclusion of all patients who have a fracture diagnosis at the time of the procedure to measure Q376: Functional Status Assessment for Total Hip Replacement. The commenter indicated the exclusion should be broader to exclude patients who have a lower extremity fracture diagnosed during the admission for THA and prior to the start of the surgery. Many patients will have a delay of over 24 hours before getting surgery for a hip fracture and the standard is to operate before 48 hours. The commenter noted that by setting the measure to exclude only those diagnosed within 24 hours of the start of the THA, CMS is effectively excluding the healthiest fracture patients who get a THA and including the sickest.

Response: We thank the commenter for supporting the substantive changes to this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53109), we are finalizing the changes to measure Q376 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.39 Children Who Have Dental Decay or Cavities

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	378
CMS eCQM ID:	CMS75v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist. **The measure initial patient population is revised to read:** Children, 1 – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the age range in the description and the initial patient population, as dental visits before age one are not significantly related to first dental examinations (*https://pubmed.ncbi.nlm.nih.gov/25422016/*). This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53110), we are finalizing the changes to measure Q378 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.40 Primary Caries Prevention Intervention as Offered by Dentists

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	379
CMS eCQM ID:	CMS74v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist. **Updated stratification: Revised:** Population 1 to reflect patient 1 – 5 years of age. **The measure initial patient population is revised to read:** Children, 1 – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated numerator: Revised:** to require two fluoride varnishes on different days during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the age range for this measure as dental visits before age one is not significantly related to first dental examinations *(https://pubmed.ncbi.nlm.nih.gov/25422016/)*. This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures. Also, we proposed to update the numerator to require two fluoride applications within the measurement period as opposed to one fluoride application. This change will also align the measure with current evidence, clinical recommendations, and with the Topical Fluoride for Children measure used in the Medicaid Child Core set as well as the Topical Fluoride for Children measure stewarded by the Dental Quality Alliance (*https://jada.ada.org/article/S0002-8177(14)60659-0/fulltext*).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53110), we are finalizing the changes to measure Q379 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.41 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	382
CMS eCQM ID:	CMS177v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.
Substantive Change:	**The measure description is revised to read:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk. **The initial patient population is revised to read:** All patient visits for those patients aged 6 through 16 at the start of the measurement period with a diagnosis of major depressive disorder.
Measure Steward:	Mathematica
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description and initial patient population for the upper age limit to specify patients should be 16 years of age at the start of the measurement period. This will align with the current measure logic, which does not include patients who are 17 years of age.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53110), we are finalizing the changes to measure Q382 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.42 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality #:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator criteria: Added:** additional outpatient place of service coding. **Updated denominator exclusion: Revised:** to exclude patients who have ever had a diagnosis of dementia.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to add additional outpatient place of service coding for use with encounter coding for the outpatient, emergency department, and non-acute inpatient setting as schizophrenia may be diagnosed at encounters within these settings. This will ensure a complete denominator patient population is captured for quality action assessment. Also, we proposed to expand the denominator exclusion so that it applies to patients who have ever had dementia as it is a chronic condition that cannot be resolved, and use of antipsychotics should be reserved for severe symptoms that have failed to respond adequately to nonpharmacological management strategies (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994396/*).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53111), we are finalizing the changes to measure Q383 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.43 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	386
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.
Substantive Change:	**The description is revised to read:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **The numerator is revised to read:** Patients who were offered assistance in planning for end of life issues or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **Updated numerator options: Revised:** to include the concept of reviewing and updating an existing end of life plan.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the description, numerator, and numerator options to reflect numerator compliance for reviewing or updating an existing end of life plan. These revisions work to clarify the intent of the measure in regard to end of life issues and frequency, as well as the quality actions that will meet the intent of this measure, continuing to stress the importance of end of life planning.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53111), we are finalizing the changes to measure Q386 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.44 Optimal Asthma Control

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	398
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.
Substantive Change:	**Updated denominator exclusion: Removed:** Patients who were permanent nursing home residents any time during the performance period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the measure criteria to remove patients who were permanent nursing home residents any time during the performance period from the denominator exclusions and allow these patients to be included within the denominator of this measure. Patients within a nursing home should still be assessed for the quality action within this measure as it supports overall health and quality of life.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53111), we are finalizing the changes to measure Q398 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.45 One-Time Screening for Hepatitis C Virus (HCV) for all Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	400
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.
Substantive Change:	**The measure title is revised from 'One-Time Screening for Hepatitis C Virus (HCV) for all patients' to:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation **The measure description is revised to read:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV **The measure instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients > =18 years AND who are seen twice for any visits **or** who have at least one preventive visit through September 30 of the performance period AND who have never received an HCV antibody test. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **This measure will be calculated with 2 performance rates:** 1. Percentage of patients age >= 18 years who have never been tested for HCV antibodies and who receive an HCV antibody test. 2. Percentage of patients age >= 18 years who have a reactive HCV antibody test, who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. The denominator of submission criteria 2 is a subset of the resulting numerator for submission criteria 1, as submission criteria 2 is limited to assessing if patients who have a reactive HCV antibody test, have a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. For all patients age >=18 years who have never been tested for HCV antibodies, submission criteria 1 is applicable, but submission criteria 2 will only be applicable for those patients who have a reactive HCV antibody test. A simple average, which is the sum of the performance rates divided by the number of the performance rates will be used to calculate performance. **NOTE:** Include only eligible encounters and HCV antibody test results documented through September 30 of the performance period. This will allow the evaluation of at least 90 days for treatment initiation or documentation of referral made within the performance period. **Updated denominator: Updated:** **THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE:** 1. All patients age >= 18 years age who have never been tested for HCV antibodies and who receive an HCV antibody test. AND 2. All patients age >= 18 years who have a reactive (positive) HCV antibody test and have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. This measure contains two submission criteria that aim to identify patients who are tested for HCV antibodies (submission criteria 1) and patients who have a reactive HCV antibody test and who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test (submission criteria 2). By separating this measure into various submission criteria, the MIPS eligible clinician will be able to better ascertain where gaps in performance exist and identify opportunities for improvement. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance, however, both performance rates must be submitted. **Updated denominator/denominator criteria: Revised:** **SUBMISSION CRITERIA 1**: Patients who have never been tested for HCV antibodies and who receive an HCV antibody test. DENOMINATOR (Submission Criteria 1): All patients >= 18 years of age who are seen twice for any visits or who have at least one preventive visit January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** At least one preventive encounter

Category	Description
	OR At least two patient encounters **AND NOT** **DENOMINATOR EXCLUSION:** Diagnosis for Chronic Hepatitis C OR Documentation or patient report of HCV antibody test or HCV RNA test which occurred prior to the performance period. **Added:** **SUBMISSION CRITERIA 2:** Patients with a reactive (positive) HCV antibody test with a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or receives a referral to a clinician who treats HCV infection within one month of the reactive HCV antibody test. **DENOMINATOR (Submission Criteria 2):** Patients >= 18 years of age who are seen twice for any visits OR who have at least one preventive visit AND have documentation of a reactive HCV antibody test between January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** All eligible instances when GXXXX is submitted for Performance Met (patient receives HCV antibody test and the test is reactive) in the numerator of Submission Criteria 1 **AND** At least one preventive encounter **OR** At least two patient encounters. **Updated denominator note: Added:** For submission criteria 1: Either documentation of the prior HCV antibody test or HCV RNA test in the medical record or patient self-report of prior HCV antibody test or HCV RNA test is acceptable for this exclusion. **Updated numerator: Revised:** For submission criteria 1: Patients who receive an HCV antibody test between January 1 and September 30 of the performance period. **Added:** For submission criteria 2: Patients who have an HCV viral test conducted that (a) does not detect HCV viremia, or (b) detects HCV viremia and treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. **Updated definitions:** **Removed:** For submission criteria 1: definition for screening for HCV Infection includes current or prior receipt of **Added:** For submission criteria 2: **Definition:** Examples of clinicians who treat HCV infection include but are not limited to: • Gastroenterologist • Hepatologist • Infectious disease clinicians Initiation of treatment definition for clinicians who do not refer patients to specialists for care: • Initiation of antiviral treatment, as appropriate, based on clinical guideline recommendations and patient characteristics. HCV viral test is defined as a test measuring an established marker of active HCV infection, including: • HCV RNA test • HCV core antigen test **Updated numerator options:** **Revised:** For submission criteria 1: **Performance Met:** Patient receives an HCV antibody test with nonreactive result. **Performance Met:** Patient receives an HCV antibody test with reactive result. **Denominator Exception:** Documentation of medical reason(s) for not receiving HCV antibody test due to limited life expectancy **Performance Not Met:** Patient does not receive HCV antibody test OR patient does receive HCV antibody test but results not documented, reason not given. **Added:** For submission criteria 2: **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, is referred within 1 month of the reactive HCV antibody test to a clinician who treats HCV infection. **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, has HCV treatment initiated within 3 months of the reactive HCV antibody test. **Performance Met:** Patient has a reactive HCV antibody test, and has a follow up HCV viral test that does not detect HCV viremia. **Performance Not Met:** Patient has a reactive HCV antibody test and does not have a follow-up HCV viral test,

Category	Description
	OR Patient has a reactive HCV antibody test and has a follow up HCV viral test that detects HCV viremia and is not referred to a clinician who treats HCV infection within 1 month and does not have HCV treatment initiated within 3 months of the reactive HCV antibody test, reason not given.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise this measure to include follow up testing for HCV and, if viremia is detected, that treatment is initiated, or patients are referred to a clinician who treats HCV infection. This will be accomplished by stratifying the measure to create submission criteria (with corresponding performance rate) for patients who have never been tested for HCV antibodies and who receive an HCV test, and a submission criterion (with corresponding performance rate) for patients who have a reactive HCV antibody test and, if HCV viremia detected, have treatment initiated or referral for treatment. This revision will be reflected within multiple components within the specification. These revisions take the measure one step further to ensure actions are being taken once the screening is completed so patients receive the appropriate care resulting in positive health outcomes. We will continue to monitor this measure throughout the rulemaking process for testing being performed by the measure steward regarding these proposed changes to the measure. Finalization of these revisions were contingent on completion of this testing. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
Comment: One commenter recommended for measure Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients that CMS define the hepatitis C screening test as hepatitis C antibody testing with reflex to RNA testing in patients with unknown or previously negative antibody status and hepatitis C viral RNA in patients with previously positive antibody and undetected RNA. Additionally, the commenter indicated that hepatitis B screening should be required to conform with CDC screening recommendations. *Response:* We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53112 through 53114), we are finalizing the changes to measure Q400 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.46 Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	409
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.
Substantive Change:	**Updated denominator exclusion: Added:** For Submission Criteria 1: Exclude patients with a baseline mRS > 2
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to add a denominator exclusion for Submission Criteria 1 to account for patients who have a baseline mRS of greater than 2 as endovascular stroke intervention will not be clinically indicated for this patient population.[73]
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53115), we are finalizing the changes to measure Q409 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

73. American Heart Association, American Stroke Association. Acute Ischemic Stroke: Current Treatment Approaches for Acute Ischemic Stroke [PowerPoint slides]. *https://www.stroke.org/-/media/Stroke-Files/Ischemic-Stroke-Professional-Materials/AIS-Toolkit/AIS-Professional-Education-Presentation-ucm_485538.*

D.47 Osteoporosis Management in Women Who Had a Fracture

Category	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator criteria: Added: For all** submission criteria: coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and federally qualified health center (FQHC) visit.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to include coding for telephone assessments with nonphysician/QHPs, and federally qualified health center (FQHC) visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53116), we are finalizing the changes to measure Q418 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.48 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
CBE # / eCQM CBE #:	2152 / N/A
Quality #:	431
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**Updated measure analytic: Revised:** data completeness will be determined utilizing submission criteria one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the analytic of the measure to utilize submission criteria one for the determination of data completeness to ensure a complete data submission for all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as unhealthy alcohol users, the intent of the measure is to also ensure screening of all patients aged 18 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53116), we are finalizing the changes to measure Q431 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.49 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	438
CMS eCQM ID:	CMS347v7
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD) including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated rate aggregation: For the eCQM Specifications collection type:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period **Added:** Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of > = 20 percent during the measurement period. **Revised:** Performance Rate to aggregate all 4 populations into a single performance rate. **Updated guidance: For the eCQM Specifications collection type: Revised:** the process to prevent counting patients more than once. **Updated denominator: For all collection types: Revised:** DENOMINATOR (SUBMISSION CRITERIA 2): Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. **Added:** DENOMINATOR (SUBMISSION CRITERIA 4): Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. **Updated instructions: For the MIPS CQMs Specification collection type: Revised:** THERE ARE FOUR SUBMISSION CRITERIA FOR THIS MEASURE**: 1. All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure. OR 2. Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. OR 3. Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. OR 4. Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent. **Revised:** There is only one performance rate calculated for this measure. Patients can only be counted once and cannot be in more than one **submission criteria**. When submitting this measure, determine if the patient meets denominator eligibility in order of each risk category defined in the denominator submission criteria. For example, first evaluate if the patient meets denominator Submission Criteria 1. If no, then evaluate if the patient meets denominator Submission Criteria 2. If yes, then the patient will be in Submission Criteria 2 and is not eligible for denominator Submission Criteria 3 and 4. **Updated initial patient population: For the eCQM Specifications collection type:** Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged >= 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes.

Category	Description
	Population 4: Patients aged 40 to 75 at the beginning of the measurement period with 10-year ASCVD risk score (i.e., 2013 ACC/AHA ASCVD Risk Estimator or the ACC Risk Estimator Plus) of >= 20 percent during the measurement period. **Updated denominator criteria: For the MIPS CQM Specifications collection type:** **Revised:** For submission criteria 2: Patient aged 20 to 75 years at the beginning of the measurement period. **Added:** For submission criteria 4: Patients aged 40 through 75 years at the beginning of the measurement period AND Calculated 10-year ASCVD risk score of ≥ 20 percent during the measurement period AND Patient encounter during the performance period AND NOT DENOMINATOR EXCLUSIONS: Patients who are breastfeeding at any time during the measurement period OR Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period **Updated numerator: For the MIPS CQM Specifications collection type: Added:** (SUBMISSION CRITERIA 4): Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period. **Updated denominator exception: For the MIPS CQMs Specifications collection type: Added:** For submission **criteria** 4: Denominator Exceptions 1. Active Liver or Hepatic Disease or Insufficiency 2. End Stage Renal Disease 3. Statin-Associated Muscle Symptoms (SAMS) **Updated numerator definition: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: Statin therapy – Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. **Updated numerator note: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: In order to meet the measure, current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; it may be called to the pharmacy. Statin medication "samples" provided to patients can be documented as "current statin therapy" if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure. It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list). Intensity of statin therapy in primary and secondary prevention: The expert panel of the 2018 ACC/AHA/MS Guidelines [1] defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time. Denominator Exceptions should be active during the measurement period. **Updated numerator options: For the MIPS CQM Specification collection type: Added:** For **submission criteria 4**: **Performance Met:** Patients who are currently statin therapy users or received an order (prescription) for statin therapy. **Denominator Exception:** Documentation of medical reason(s) for not currently being a statin therapy user or receiving an order (prescription) for statin therapy (e.g., patient with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, patients with end stage renal disease [ESRD] or other medical reasons). **Performance Not Met:** Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure that will allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.[74] Submission criteria one was updated to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[75] Additionally, we proposed to add submission criteria 4, which specifically assesses statin use for patients that have a 10-year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria will be considered high risk and

Category	Description
	based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[76] Furthermore, we proposed to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4. Due to the proposal of submission criteria 4, we proposed to revise the measure instructions to explain to interested parties how this measure will be calculated for the purpose of MIPS. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
Comment: One commenter agreed that the substantive changes proposed to measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease are consistent with the most recent AHA/ACC guidelines referenced. *Response:* We thank the commenter for supporting the substantive changes to this measure. *Comment:* One commenter was concerned about the exclusions of those receiving palliative care services from measure Q438. While those with an end-stage serious illness receiving palliative care would not benefit from these services, others earlier in an illness receiving palliative care might. *Response:* We agree palliative care is appropriate at any point in a serious illness and can be provided with any curative, disease-modifying treatment. It is our expectation clinicians and vendors collaborate to understand these concepts and their differences in order to implement them accurately into their systems. Palliative care is generally provided by an interdisciplinary medical team that focuses on the patient as a whole and would be inclusive of the types of services addressed by this measure as needed. Due to the complexities of care required for this population, clinicians that support patients receiving palliative care may inadvertently not perform well from the aspect of producing quality metrics (*https://doi.org/10.1186/s12913-019-3961-0*). However, we encourage clinicians to provide care as they determine best supports all patients during their healthcare journey even if the patient population is not included within the targeted denominator of a given measure specification. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53117 through 53119), we are finalizing the changes to measure Q438 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

74. Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., … & Ziaeian, B. (2019). 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596-e646. *https://doi.org/10.1161/CIR.0000000000000678*.
75. Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.
76. Arps, K., Blumenthal, R., & Martin, S. (2019, November 15). New Aspects of the Risk Assessment Guidelines, Scientific Evidence and Future Goals. *https://www.acc.org/latest-in-cardiology/articles/2018/11/14/07/10/new-aspects-of-the-risk-assessment-guidelines*.

D.50 Non-Recommended Cervical Cancer Screening in Adolescent Females

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	443
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.
Substantive Change:	**Updated denominator exclusion: Added:** coding for Cytokine Release Syndrome.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusions criteria by adding ICD-10-CM codes for Cytokine Release Syndrome, which will allow clinicians to capture and exclude patients with Cytokine Release Syndrome, as it may be appropriate for these patients to receive cervical cancer screening. It will also create alignment with the HEDIS measure.
Comment: One commenter supported the substantive changes proposed to measure Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53119), we are finalizing the changes to measure Q443 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.51 Appropriate Workup Prior to Endometrial Ablation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	448
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**Updated denominator criteria: Removed:** coding for extraction of endometrium.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove ICD-10 codes 0UDB7ZZ and 0UDB8ZZ from the denominator criteria as these codes do not represent endometrial ablation, but rather endometrial extraction. This change will ensure that the patients included within the denominator will truly meet the intent of the measure. Additionally, it will ensure all patients undergoing this procedure are included within the denominator to be assessed for the quality action described in the numerator.
Comment: One commenter supported the substantive changes proposed to measure Q448: Appropriate Workup Prior to Endometrial Ablation. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53119), we are finalizing the changes to measure Q448 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.52 Functional Status After Primary Total Knee Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	470
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Postoperative Assessment Oxford Knee Score (OKS) or KOOS, JR - A postoperative Oxford Knee Score (OKS) or KOOS, JR functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months postoperatively will not be used for measure calculation.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to add KOOS, JR. The "KOOS, JR." was developed from the original long version of the Knee injury and Osteoarthritis Outcome Score (KOOS) survey using Rasch analysis. The "KOOS, JR." contains seven items from the original KOOS survey. Items are coded from 0 to 4, none to extreme respectively. "KOOS, JR." is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health. This short form tool was developed in 2017 (*https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp*). Additionally, the language has been revised and will allow for assessments completed via telephone.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53120), we are finalizing the changes to measure Q470 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.53 HIV Screening

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	475
CMS eCQM ID:	CMS349v6
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).
Substantive Change:	**Updated denominator exception: Added:** Patients who die on or before the end of the measurement period.
Measure Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a denominator exception for patients who die before receiving an HIV screening. Since it is possible that a clinician could advance schedule an HIV test for a patient who potentially may die prior to the test, allowing this denominator exception will preserve performance of reporting clinicians while maintaining the intent of the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53120), we are finalizing the changes to measure Q475 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

D.54 Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	485
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. Also, we proposed to add a note to the Visual Rating Scale (VRS) for Pruritis definition as this tool is only validated for patients 18 years and older. We proposed a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. This skin condition has an annual prevalence of up to 0.71 percent within the pediatric patient population. Therefore, inclusion of the pediatric patient population will provide support for this frequently seen chronic inflammatory skin disorder and have significant impact on their overall quality of life (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/)*.

Comment: One commenter supported the substantive changes proposed to measure Q485: Psoriasis – Improvement in Patient-Reported Itch Severity.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: One commenter opposed the changes to measures Q485 and Q486: Dermatitis – Improvement in Patient-Reported Itch Severity (see Table D.55 of this Appendix) stating that although these measures have been available within a QCDR with actionable feedback for years, 2023 was the first year they were accepted in traditional MIPS measures. The commenter stated these measures should not undergo any substantive changes until the submitting clinicians and groups have a chance to review the peer benchmarking from the 2023 performance year. If any changes are to be made to this measure, the commenter requested they not be put into effect until at least 2025.
In addition, any substantive changes made to these measures will eliminate any benchmarks which would have been established by the 2023 submission and therefore would be worth only 3 points for a small practice since there would be no benchmark. If measures Q138: Melanoma: Coordination of Care and Q402: Tobacco Use and Help with Quitting Among Adolescents are finalized for removal, and there is a proposed lack of benchmarks for measures Q485 and Q486, this would have a significant negative impact on dermatology clinicians who already have a limited quality measures set.

Response: While we acknowledged the commenters' concerns regarding the benchmark, this is an important high priority measure that should be enhanced to support the pediatric patient population as they are frequently affected by this chronic inflammatory skin disorder which has a significant impact on their lives process. While the benchmark is an important consideration programmatically, we strive to implement quality measures that are meaningful to patients and are applicable to all who would benefit from the quality care described within the measure. However, the changes being finalized within this measure do not necessitate the creation of a new benchmark. In addition, changes in assessment scores are necessary to align with current clinical guidelines.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53121), we are finalizing the changes to measure Q485 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.55 Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	486
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of dermatitis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition: Removed:** Visual Rating Scale (VRS) for Pruritis. **Updated denominator criteria:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. We also proposed to add a note to the VRS for Pruritis definition as this tool is only validated for patients 18 years and older. We proposed a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. Optimizing management of dermatitis in pediatric patients is critical to reduce signs of inflammation, alleviate pruritus and sleep disturbance, minimize the development and/or impact of comorbidities, and improve the patient and caregiver's quality of life (*https://pubmed.ncbi.nlm.nih.gov/33838839/*).

Comment: One commenter supported the substantive changes proposed to measure Q486: Dermatitis – Improvement in Patient-Reported Itch Severity.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: One commenter opposed the changes to measure Q486 (see Table D.54 of this Appendix for the full comment).

Response: While we acknowledged the commenters' concerns regarding the benchmark, this is an important high priority measure that should be enhanced to support the pediatric patient population as they are frequently affected by this chronic inflammatory skin disorder which has a significant impact on their lives process. While the benchmark is an important consideration programmatically, we strive to implement quality measures that are meaningful to patients and are applicable to all who would benefit from the quality care described within the measure. However, the changes being finalized within this measure do not necessitate the creation of a new benchmark.
In addition, changes in assessment scores are necessary to align with current clinical guidelines.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53121), we are finalizing the changes to measure Q486 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.56 Screening for Social Drivers of Health

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	487
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Substantive Change:	**Updated denominator criteria: Added:** coding for occupational therapy. **Updated denominator exception:** **Added:** **Denominator Exception:** Patient reason for not screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety (e.g., patient declined or other patient reasons)
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add encounter codes for MIPS eligible occupational therapists based upon interested parties' feedback: "Occupational therapy practitioners across practice settings should consider how current housing status and social determinants of health may impact their clients' occupational performance and ability to manage health conditions" (*https://pubmed.ncbi.nlm.nih.gov/32007967/)*. Also, we proposed to include a denominator exception as some patients may prefer not to discuss this information, however, attempting to screen every patient is important.

Comment: One commenter supported the substantive changes to add an exclusion to measure Q487: Screening for Social Drivers of Health to account for patient choice because adding this exclusion would reduce the risk a person would be pressured to complete a screening after declining to do so and ensure clinicians can respect a person's choice and agency without risking their performance on this measure. Another commenter supported the addition of occupational therapy coding to this measure to reflect services provided by OT practitioners to these patient populations.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53122), we are finalizing the changes to measure Q487 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

D.57 Adult Immunization Status

Category	Description
CBE # / eCQM CBE #:	3620 / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**Updated denominator:** **Removed:** For all submission criteria: Active chemotherapy during the measurement period OR Bone marrow transplant during the measurement period OR History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & Hemoglobin (HB)-S disease or cerebrospinal fluid leaks any time during the patient's history prior to or during the measurement period: • Anatomic or Functional Asplenia • Cerebrospinal Fluid Leak • Cochlear Implant • Cochlear Implant Device • Cochlear Implant Diagnosis • Immunocompromising Conditions • Sickle Cell Anemia and HB-S Disease **Updated denominator exception:** **Added:** For submission criteria 3: Documentation that administration of second recombinant zoster vaccine could not occur during the performance period due to the recommended 2-6 month interval between doses (i.e., first dose received after October 31)
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove denominator exclusions for all submission criteria for patients receiving active chemotherapy, who have a bone marrow transplant, or history of immunocompromising conditions as these are not contraindicators for receiving these vaccines and is in alignment with ACIP recommendations (*https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html*). We proposed to add a denominator exception if there is a system reason that the second dose of recombinant zoster vaccine could not be administered within the prescribed interval during the performance period, as there is a minimum interval requirement between doses.

Comment: One commenter indicated that the substantive changes proposed to measure Q493: Adult Immunization Status (AIS) for zoster vaccine documentation should not have significant implications for clinicians' reporting of vaccines under this measure. However, the commenter wanted to ensure it is CMS' goal that the second dose will be captured in the subsequent performance period. It is also important to note that the zoster-component of the AIS measure numerator still includes either two doses of the herpes zoster recombinant vaccine OR one dose of the herpes zoster live vaccine as ways to meet numerator compliance. The inclusion of the zoster live vaccine (ZVL) in the measure numerator is misaligned with recent clinical guidance.

The commenter stated that the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) no longer recommend the ZVL for the prevention of herpes zoster. ACIP has made the following recommendations[77 78]: (1) Recombinant zoster vaccine (RZV) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years; (2) RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received ZVL, and (3) RZV is preferred over ZVL for the prevention of herpes zoster and related complications. The commenter also stated that the CDC similarly includes a 2-dose series RZV for adults ages 50 years and older in their vaccine schedule, including for adults who have previously received the ZVL (CDC). Additionally, the ZVL is no longer available for use in the United States. Consequently, there should be serious consideration of re-specification of the measure to align with the latest ACIP and CDC guidance.

Response: We thank the commenter for their comment regarding ACIP recommendations on the administration of herpes zoster vaccine. The intent of the measure is the patient has received the herpes zoster vaccine. Based on the comment from ACIP, CMS will remove the ZVL vaccine from numerator compliance. Therefore, numerator compliance will be defined as a patient receiving two doses of the herpes zoster recombinant vaccine and will remove all reference to the herpes zoster live vaccine. Additionally based on this update the numerator statement will also be revised for clarification on this clinical intent for receipt of the herpes zoster vaccination.

After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53122), we are finalizing the changes and in addition to removing ZVL vaccination for numerator compliance to measure Q493 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

77. Dooling, K.L., Guo A., Patel M., et al. (2018). Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. MMWR. Morbidity and mortality weekly report, 67,103–108. *http://dx.doi.org/10.15585/mmwr.mm6703a5*.
78. Anderson, T. C., Masters, N. B., Guo, A., Shepersky, L., Leidner, A. J., Lee, G. M., Kotton, C. N., & Dooling, K. L. (2022). Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices – United States, 2022. MMWR. Morbidity and mortality weekly report, 71(3), 80–84. *https://doi.org/10.15585/mmwr.mm7103a2*.

Table Group DD: Previously Finalized Quality Measures with Substantive Changes Finalized for Partial Removal as Component Measures in Traditional MIPS and Finalized for Retention for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

As noted under Table Group CC of this Appendix, beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we finalized to maintain measures Q112**:** Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128**:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan for MIPS Value Pathways (MVP) development, and maintain measures Q112 and Q113 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this final rule. These measures have finalized substantive changes under Table Group DD and Table Group E of this Appendix.

Note: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

The DD Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2024. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the DD table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the finalized substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Shared Savings Program ACOs reporting through the APP (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type collection type is not listed in any table under Table Group DD of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this final rule. For information regarding finalized changes to the CMS Web Interface measures for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

We solicited comments on these substantive changes.

DD.1 Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated measure description: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 40 – 74. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore will align with intent of the measure to exclude patients with this condition from the measure. Additionally, we proposed to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF.[79]
Comment: The commenter supported updating the eligible age criteria for screening for measure Q112: Breast Cancer Screening, as it aligns with NCCN guidelines that individuals with average risk of breast cancer should have annual mammography screening starting at age 40. *Response:* We thank the commenter for supporting the substantive changes to this measure. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53124), we are finalizing the changes to measure Q112 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note that under Table CC.1, we are finalizing the partial removal of measure Q112 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

79. USPSTF (2023). Task Force Issues Draft Recommendation Statement on Screening for Breast Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/breast-cancer-screening-draft-rec-bulletin.pdf.*

DD.2 Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore will align with intent of the measure to exclude patients with this condition from the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53124), we are finalizing the changes to measure Q113 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. Note that under Table CC.2, we are finalizing the partial removal of measure Q113 from traditional MIPS and retaining the measure for use in relevant MVPs as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

Table Group E: Previously Finalized CMS Web Interface Quality Measures with Substantive Changes Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

The E Tables within this final rule provide the substantive changes finalized for the CMS Web Interface quality measures in CY 2024. It should be noted that for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS).

The changes that are made to the code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within the final rule due to the availability of these changes to the public. The 2024 CMS Web Interface Measure Coding Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to stakeholders. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2024 CMS Web Interface Measure Coding Release Notes once posted to review all coding changes.

The 2024 eCQM collection type measures had substantive changes that could prove burdensome to collect, therefore, the CMS Web Interface specifications will align with the 2024 MIPS CQMs specifications changes for these measures.

The tables below contain finalized changes for performance year 2024 CMS Web Interface measure specifications to be used in the Shared Savings Program for quality reporting. Note: there are substantive changes for 9 of the 10 CMS Web Interface measures.

E.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE #	0059
Quality #:	001 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	DM-2
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53125), we are finalizing the substantive changes to measure Q001 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

E.2 Preventive Care and Screening: Influenza Immunization

Category	Description
CBE #	0041
Quality #:	110 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-7
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated denominator exclusion criteria: Added:** Anaphylaxis due to the vaccine on or before the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion by adding an exclusion for patients who experienced anaphylaxis due to the vaccine. While anaphylaxis due to the flu vaccine is rare, patients who have previously experienced a severe allergic reaction due to the influenza vaccine, regardless of the component suspected of being responsible for the reaction, should not receive additional doses of the vaccine (*https://www.cdc.gov/flu/prevent/egg-allergies.htm#:~:text=A%20person%20who%20has%20previously,get%20a%20flu%20vaccine%20again*).
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53126), we are finalizing the substantive changes to measure Q041 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. We have identified an error in the current measure description. We inadvertently indicated the measure applied to patients seen for a visit between October 31 and March 31. To resolve this error, we clarified that the timeframe is "during the measurement period" as there are no changes to the measure description. We have updated the language for the description as follows: **Current:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31who received an influenza immunization OR who reported previous receipt of an influenza immunization. **Revised to read:** Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.	

E.3 Breast Cancer Screening

Category	Description
CBE #	2372
Quality #:	112 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-5
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated measure description: Revised:** Patient age to 40 – 74. **Updated denominator: Revised:** Patient age to 41 – 74. **Updated initial population: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally, we proposed to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF for breast cancer screening.[80]
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53126), we are finalizing the substantive changes to measure Q112 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

80. USPSTF (2023). Task Force Issues Draft Recommendation Statement on Screening for Breast Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/breast-cancer-screening-draft-rec-bulletin.pdf.*

E.4 Colorectal Cancer Screening

Category	Description
CBE #	0034
Quality #:	113 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface:	PREV-6
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53127), we are finalizing the substantive changes to measure Q113 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. We have identified an error in the current measure description. We inadvertently indicated the measure applied to patients 50-75 years of age. To resolve this error, we clarified that the appropriate age range is 45-75 years of age, as there are no changes to the measure description. We have updated the language for the description as follows: **Current:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer. **Revised to read:** Percentage of adults 45 – 75 years of age who had appropriate screening for colorectal cancer.	

E.5 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE #	N/A
Quality #:	134 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-12
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Updated guidance: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder prior to the qualifying encounter used to evaluate the numerator. Patients who have ever been diagnosed with bipolar disorder will be excluded from the measure. **Updated denominator exclusion: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator criteria: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion and applicable measure guidance to remove a previous diagnosis of depression as an exclusion, as patients with a history of depression clinically may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We proposed to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53127), we are finalizing the substantive changes to measure Q134 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years. We have identified an error in the current measure description. The current measure description did not include language stating that follow-up plan may be documented on the date of or up to two dates after the date of the qualifying encounter. To resolve this error, we added clarifying language and note there are no substantive changes to the measure description. We have updated the language for the description as follows: **Current:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **Revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	

E.6 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE #	N/A
Quality #:	226 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-10
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 12 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months. **The initial population is revised to read:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure to lower the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Lowering the denominator eligible age aligns with proposed changes for all other collection types, which combine the patient population within measure Q402: Tobacco Use and Help with Quitting Among Adolescents with that of measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53128), we are finalizing the substantive changes to measure Q226 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

We have identified an error in the current measure description. We inadvertently included the measure description for PREV-12: Preventive Care and Screening: Screening for Depression and Follow-Up Plan. To resolve this error, we revised the description to reflect tobacco use screening, and to clarify that the tobacco cessation intervention may take place during the measurement period or in the 6 months prior to the measurement period. The only revision to the CY 2024 PREV-10 measure is to lower the denominator eligible age to 12 years and older.
Current: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.
Revised to read: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.

E.7 Controlling High Blood Pressure

Category	Description
CBE #	N/A
Quality #:	236 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	HTN-2
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18-85 years of age who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **Updated guidance: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated numerator note: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to revise the initial patient population to specify the patient visit must occur during the measurement period. This revision provides clarification of the encounter timing. Additionally, we proposed to update the denominator exclusion to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. We proposed to revise the measure guidance and the numerator note around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53129), we are finalizing the substantive changes to measure Q236 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

E.8 Depression Remission at Twelve Months

Category	Description
CBE #	0710
Quality #:	370 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	MH-1
Current Collection Type:	CMS Web Interface
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event.
Substantive Change:	**Updated denominator exclusion: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it is not a meaningful exclusion for the measure.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53130), we are finalizing the substantive changes to measure Q370 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

E.9 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE #	N/A
Quality #:	438 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-13
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated denominator guidance:** **Revised:** Denominator Population Guidance: The denominator population covers four distinct populations. There is only one performance rate calculated for this measure. Use the following process to prevent counting patients more than once. Denominator Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the measurement period. If YES, patient meets Denominator Population 1 risk category. If NO, screen for next risk category. Denominator Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. If YES, patient meets Denominator Population 2 risk category. If NO, screen for next risk category. Denominator Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with a diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period. If YES, patient meets Denominator Population 3 risk category. If NO, screen for next risk category. Denominator Population 4: Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. If YES, patient meets Denominator Population 4 risk category. If NO, patient does NOT meet denominator criteria and is NOT eligible for measure inclusion. **Added:** For Denominator Population Guidance for Encounter: To meet Denominator Population 4: There is no LDL-C result required. **Removed:** For Denominator Population Guidance for Encounter: Lifestyle modification coaching: A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time. **The initial population is revised to read:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes.

Category	Description
	Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent. **Updated denominator:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. **Added:** Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. **Updated numerator definition: Added:** 10 Year Risk Assessment - The 10-year ASCVD risk score is calculated using the Pooled Cohort Equations: 1) the 2013 ACC/AHA ASCVD Risk Estimator OR 2) the ACC Risk Estimator Plus. If your EHR does not have either of these risk calculators, we recommend that you use the on-line versions. The 10-year ASCVD risk assessment must be performed during the measurement period. **Updated submission guidance: Revised:** DENOMINATOR CONFIRMATION, POPULATION 2 o Determine if the patient is aged 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. o If the patient is 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL documented OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia select "Yes". **OR** o If the patient is not 20 to 75 years at the beginning of the measurement period OR has never had a laboratory result of LDL-C ≥ 190 mg/dL AND has never been previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia documented select "No – Diagnosis". **Added:** DENOMINATOR CONFIRMATION, POPULATION 4 o Determine if the patient is aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. o If the patient is aged 40-75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "Yes". **OR** o If the patient is not aged 40 to 75 years at the beginning of the measurement period or does not have a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "No – Risk Assessment". **OR** o If there is a denominator exclusion for patient disqualification from the measure select "Denominator Exclusion". **OR** o If there is an "other" CMS approved reason for patient disqualification from the measure select "No- Other CMS Approved Reason".
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revisions to this measure that will allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.[81] We proposed to update submission criteria 2 to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[82] Additionally we proposed to add submission criteria 4, which specifically assesses statin use for patients that have a 10-year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria will be considered high risk and based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[83] Furthermore, we proposed to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4.
We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (88 FR 53130 through 53132), we are finalizing the substantive changes to measure Q438 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

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College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596–e646. *https://doi.org/10.1161/CIR.0000000000000678*.

82. Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.
83. Arps, K., Blumenthal, R., & Martin, S. (2018, November 15). New Aspects of the Risk Assessment Guidelines, Scientific Evidence and Future Goals. *https://www.acc.org/latest-in-cardiology/articles/2018/11/14/07/10/new-aspects-of-the-risk-assessment-guidelines*.

APPENDIX 2: IMPROVEMENT ACTIVITIES

We refer readers to the CY 2024 Physician Fee Schedule (PFS) proposed rule (88 FR 52576 through 52578 and 88 FR 53132 through 53143), where we proposed for the CY 2024 performance period/2026 MIPS payment year and future years to add five new improvement activities, modify one previously adopted improvement activity, and remove three previously adopted improvement activities. We refer readers to 88 FR 52576 through 52577 of the CY 2024 PFS proposed rule for additional details on the Call for Improvement Activities process.

Table A: New Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_PM_22**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
Proposed Activity Description:	Establish policies and procedures to improve practice capacity to increase HIV prevention screening, improve HIV prevention education and awareness, and reduce disparities in pre-exposure prophylaxis (PrEP) uptake. Use one or more of the following activities: • Implement electronic health record (EHR) prompts or clinical decision support tools to increase appropriate HIV prevention screening; • Require that providers and designated clinical staff take part in at least one educational opportunity that includes components on the importance and application of HIV prevention screening and PrEP initiation in clinical practice; and/or • Assess and refine current policies for HIV prevention screening, including integrated sexually transmitted infection (STI)/HIV testing processes, universal HIV screening, and PrEP initiation.
Proposed Weighting:	Medium
Rationale:	The Centers for Disease Control and Prevention (CDC) estimates that nearly 1.2 million Americans are living with HIV and that nearly one in eight are not aware that they are infected.[10,11] Social determinants of health (SDOH) factors, including low socioeconomic status, living in poverty, lack of transportation to care services, low health literacy levels to complete medical forms, homelessness, and intimate partner violence can lead to limitations in seeking preventive measures, including accessing healthcare providers or HIV testing sites.[40] The CDC recommends that all individuals between the ages of 13 and 64 get tested for HIV at least once as part of routine healthcare.[13] Individuals at greater risk, including gay, bisexual, and other men who have sex with men (MSM), and persons who inject drugs, are recommended for more frequent, annual HIV screening.[12,13] The CDC also recommends that all sexually active adult and adolescent patients should receive information about HIV pre-exposure prophylaxis (PrEP), and recommends PrEP as an effective HIV prevention strategy.[14] Taking PrEP as prescribed reduces the risk of transmitting HIV through sexual contact by about 99 percent, and limits the risk of acquiring HIV by at least 74 percent among people who inject drugs.[14] Lack of HIV preventive care and referrals among vulnerable populations in the U.S. leads to inequities in access to HIV prevention treatment.[30,36] One study reported that fewer Black, Hispanic, or Latino people who tested negative for HIV and were eligible for PrEP received a referral for treatment as compared with other racial and ethnic groups.[36] Among both males and females, Black and Hispanic people have far lower PrEP uptake rates relative to their risk than do White males, a disparity that is starkest among Black males.[29] Despite MSM representing the highest proportion of Americans diagnosed with HIV, lack of awareness and understanding of PrEP has led to low rates of PrEP use

	among this group; in one study conducted among Black/African American and White PrEP-eligible MSM, 61 percent were aware of PrEP, but only 9 percent used it.[36] In another study conducted among Black/African American MSM, PrEP awareness was 39 percent, but actual use was less than 5 percent.[36] Barriers to PrEP uptake have contributed to low rates of use, with more than one-half of PrEP-eligible MSM being reported as failing to reach the contemplation stage (for example, willing and self-identified as appropriate candidates) of PrEP adoption.[34] Implementation of an electronic HIV screening alert almost doubled the rates of universal HIV screening in one study of primary care providers in a Midwestern practice and this implementation also reduced racial disparities in care.[38] Provider knowledge about PrEP was associated with both past and potential future initiation of PrEP, and an observed greater willingness to prescribe PrEP was associated with higher PrEP knowledge.[7] HIV diagnoses in MSM in New South Wales, Australia, declined from 295 (cases) in the 12 months before PrEP roll-out to 221 (cases) in the 12 months after roll-out. ; a decline both in recent HIV infections (from 149 cases to 102) and in other HIV-related diagnoses was also noted.[27] This HIV prevention-focused activity, including clinician education, will help to narrow gaps and inequities in care related to HIV prevention in clinical practice, and that it will highlight HIV prevention guidelines, including recommendations to enhance prevention screening and PrEP awareness and use. We proposed weighting this activity medium, because this activity may be accomplished by establishing or refining policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781).
Comments:	We received several comments in support of this proposed new improvement activity.
Response:	We appreciate commenters' support.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA__MVP**
Proposed Subcategory:	N/A
Proposed Activity Title:	Practice-Wide Quality Improvement in MIPS Value Pathways
Proposed Activity Description:	Create a quality improvement initiative within your practice and create a culture in which all staff actively participates. Clinicians must be participating in MIPS Value Pathways (MVPs) to attest to this activity. Create a quality improvement plan that involves a minimum of three of the measures within a specific MVP and that is characterized by the following: • Train all staff in quality improvement methods, particularly as related to other quality initiatives currently underway in the practice; • Promote transparency and accelerate improvement by sharing practice-level and panel-level quality of care and patient experience and utilization data with staff; • Integrate practice change/quality improvement into all staff duties, including communication and education regarding all current quality initiatives; • Designate regular team meetings to review data and plan improvement cycles with defined, iterative goals as appropriate; or • Promote transparency and engage patients and families by sharing practice-level quality of care and patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data. Optional activities related to this activity (but do not count towards completion of this IA) include the following: • Creation of specific plans for recognition of individual or groups of clinicians and staff when they meet certain practice-defined quality goals. Examples include recognition for

	achieving success in measure reporting and/or a high level of effort directed to quality improvement and practice standardization; and • Participation in the American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Proposed Weighting:	High
Rationale:	Clinical practice quality improvement (QI) activities are commonly limited to staff members directly involved in the performance of the specific activity. Creating a culture of QI among all staff working as a team drives outcomes more effectively than when the work is done in isolation. This collaborative approach allows for a more comprehensive view of QI goals and, in turn, the development of most efficient and effective initiatives. Additionally, the positive and unpredictable ideas that come from a high-functioning collaborative team can be crucial to achieving QI that is more meaningful to both patients and providers. Team-based quality improvement approaches have been found to be highly effective in healthcare.[18,32] Creating coordination between the goals of this activity and the goals of the measures within an MVP will create an intuitive focus within a specific clinical area, which will allow clinicians and other staff members to be most productive in their QI efforts. This coordinated clinical focus is likely to lessen the perceived burden of MVP while the effort required will still be sufficiently high. In addition, this activity will incentivize voluntary MVP adoption, which will drive clinician accountability and quality improvement on factors that are more relevant to their practice. For a discussion of the benefits of MVPs, please see the 2021 PFS final rule (85 FR 84844 through 84846). We proposed making this activity high-weighted because MIPS eligible clinicians will need considerable time and resources to implement practice-wide quality improvement via MVPs. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781). While this MVP-only activity could appear duplicative on the surface, this MVP activity specifically defines the nature of the QI project that clinicians must complete, and it is particular to the measures they are reporting on in the MVP they have chosen. We required that clinicians complete the project focused on three separate measures. In contrast, IA_PSPA_19 requires only a focused single improvement. This is consistent with the work that clinicians will need to complete to be successful with MVPs.
Comments:	We received several comments in support of this proposed new improvement activity. We received one comment that was not supportive of this activity; this commenter stated that since MVPs have the same quality improvement goals as traditional MIPS, an activity linking a formal quality improvement model to an MVP seems unnecessary and potentially confusing.
Response:	We thank the commenters for their support. We disagree that this MVP specific activity is unnecessary and potentially confusing, as conducting the quality improvement initiatives detailed in this MIPS improvement activity will serve to prepare clinicians and staff for adoption of MVPs, which aligns with the CMS goal to allow for a more cohesive participation experience by connecting measures and activities that are most relevant to a clinician's practice. This activity is specifically designed to encourage quality improvement initiatives within the construct and environment of an MVP and therefore is only applicable for clinicians reporting in the MVP program and not traditional MIPS. We will ensure that education with the public about this activity and its connection to MVP reporting will be clear.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_23**
Proposed Subcategory:	Population Management

Proposed Activity Title:	Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
Proposed Activity Description:	Incorporate the Cervical Cancer Screening and Management (CCSM) Clinical Decision Support (CDS) tool within the electronic health record (EHR) system to provide clinicians with ready access to and assisted interpretation of the most up-to-date clinical practice guidelines in CCSM to ensure adequate screening, timely follow-up, and optimal patient care. The CCSM CDS helps ensure that patient populations receive adequate screening and management, according to evidence-based recommendations in the United States Preventive Services Task Force (USPSTF) screening and American Society for Colposcopy and Cervical Pathology (ASCCP) management guidelines for cervical cancer. The CCSM CDS integrates into the clinical workflow a clinician-facing dashboard to support the clinician's awareness and adoption of and preventive care for cervical cancer, including screening and any necessary follow-up treatment. The CCSM CDS is fully conformant with the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, so it can be used with any Office of the National Coordinator for Health Information Technology (ONC) certified EHR platform. The CDS Hooks and SMART-on-FHIR interoperability interface standards provide two ways to integrate with the clinical workflow in a way that complements existing displays and information pre-visit, during visit, and for post-visit follow-up. CCSM CDS helps the clinician evaluate the patient's clinical data against existing guidance and displays patient-specific recommendations.
Proposed Weighting:	High
Rationale:	Cervical cancer is largely a disease of health inequity, with higher rates among lower socio-economic groups, immigrant populations, and women in rural settings.[22] Cervical cancer is highly preventable when precancerous lesions are detected early and appropriately managed.[53] However, the complexity of and frequent updates to existing evidence-based clinical guidelines make it challenging for clinicians to stay abreast of the latest recommendations.[53] In addition, limited availability of and accessibility to CDS make it difficult for groups who are medically underserved to receive screening and/or appropriate follow-up care. The CCSM CDS is one solution to help improve cervical cancer outcomes. The CCSM CDS provides clinical guidelines in a shareable, structured, and computer-interpretable format to facilitate meaningful improvements in the number of patients screened and treated for cervical precancer. This includes addressing current gaps in screening uptake and timely follow-up care among populations that are often medically underserved.[22] Analysis of data collected from 1,037 Federally Qualified Health Centers from 2016 to 2021 by the Health Resources and Services Administration (HRSA) Uniform Data System (UDS) found that only about 50 percent of women received recommended cervical cancer screening.[16] Additionally, National Quality Assurance Committee (NCQA) Healthcare Effectiveness and Data Information Set (HEDIS) measures of cervical cancer screening rates show that Medicaid HMOs have rates at least 10% lower than Commercial HMOs.[42] The CDC-developed CCSM CDS tool has been developed in a standards-based, EHR-agnostic way.[21,44] The CDS tools are designed to help clinicians more efficiently evaluate patient clinical data against CCSM guidance and display patient-specific recommendations. This reduces the manual workload of monitoring patients who need screening and potential follow-up. Evidence suggests that clinician adherence to the CCSM guidelines can assist clinicians in improving screening and management outcomes and address existing disparities in guideline concordant care.[46] This activity will leverage the convenience and efficiency of more sophisticated, standards-based decision support tooling to assist clinicians in applying complex data-driven guidelines.[21] This CCDS CDS can help provide optimal care and better engagement with diverse patient populations, including historically underserved populations.[22,53,16,42]

	We proposed weighting this activity high, because this activity will require integrating the CCSM CDS tool into clinicians'/practices' EHR dashboards, learning how to use it, and then using it. See the definition of high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	We received many comments in support of the proposed new improvement activity. We also received a comment suggesting that any CDS tool incorporated into a clinician's EHR system for this activity should first be found to be valid and reliable, as well as based upon the most current USPSTF recommendations for cervical cancer screening. We also received a comment suggesting that this activity not be focused on the CCSM CDS tool exclusively.
Response:	We appreciate commenters' support and feedback. The CCSM CDS tool has been validated and is based on both USPSTF and ASCCP guidance. The CCSM CDS tool is can assist clinicians in applying complex data-driven guidelines to provide patients with optimal care. We will consider commenters' suggestions going forward, including as guidelines are updated.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_14**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women
Proposed Activity Description:	Screen for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, and screen and refer to treatment and/or refer to appropriate social services, and document this in patient care plans.
Proposed Weighting:	High
Rationale:	As many as one in five women are affected by perinatal mood and anxiety disorders (PMADs) in their lifetimes [23,24]yet studies estimate that between 50-80 percent of women are not screened during the prenatal or postpartum periods.[6] This highlights barriers to receiving behavioral healthcare in the perinatal period, such as stigma in receiving mental health care, lack of awareness about the prevalence of PMADs, and limited access to affordable behavioral health services.[51] Though all women can experience PMADs, those that are particularly vulnerable include historically underserved racial and ethnic populations, those with lower socioeconomic status, and younger mothers.[51] Research has demonstrated a link between untreated PMADs and maternal SUD[3,33,39,43] While there are limited data estimating the prevalence of maternal SUD, opioid use among perinatal women quadrupled between 1998 and 2014, leading to an increase in infants born with Neonatal Abstinence Syndrome (NAS)[2,3]. Methamphetamine and marijuana use among pregnant and postpartum women has also increased.[1,62] The largest disparity in maternal SUD, particularly opioid use disorder, is seen among mothers living in rural areas[61] Increased costs associated with maternal SUD, particularly for infants born with NAS was estimated at approximately $93,400 per infant in 2012.[43] While the effects of untreated PMADs and maternal SUD can lead to increased severity of PMADs (including risk of maternal suicide), initiation or increased substance use behaviors, and pregnancy complications,[5,19] the implications extend beyond mothers. Infants and children can also be impacted by lower rates of mother/infant bonding, breastfeeding, safe sleep and other infant safety practices, and other activities impacting neurodevelopment.[8,51] Infants, children, and partners of mothers who experience PMADs are also more likely to experience a depressive disorder.[35,51] Furthermore, prevalence of maternal substance use disorders is associated with increased number of children entering the foster system and increased risk of substance use among these children.[51,54] Rates of screening for PMADs and maternal SUD greatly vary during pregnancy and postpartum.[6] The American College of Obstetricians and Gynecologists (ACOG)

	recommends that all perinatal women be screened for PMADs, and referred for services upon positive screen.[2] The American Academy of Pediatrics recommends that pediatricians routinely screen mothers of patients for postpartum depression at the one-, two-, four- and six-month well child visits.[17] The U.S. Preventive Services Task Force also recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions and has determined that doing so provides improved outcomes for those at increased risk.[4,7] There are several prominent guidelines for screening and treating substance use disorder in pregnant women, including the Substance Abuse and Mental Health Services Administration Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and their Infants.[45] The Biden-Harris Administration has also released the National Drug Control Strategy and Substance Use in Pregnancy: Improving Outcomes for Families plan that outlines key steps to "explore, identify barriers, and establish policy to help pregnant women with substance use disorder (SUD) obtain prenatal care and addiction treatment without fear of child removal."[56,57,58,59] Many of these guidelines describe the need for routine verbal screenings to reduce bias and discrimination in those who are screened using specimens.[25] We proposed making this activity high-weighted, because MIPS-eligible clinicians will need considerable time and resources to implement the requirements for this activity to train providers on appropriate screening practices, integrate screenings into clinical workflow, and establish a mechanism for referring, linking, and following up with patients upon positive screen. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	We received many comments in support of this proposed new improvement activity, many noting the importance of a focus on behavioral and mental health.
Response:	We appreciate commenters' support.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_15**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
Proposed Activity Description:	Complete age-appropriate screening for mental health and substance use in older adults, as well as screening and referral to treatment and/or referral to appropriate social services, and document this in patient care plans.
Proposed Weighting:	High
Rationale:	Social isolation in the elderly is associated with depression; anxiety; cognitive decline; physical disabilities; lower self-ratings of health; and premature mortality from all causes.[19,26,41,54] Nearly one-quarter (24 percent) of Americans aged 65 and older living in the community are considered to be socially isolated, and a sizable proportion of adults in the US report feeling lonely (35 percent of adults aged 45 and older and 43 percent of adults aged 60 and older).[34] Also, unhealthy alcohol use and use of other drugs has been increasing rapidly among older adults.[37,63] The Substance Abuse and Mental Health Services Administration (SAMHSA), the American Society of Addiction Medicine (ASAM), and the American Psychiatric Association (APA) all recommend routine screening for mental health and substance use issues in elders to identify ongoing concerns or patients at risk for future issues.[39] Many mental health screening tools available for the general adult population, such as the Patient Health Questionnaire (PHQ-9) depression screener and the Generalized Anxiety Disorder 7-item scale (GAD-7), are appropriate for older adults.[38] The APA recommends that "older individuals be referred to treatment settings that offer age-appropriate group therapy and non-confrontational individual therapy focusing on late-

	life issues of loss and sources of social support. Older adults also deserve to receive full consideration for the potential benefits of medication management for substance use disorders."[4] We proposed making this activity high-weighted, because MIPS eligible clinicians will need considerable time and resources to implement the requirements for this activity. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	We received many comments in support of this proposed new improvement activity, many noting the importance of a focus on behavioral and mental health.
Response:	We appreciate commenters' support.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.

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[13]Centers for Disease Control and Prevention (CDC). 2006. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. Retrieved from *https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.*

[14]Centers for Disease Control and Prevention (CDC). 2021. Preexposure Prophylaxis for the prevention of HIV Infection in the United States – 2021 update. Retrieved from *https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.*

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Table B: Changes to Previously Adopted Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we propose to modify one previously finalized improvement activity for the CY 2024 performance period/2026 MIPS payment year and future years.

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_16**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Decision Support and Standardized Treatment Protocols
Current Activity Description:	Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed to modify this activity's description, "Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs," and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. "Moving the needle" to make progress toward interoperability continues to be an essential Federal goal, as demonstrated by new rules that the Office of the National Coordinator for Health Information Technology (ONC) announced on April 11, 2023, that it will be proposing for Cures Act implementation.[1] The urgent importance of interoperability is noted on the HealthIT.gov website: "Interoperability helps clinicians deliver safe, effective, patient-centered care. It also provides new ways for individuals and caregivers to access electronic health information to manage and coordinate care. Advancing interoperability is now an essential part of most health care activities ranging from health equity to public health emergency response."[2]
Proposed Revised Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs.
Proposed Revised Activity Description:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs. Clinicians should focus on utilizing open-source, freely available, interoperable CDS in completing the requirements of this activity.
Comments:	We received comments in support of this modification. One commenter recommended against making this modification on the grounds that making the interest in interoperable CDS tools explicit would discourage other types of efforts being made to attest to this activity. This commenter stated that "limiting this activity to interoperable CDS tools would remove incentive for many practices to implement important standardized treatment protocols that improve patient experience and care [and] would reduce the practice's available options to report on this activity and, thus, inhibit the ability of this activity to promote the identification of ways the practice can improve patient safety and care above and beyond what is already in place.."
Response:	We appreciate commenters' support and feedback. We disagree that encouraging the use of interoperable CDS tools necessarily discourages other efforts that satisfy the requirements of this activity. Here, the language used in the new activity title and description make clear that the use of such tools is preferred but not required.
Final Action:	After consideration of the public comments, we are finalizing this activity as proposed.

[1]Fox, A. (2023, April 11). *ONC proposes new rules for Cures Act implementation, certifications and more. https://www.Healthcareitnews.com*. Retrieved April 11, 2023, from onc-proposes-new-rules-cures-act-implementation-certifications-and-more.

[2]Health IT (2022, September 9). Interoperability. h*ttps://www.Healthit.gov*. Retrieved May 2, 2023, from *https://www.healthit.gov/topic/interoperability.*

TABLE C: Improvement Activities Proposed for Removal for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we proposed to remove three previously finalized improvement activities from the CY 2024 performance period/2026 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_ BMH_6**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Implementation of co-location PCP and MH services
Current Activity Description:	Integration facilitation and promotion of the colocation of mental health and substance use disorder services in primary and/or non-primary clinical care settings.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor two, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice, and factor three, activity does not align with current clinical guidelines or practice. We have received interested-party feedback expressing concern that this activity is out-of-date, and that IA_BMH_6 substantially overlaps with IA_BMH_7 (Implementation of Integrated Patient Centered Behavioral Health Model). IA_BMH_7 better aligns with evidence supporting improved patient outcomes.[1] Furthermore, IA_BMH_6 focuses on co-location of mental health and substance use disorder services in primary and/or non-primary clinical care settings, which has not been found to consistently improve patient outcomes.[2] In the current rulemaking cycle, we proposed two new activities in the Behavioral and Mental Health subcategory. We noted that the removal of IA_BMH_6 was proposed to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular.
Comments:	We received comments in support of the proposed removal of this improvement activity. One commenter expressed their support for integrated behavioral health and primary care physicians in treating patients with mental and behavioral health conditions and suggested that we consider not removing this activity. However, the commenter provided no evidence-based rationale for its retention.
Response:	We appreciate commenters' support and feedback. We are removing this activity because the evidence indicates that this activity is no longer in accordance with best practices (*see* Wray 2018). We also note that another existing activity, IA_BMH_7, Implementation of Integrated Patient Centered Behavioral Health Model, includes elements related to this activity and is more robust.
Final Action:	After consideration of the public comments, we are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_13**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder
Current Activity Description:	Complete any required training and obtain or renew an approved waiver for provision of medication-assisted treatment of opioid use disorders using buprenorphine. Note: This activity may be selected once for low-capacity waivers, as these do not expire, and once every 3 years for the expanded waiver, in keeping with renewal requirements.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor three, activity does not align with current clinical guidelines or practice. In late December 2022, the end of the "X-waiver" was announced, so doctors/nurse practitioners no longer need to complete training and obtain a waiver from the Drug Enforcement Administration (DEA) to be able to prescribe buprenorphine (medication-assisted treatment; MAT). Section 1262 of

	the Consolidated Appropriations Act of 2023 (also referred to as the "Omnibus Bill") was passed in December 2022.[3] We noted that the removal of IA_BMH_13 is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular. This removal is necessary as the X-waiver is no longer a requirement of MAT prescribing.
Comments:	We received many comments in support of the removal of this improvement activity. We also note that this activity was suspended on 6/14/23 because use of the "X-waiver" has ended.
Response:	We appreciate commenters' support.
Final Action:	After consideration of the public comments, we are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_ PSPA_29**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging
Current Activity Description:	Clinicians attest that they are consulting specified applicable AUC through a qualified clinical decision support mechanism for all applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2018. This activity is for clinicians that are early adopters of the Medicare AUC program (2018 performance year) and for clinicians that begin the Medicare AUC program in future years as specified in our regulation at § 414.94. The AUC program is required under section 218 of the Protecting Access to Medicare Act of 2014. Qualified mechanisms will be able to provide a report to the ordering clinician that can be used to assess patterns of image-ordering and improve upon those patterns to ensure that patients are receiving the most appropriate imaging for their individual condition.
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor seven, improvement activity is "obsolete." We stated in the CY 2024 PFS proposed rule that "The AUC CDS program has ended, so it will no longer be possible to attest to this activity" (88 FR 53142 and 53143). That was not precisely correct. CMS proposed to pause the program for reevaluation at that time (88 FR 52512). The removal of IA_PSPA_29 was proposed in light of that proposal. We are pausing the AUC CDS program and rescinding the regulations, so this activity will be obsolete.
Comments:	We received comments in support of this removal. A few commenters suggested that we consider not removing this activity, citing benefits of AUC and similar advanced diagnostic imaging guidelines. One commenter stated that "consultation of AUC outside of [the AUC CDS] program can be valuable and several CDSMs are already in use by physicians and other health care professionals. It is also important to recognize that clinicians can consult AUC using mechanisms other than a CDSM. Accordingly, [we] recommend[]s that this [activity] provide flexibility for the consultation of physician-developed, evidence-based, and transparent AUC or advanced diagnostic imaging guidelines using a mechanism best suited for their practice, specialty, and workflow." Another commenter stated that the activity "provides CMS an avenue to meet the statutory requirements of the AUC program without adding extra burden to Medicare providers or CMS staff."
Response:	We appreciate commenters' support and feedback. We understand commenters' suggestion to retain this activity due to the benefits of using AUC CDS tools. However, as we are pausing the AUC CDS program and rescinding the regulations, the activity is obsolete. To continue an activity linked to a program that is not available will cause unnecessary confusion. Additionally, there are other activities available that provide credit for the use of CDS, including IA_PSPA_16.
Final Action:	After consideration of the public comments, we are finalizing this removal as proposed.

[1] Fortney, J. C., Unützer, J., Wrenn, G., Pyne, J. M., Smith, G. R., Schoenbaum, M., & Harbin, H. T. . (2017). Tipping point for measurement-based care. *Psychiatric Services*, *68*(2), 179-188. *https://doi.org/10.1176/appi.ps.201500439*.

[2] Possemato, K., Johnson, E. M., Beehler, G. P., Shepardson, R. L., King, P., Vair, C. L., Funderburk, J. S., Maisto, S. A., & Wray, L. O. (2018). Patient outcomes associated with primary care behavioral health services: A systematic review. *General Hospital Psychiatry*, *53*, 1-11. *https://doi.org/10.1016/j.genhosppsych.2018.04.002*
[3] SAMHSA.2022. Removal of DATA Waiver (X-Waiver) Requirement. Retrieved from *https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement*.

APPENDIX 3: MVP INVENTORY

MVP Development Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of MVP tables: Group A, which includes five new MVPs and Group B, which includes modifications to 12 previously finalized MVPs. We received comments on all Group A and Group B MVPs with the comment summaries and responses embedded in each MVP table.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, each MVP includes a foundational layer comprised of population health measures and Promoting Interoperability performance category measures.

MVP Development Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures considered in developing the MVPs are located in the 2023 MIPS Quality Measures List on the Quality Payment Program website.[578] In addition, see Appendix 1: MIPS Quality Measures of this final rule for any removals, additions, and modifications to the existing quality measures.
- Existing QCDR measures considered in developing the MVPs were based on the most recent publication of the 2023 QCDR Measure Specification file and is located on the Quality Payment Program website.[579] We plan to modify the list of 2024 QCDR measures around December 2023. We refer readers to the to the CY 2022 PFS final rule (86 FR 65405 through 65408) for additional details regarding QCDR measures and selection of measures within an MVP.
- Improvement activities considered in developing the MVPs are located in the 2023 Improvement Activities Inventory, and the 2023 MIPS Data Validation Criteria in the Quality Payment Program website.[580] In addition, see Appendix 2: Improvement Activities of this final rule for any removals, additions, or modifications to existing improvement activities.
- Existing cost measures considered in developing the MVPs are located in the 2023 Cost Measures Inventory.[581] In addition, see section IV.A.4.f.(2) of this final rule for proposals regarding the cost performance category.
- For further details on the population health measures (attributed to the Quality Performance Category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability performance category measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[582] In addition, see section IV.A.4.f.(4) of this final rule for proposals regarding the existing Promoting Interoperability performance category measures.

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[578] See the 2023 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2217/2023%20MIPS%20Quality%20Measures%20List.xlsx.

[579] See https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2174/2023_QCDR_Measure_Specifications.xlsx for QCDR measures.

[580] See the 2023 Improvement Activities Inventory: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2237/2023%20Improvement%20Activities%20Inventory.zip and 2023 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2313/2023%20MIPS%20Data%20Validation%20Criteria.zip for improvement activity details.

[581] See the 2023 Cost Measures Inventory: https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2023.

[582] See the 2023 Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2223/2023%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip for Promoting Interoperability measure details.

MVP Development: Global Inclusion of a Quality Measure and an Improvement Activity

● Consistent with the priority to advance health equity throughout various CMS programs, including the Quality Payment Program, we proposed to include Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. Health equity supports health for all the people served by our programs by designing, implementing, and operationalizing policies and programs that eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved while providing the care and support beneficiaries need to thrive (*https://www.cms.gov/pillar/health-equity*). The measure supports the process of collecting drivers of health (DOH) data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who choose to submit this measure though it is not required. For further details regarding the basis on which CMS determined Q487: Screening for Social Drivers of Health is appropriate to measure clinician performance as well as how it does so, see 87 FR 69872 through 69784. We received several comments in support of this proposal, and we are finalizing our proposal to include Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs as proposed.

● We proposed the addition of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways, a high weighted activity, to each of the new and previously finalized MVPs. This activity will expand the opportunity for quality improvement (QI) activities across and among practices, ultimately leading to improvements in quality of care and fostering a culture of participation by all staff. In addition, this activity incentivizes voluntary MVP adoption, which is important to the transformation of clinical practice by encouraging participation in payment options such as MVPs and APMs that measure performance in ways more relevant to practice members. We received a couple of comments in support of this proposal, and we are finalizing our proposal to include IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways in both new and previously finalized MVPs as proposed. See Appendix 2: Improvement Activities: Table A of this final rule for detailed information regarding the IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways activity.

MVP Table Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in the Group A and Group B tables below:

● New quality measures, improvement activities, and cost measures finalized for inclusion in MIPS beginning with the CY 2024 performance period/2026 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1: MIPS Quality Measures: Table Group A of this final rule for further information regarding new MIPS measures. See Appendix 2: Improvement Activities: Table A of this final rule for further information regarding new improvement activities. See section IV.A.4.f.(2) of this final rule for further information regarding new cost measures.

● Quality measures, improvement activities, and cost measures that we are finalizing to add to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

● Existing quality measures and improvement activities with finalized revisions are identified with an asterisk (*).

● Quality measures identified with a double asterisk (**) are individual measures duplicating a component of the Q497: Preventive Care and Wellness (composite) measure. The quality measures that include the (**) can only be submitted when included in an MVP. Please see Appendix 1: MIPS Quality Measures Table A.6 of this final rule for any additional information regarding the Preventive Care and Wellness (composite) measure.

● Quality measures that are considered high priority (as defined in § 414.1305) are illustrated with an exclamation point (!) and outcome measures (as defined in § 414.1305) are illustrated with a double exclamation point (!!). Further details of these types of measures are located in the CMS Measures Management System Hub.[583]

● To determine whether a QCDR measure may be finalized within an MVP, we requested QCDR measure testing data for review by the end of the self-nomination period (that is, no later than September 1 of the year prior to the applicable performance period). If a QCDR was unable to submit testing data that demonstrated their QCDR measure was fully tested by the end of the self-nomination period or otherwise did not meet our requirements, we were unable to finalize the inclusion of the QCDR measure within an MVP. In this final rule, we are finalizing the QCDR measures within the relevant MVPs where evidence of testing data at the clinician level was received and fully tested. We refer readers to CY 2022 PFS final rule for additional details regarding requirements for QCDR measures within the MVP (86 FR 65407 through 65408).

● Improvement activities that include a health equity component are illustrated with a tilde (~) within the MVP table.

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[583] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.

● IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is illustrated with a percent (%) to indicate that attestation to this improvement activity provides full credit for the improvement activity performance category within an MVP.

In addition, quality measure collection types are identified in parentheses after each quality measure title within each MVP table and improvement activity medium/high weight designations are identified in parentheses after each improvement activity.

Group A: New MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

Focusing on Women's Health MVP

In the CY 2024 PFS proposed rule (88 FR 53148 through 53150), we proposed and solicited comments on the Focusing on Women's Health MVP. The proposed Focusing on Women's Health MVP focuses on the clinical theme of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practice of gynecology, obstetrics, and urogynecology, including nonphysician practitioners (NPPs) such as certified nurse-midwives, nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are embedded within Table A.1.

Quality Measures

We proposed to include 18 MIPS quality measures and one QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of women's health by assessing three critical areas of care: obstetrics, preventive women's health, and urogynecology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in women's health:

- Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures annual assessment for the presence or absence of urinary incontinence for women.
- Q112: Breast Cancer Screening: This MIPS quality measure ensures women have a mammogram to screen for breast cancer in accordance with clinical guidelines.
- Q309: Cervical Cancer Screening: This MIPS quality measure assesses for the performance of cervical cancer screening in women in accordance with clinical guidelines.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q335: Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse): This inverse MIPS quality measure identifies patients who have delivered a live singleton at < 39 weeks of gestation and assesses for elective deliveries (without medical indication) by cesarean birth or induction of labor.
- Q336: Maternity Care: Postpartum Follow-up and Care Coordination: This MIPS quality measure ensures the following postpartum care is completed: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and assurance immunization are reviewed and updated.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
- Q422: Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury: This MIPS quality measure evaluates patients that undergo cystoscopy at the time of hysterectomy for pelvic organ prolapse to evaluate for lower urinary tract injury.
- Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair: This MIPS quality measure evaluates for injury, during or within 30 days, to the bladder after surgery for patients that undergoing pelvic organ prolapse repair.
- Q448: Appropriate Workup Prior to Endometrial Ablation: This MIPS quality measure ensures endometrial sampling or hysteroscopy with biopsy with results documented prior to an endometrial ablation.
- Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Facto Profile for Osteoporotic Fracture: This MIPS quality measure ensures women receive an order for a dual-energy x-ray absorptiometry (DXA) scan if they exhibit select risk factors for osteoporotic fracture.
- Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.

- Q496: Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument: This proposed MIPS quality measure evaluates pregnant or postpartum patients for a completed cardiovascular disease (CVD) risk assessment utilizing a standard instrument.
- UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved: This MIPS quality measure ensures patients diagnosed with osteopenia or osteoporosis achieve a serum 25 Hydroxy-Vitamin D result greater than or equal to 30.0 ng/dL.

In addition, we proposed to include the following broadly applicable MIPS quality measures that are relevant to clinicians who specialize in women's health. The quality measures below assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients, aged 18 years and older, for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. If the patient is screened positive for unhealthy alcohol use, then they should receive brief counseling.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 14 improvement activities that reflect actions and processes undertaken by clinicians who specialize in women's health, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients being seen for women's health care. We proposed the following improvement activities for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BMH_11: Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- IA_BMH_14: Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PM_23: Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

Cost Measures

We proposed to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of women's health. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this

MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in women's health and align with other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure assesses the costs of services provided to a patient for the period immediately prior to, during, and following the patient's hospital stay, with exceptions for services identified as unlikely to be influenced by the clinician's care decisions. It applies to clinicians providing care in inpatient hospitals, including those providing obstetric and gynecological care.
- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Obstetricians and gynecologists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures available, but one could be considered for development in the future.

TABLE A.1: Focusing on Women's Health MVP

Table A.1 serves to represent the measures and activities that are finalized within the Focusing on Women's Health MVP.

Symbol Key:
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with revisions
Double asterisk (**): quality measures that can be submitted only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(*)(**) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(!!) Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q336:** Maternity Care: Postpartum Follow-up and Care Coordination	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice (Medium) **(^) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQMs Specifications) **Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications) **(*)(!) Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **(!!) Q432:** Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQMs Specifications) **(*)(!) Q448:** Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQMs Specifications) **(!) Q472:** Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture (Collection Type: eCQM Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^) Q496:** Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQMs Specifications) **(!!) UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	(High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **(^) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)	

	Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: A few commenters expressed support for the following quality measures and improvement activities included in this MVP: Q112: Breast Cancer Screening, Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling, Q475: HIV Screening, Q487: Screening for Social Drivers of Health, Q493: Adult Immunization Status,IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, and IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. Several commenters support the inclusion of this MVP in the MIPS program.

Response: We thank the commenters for their support.

Comment: Commenters recommended additional quality measures be considered for this MVP. Recommendations included adding measures to address fracture-related care such as Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older and Q418: Osteoporosis Management in Women Who Had a Fracture. One commenter recommended that measures such as Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries be included to ensure they are carried forward as traditional MIPS is sunset. A couple commenters recommended Q498: Connection to Community Service Provider be included and one commenter recommended the inclusion of IA_PM_22: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services to this MVP.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended expanding this MVP to include pelvic health that applies to all patients.

Response: We may consider the inclusion of pelvic health measures that meet the inclusion criteria and address a measurement gap through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Currently, the clinical focus of this MVP is women's health.

Comment: One commenter stated the statement regarding the rationale for the inclusion of Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture is inaccurate. The commenter noted the measure is designed to assess whether a patient under 65 receiving a dual energy x-ray absorptiometry (DXA) scan has documented risk factors. It cannot, therefore, ensure that those with risk factors receive appropriate testing. The commenter stated the effect of this measure is more likely to discourage DXA use since providers face a documentation burden for each DXA provided to a woman under age 65.

Response: We agree with the commenters understanding of the measure intent and note that the above statement could have been made clearer by stating "…women, aged 50 – 64**,** receive an order for a dual-energy x-ray absorptiometry DXA scan **only** if they exhibit select risk factors for osteoporotic fracture." The goal of this measure is to discourage utilization of DXA scanning unless medically indicated for the denominator eligible patient population. This measure is only available for the eCQM collection type and as such would be associated with minimal clinician burden.

Comment: One commenter expressed concern that measure UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved promotes a standard of care that does not align with current scientific understanding of Vitamin D and its use in treating osteoporosis. The commenter stated clinical guidelines recommend that clinicians select treatments for high-risk patients based on the specific patient's future fracture risk and other patient specific factors. In addition, the commenter noted the measure applies only to clinicians treating osteoporosis in women and will almost certainly delay, precluding patient access to FDA-approved treatments appropriate and necessary to reduce future fracture risk. Furthermore, the commenter believes clinicians treating men for osteoporosis would, assumedly, base their treatment decisions on the standard of care within clinical guidelines.

Response: The denominator for measure UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved applies to patients aged 65 years and older as of the date of service with an established diagnosis of low bone mass/osteopenia or osteoporosis and an eligible encounter during the performance period. Currently this measure is not limited to women and specifically addresses patients with an established diagnosis; however, this would not preclude clinicians from treating the at-risk patient population accordingly. The National and International Osteoporosis Foundation as well as the Endocrine Society and American Geriatric Society consider a 25-hydroxyvitamin (25 OH D) level of less than 30 ng/mL as vitamin D deficient. The Endocrine Society indicates patients with bone diseases, such as osteoporosis, that may either be improved with vitamin D treatment or who are receiving a treatment where correction of vitamin D deficiency, would be appropriate for receiving this test as it can

inform upon vitamin D treatment recommendations.[584] The measure also allows for denominator exceptions including for those patients responding well to treatment and no longer require assessment. This measure does not assess for or dictate treatment, rather it only assesses for an adequate vitamin D level for performance as outlined within the measure. As such, we maintain this measure aligns with the best practices regarding assessment of vitamin D levels.

Comment: A few commenters recommended postponing the adoption of this MVP because they noted it does not appropriately distinguish between the maternity care population and the gynecologic population and the measures are not limited, connected, or complementary as emphasized by the current MVP Guiding Principles. One commenter noted it would be logical to have a women's health MVP that is focused on screenings and assessments for gynecologic and the general health needs of women and those seeking gynecologic care entirely separate from services for pregnant persons. Additionally, the commenter believes an MVP for general health and a separate MVP for the pregnancy episode of care better aligns with alternative payment model (APM) development.

Response: The MVPs are intentionally broad to allow for broad reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting, as this would create an unattainable MVP inventory state, these nuances would be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would submit this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing women's health and allows for clinician choice in choosing quality measures that best represent their scope of care.

Comment: One commenter recommended development of new measures that focus on women's health issues for this MVP. The commenter believes that adding measures to the MVP that more clinicians can report would incentivize interdisciplinary referrals and coordination enabling more clinicians to engage in the MVP indirectly if direct engagement is not possible.

Response: We encourage the commenter to reach out to measure developers/stewards to develop additional measures ensuring all important aspects of care are being assessed for submission to the Call for Measures for possible future implementation.

Comment: One commenter is opposed to the TPCC cost measure being included in this MVP. The commenter believes that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We maintain the TPCC measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Focusing on Women's Health MVP* as proposed in Table A.1 for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

In the CY 2024 PFS proposed rule (88 FR 53151 through 53154), we proposed and solicited comments on Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. The proposed Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on the clinical theme of providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL) and otitis media. This MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are embedded within Table A.2.

Quality Measures

We proposed to include eight MIPS quality measures and four QCDR measures within the quality performance category of this MVP, which promote the management and care associated with otolaryngology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with otolaryngology conditions:

- Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis: This MIPS quality measure ensures adults diagnosed with obstructive sleep apnea have an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.

[584] https://www.endocrinology.org/media/3593/nos_vitamin_d_and_bone_-health_in_adults_web.pdf.

- Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse): This overuse MIPS quality measure assesses for prescribed antibiotics within 10 days after the onset of symptoms for those patients diagnosed with acute viral sinusitis.
- Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): This appropriate use MIPS quality measure ensures patients diagnosed with acute bacterial sinusitis are prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
- Q355: Unplanned Reoperation within the 30 Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- AAO16: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures patients aged 60 years and older who have failed a hearing screening and/or who report suspected hearing loss receive, are ordered, or referred for comprehensive audiometric evaluation.
- AAO20: Tympanostomy Tubes: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) receive tympanostomy tube insertion and a comprehensive audiometric evaluation within 6 months prior to tympanostomy tube insertion.
- AAO21: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) including chronic serous, mucoid, or nonsuppurative OME of > or = 3 months duration receive an order or referral for comprehensive audiometric evaluation.
- AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines: This MIPS quality measure ensures patients 2 years and older with a diagnosis of allergic rhinitis are prescribed or recommended intranasal corticosteroids (INS) or non-sedating oral antihistamines.

In addition, we proposed to include the following broadly applicable MIPS quality measures that are relevant to otolaryngology. The quality measures below assess for age specific screenings, and follow-up actions for select measures:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in treating patients with otolaryngology conditions, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care patients with otolaryngology conditions. We proposed the following improvement activities for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_16: Implementation of medication management practice improvements

- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of otolaryngology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in otolaryngology care and aligns with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including otolaryngologic care. This aligns with the surgical measures within this MVP, including Q355: Unplanned Reoperation within the 30 Day Postoperative Period and Q357: Surgical Site Infection (SSI).

Currently, there are no applicable episode-based cost measures available, but one could be considered for development in the future.

TABLE A.2: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

Table A.2 serves to represent the measures and activities that are finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP.

Symbol Key:
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with revisions
Double asterisk (**): quality measures that can be submitted only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(**) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQMs Specifications) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQMs Specifications) **(!!) Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQMs Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (Medium) **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(*)(!) Q487: Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!) AAO16:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR) **AAO23:** Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines (Collection Type: QCDR)	(High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in this MVP. Another commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. A few commenters supported the inclusion of this MVP in the MIPS program.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider to this MVP.

Response: We may consider the inclusion of Q498: Connection to Community Service Provider through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters recommended CMS remove audiologists from this MVP, noting the majority of measures are outside the scope of practice of audiology. The commenters stated measures tied to referring patients for comprehensive audiologic evaluation are in scope for referring physicians, not audiologists themselves. The commenters stated that the only measures audiologists can currently report include Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and Q487: Screening for Social Drivers of Health.

In addition, the commenters believe the MSPB Clinician cost measure aligns with the surgical quality measures within this MVP, which are also outside the scope of the practice of audiology.

Response: We note that while this MVP may not be applicable to all audiologists, there are sufficient quality and QCDR measures contained within this MVP that allow these clinicians to report the MVP and align with historical submission patterns. Our goal is to make it easier for clinicians to identify MVPs to report by distinguishing specialties for which each MVP may be appropriate, though specialties are not required to follow these recommendation. We acknowledge audiologists would need to submit via a QCDR in order to report, and as this is not an ideal dynamic, we will continue to work with interested parties to propose future revisions. However, as reporting of MVPs remains voluntary, we continue to ensure specialties are aware of potential MVP options so they may make decisions based upon appropriateness and applicability of reporting based upon their own situation. Regarding measure Q261: Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness, we received public comment during CY 2023 QPP rulemaking indicating this was an important audiology-specific measure and is preferably submitted by a physician specifically trained in disorders of the ear. In addition, it is appropriate to include the MSPB Clinician cost measure in this MVP, as it is applicable clinicians who treat patients within the practice of otolaryngology, specifically otolaryngologists who practice in an inpatient setting and provide care such as performing head and neck procedures. At this time, no additional cost measures applicable to audiologists are available for use in MVPs. If a clinician cannot be scored on the MSPB Clinician cost measure, the cost performance category will be reweighted in alignment with existing MIPS scoring policies under 42 CFR 414.1380(b)(2)(v), where the clinician will not be penalized if there is not a cost measure applicable to their practice. Should applicable measure become available for use in MVPs, we will consider the addition of quality and cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Additionally, we encourage the commenters to reach out to measure developers/stewards to develop new outcome/high priority quality measures and cost measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, we are finalizing the *Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP* as proposed in Table A.2 for the CY 2024 performance period/2026 MIPS payment year and future years.

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

In the CY 2024 PFS proposed rule (88 FR 53155 through 53158), we proposed and solicited comments on Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. The proposed Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on the clinical theme of promoting quality care for patients suffering from infectious disorders. This MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are embedded within Table A.3.

Quality Measures

We proposed to include 14 MIPS quality measures within the quality performance category of this MVP, which focus on a variety of infectious disease conditions that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in the prevention and treatment of infectious disorders within their patient population:

- Q205: Sexually Transmitted Infection (STI) Testing for People with HIV: This MIPS quality measure ensures patients aged 13 years and older with a diagnosis of HIV/AIDS are screened for chlamydia, gonorrhea, and syphilis at least once during the performance period. Please reference Appendix 1: MIPS Quality Measures: Table D.21 for further information.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q338: HIV Viral Suppression: This MIPS quality measure ensures all patients with a diagnosis of HIV annually achieve a HIV viral load less than 200 copies/mL at last HIV viral load test.
- Q340: HIV Medical Visit Frequency: This MIPS quality measure ensures all patients with a diagnosis of HIV had at least one medical visit in each 6 month period within a 24 month measurement period.
- Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: This MIPS quality measure ensures all patients that are identified as active injection drug users receive screening for HCV each year.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
- Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: This MIPS quality measure ensures adult patients with a diagnosis of chronic hepatitis C cirrhosis receive imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once each year.
- Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.

In addition, we proposed to include the following broadly applicable MIPS quality measures that are relevant to infectious disorders. The quality measures below encourage antimicrobial stewardship, medication reconciliation, appropriate immunization receipt and preventive screenings:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q240: Childhood Immunization Status: This MIPS quality measure ensures children 2 years of age receive four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.

- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 14 improvement activities that reflect actions and processes undertaken by clinicians who provide prevention and treatment for infectious disorders to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing infectious disorder care. We proposed the following improvement activities for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_22: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- IA_PSPA_23: Completion of CDC Training on Antibiotic Stewardship
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of infectious disorders. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in treating infectious disorders and aligns with the other measures and activities within this MVP:

- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Infectious Disease specialists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures applicable to the clinical topics assessed within other components of this MVP, but one could be considered for development in the future.

TABLE A.3: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

Table A.3 serves to represent the measures and activities that are finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP.

Symbol Key:
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with revisions
Single exclamation point (!): quality measures that are considered high priority

Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: MIPS CQMs Specifications, eCQM Specifications) **(*) Q240:** Childhood Immunization Status (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(*)(!!) Q338:** HIV Viral Suppression (Collection Type: MIPS CQMs Specifications, eCQM Specifications) **(!) Q340:** HIV Medical Visit Frequency (Collection Type: MIPS CQMs Specifications) **Q387:** Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQMs Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQMs Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities (Medium) **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **(^) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship (High) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-	Security Risk Analysis	

Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: Various commenters supported the inclusion of the following quality measures and improvement activities: Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis, Q338: HIV Viral Load Suppression (VLS), Q340: HIV Medical Visit Frequency, and Q487: Screening for Social Drivers of Health, IA_PM_22: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services, and IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. Several commenters supported the inclusion of this MVP in the MIPS program.

Response: We thank the commenters for their support.

Comment: One commenter requested adding the following quality measures and improvement activities they believe are relevant to the patient population receiving care from infectious disease clinicians in small group practices: Q047: Advance Care Plan, Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, IA_CC_10: Care transition documentation practice improvements, IA_BE_14: Engage Patients and Families to Guide Improvement in the System of Care, and IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan. One commenter recommended the adoption of the eCQM measures CMS 341: HIV Viral Suppression and CMS 1188: Sexually Transmitted Testing for People with HIV so that alternatives to registry reported measures are readily available in this MVP where possible. Another commenter recommended the addition of quality measure Q498: Connection to Community Service Provider.

Response: We maintain the current scope of measures and improvement activities proposed in this MVP are appropriate for the clinical intent of this MVP. We also note all the collection types available for each quality measure are available for use within the MVP, including the eCQM measures mentioned above. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that all collection types for each MIPS quality measure finalized through rulemaking will be available for use within the MVP.

Comment: One commenter stated this MVP is extremely specific for two infectious diseases, but infectious disease specialists treat more than just those two diseases. They believe it would be difficult for them to identify providers that fit this specific MVP.

Response: This MVP focuses on the clinical theme of promoting quality care for patients suffering from infectious disorders and includes measures within the current inventory that assess for quality actions that can impact health for this patient population. While this MVP may not be applicable to all infectious disease specialists, the MVP allows for clinician choice in choosing quality measures that best represent their scope of care. Understanding infectious disease specialists treat a variety of conditions, it would not be expected that all patients under the clinician's care would be represented by a measure, rather that the clinician could choose those measures that best represent their scope of care and case mix. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that all collection types for each MIPS quality measure finalized through rulemaking will be available for use within the MVP.

Comment: One commenter opposed the TPCC cost measure being included in this MVP. The commenter noted that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also

expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We maintain the TPCC measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. We also clarify that the TPCC measure undergoes annual maintenance, where CMS and the measure developer determine whether to make updates to the measure specifications based on new, revised, or deleted CPT codes. The Measure Codes Lists that detail the specific codes used to construct the measures are also updated annually and made publicly available. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP* as proposed in Table A.3 for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Care in Mental Health and Substance Use Disorders MVP

In the CY 2024 PFS proposed rule (88 FR 53159 through 53162), we proposed and solicited comments on Quality Care in Mental Health and Substance Use Disorders MVP. The proposed Quality Care in Mental Health and Substance Use Disorders MVP focuses on the clinical theme of promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are embedded within Table A.4.

Quality Measures

We proposed to include 12 MIPS quality measures and three QCDR measures within the quality performance category of this MVP, which focus on a variety of behavioral health, including mental health and SUDs that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures within this MVP would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with behavioral health, including mental health and SUDs:

- Q009: Anti-Depressant Medication Management: This MIPS quality measure ensures adult patients diagnosed with major depression treated with antidepressant medication remained on an antidepressant medication treatment. There are two performance rates for this measure that evaluate compliance for at least 84 days or 180 days.
- Q305: Initiation and Engagement of Substance Use Disorder Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new SUD episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q366: Follow-Up Care for Children Prescribed ADHD Medication (ADD): This MIPS quality measure ensures children 6-12 years of age with a newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) receive appropriate follow-up care.
- Q370: Depression Remission at Twelve Months: This MIPS quality measure assesses adolescent and adult patients diagnosed with major depression or dysthymia for achieved remission in 12 months (+/- 60 days).
- Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: This MIPS quality measure ensures pediatric patients with a diagnosis of major depressive disorder (MDD) receive an assessment for suicide risk.
- Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia: This MIPS quality measure assesses an adult patient diagnosed with schizophrenia or schizoaffective disorder prescribed an antipsychotic medication had a Proportion of Days Covered (PDC) of at least 0.8 for their antipsychotic medications.
- Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD): This MIPS quality measure assesses for the continuous treatment (180 days) of pharmacotherapy treatment for adult patients diagnosed with opioid use disorder.
- Q502: Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder for maintenance or improvement in functioning at 30 to 180 days after index assessment.
- Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
- Q505: Reduction in Suicidal Ideation or Behavior Symptoms: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder with suicidal thoughts, behaviors, or risk symptoms for a reduction in suicidal ideation and/or behavior symptoms within 120 days of index assessment of the Columbia-Suicide Severity Rating Scale (C-SSRS).
- MBHR2: Anxiety Response at 6-months: This MIPS quality measure ensures adult patients with an anxiety disorder demonstrate a response to treatment at 6-months (+/- 60 days).

- MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children: This MIPS quality measure ensures patients with a history of a traumatic event and report symptoms consistent with PTSD for at least one month following the traumatic event have a symptom improvement based on a standardized symptom monitor in response to treatment in at least six months.
- MBHR15: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment: This MIPS quality measure ensures patients are referred for evaluation due to concerns for cognitive changes or difficulties receive a standardized valid assessment of cognition with results documented, including documentation of provider's consideration of relevant cultural-linguistic and demographic factors that may have affected assessment and resulting assessment.

In addition, we proposed include the following broadly applicable MIPS quality measures that are relevant to behavioral health, including mental health and SUDs. The quality measures below address preventive screenings, which support the capture of the patient's voice and safety for patients who are experiencing behavioral health, including mental health and SUD disorders:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for patients who screen positive.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 18 improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. We proposed the following improvement activities for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_12: Use evidence-based decision aids to support shared decision-making.
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_23: Integration of patient coaching practices between visits
- IA_BMH_2: Tobacco use
- IA_BMH_5: MDD prevention and treatment interventions
- IA_BMH_7: Implementation of Integrated Patient Centered Behavioral Health Model
- IA_BMH_14: Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women
- IA_BMH_15: Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We proposed to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic behavioral health, including mental health and SUDs. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in mental health and SUDs and align with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including hospitalizations for mental health conditions and SUDs.
- Depression: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this final rule. This is a new measure that will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.
- Psychoses and Related Conditions: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who receive inpatient treatment for psychoses or related conditions during the performance period. This acute inpatient medical condition measure includes costs of services that are clinically related to the attributed clinician's role in managing care during each episode, from the clinical event that opens, or "triggers," the episode through 45 days after the trigger. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this final rule. This measure is a new measure that will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.

TABLE A.4: Quality Care in Mental Health and Substance Use Disorders MVP

Table A.4 serves to represent the measures and activities that are finalized within the Quality Care in Mental Health and Substance Use Disorders MVP.

Symbol Key:
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with revisions
Double asterisk (**): quality measures that can be submitted only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
Q009: Anti-Depressant Medication Management (Collection Type: eCQM Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High)	**(^) Depression**
(!) Q305: Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications)	**(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium)	**(^) Psychoses and Related Conditions**
(*) Q366: Follow-Up Care for Children Prescribed ADHD Medication (ADD) (Collection Type: eCQM Specifications)	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium)	
(*)(!!) Q370: Depression Remission at Twelve Months (Collection Type: eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High)	
(*)(!) Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications)	**IA_BE_12:** Use evidence-based decision aids to support shared decision-making. (Medium)	
(*)(!!) Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQMs Specifications)		

(!) Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQMs Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(^)(!!) Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQMs Specifications) **(^) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications) **(^)(!!) Q505:** Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQMs Specifications) **(!!) MBHR2:** Anxiety Response at 6-months (Collection Type: QCDR) **(!!) MBHR7:** Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	**IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_23:** Integration of patient coaching practices between visits (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_5:** MDD prevention and treatment interventions (Medium) **(~) IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model (High) **(^) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women (High) **(^) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR**	

	Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: Various commenters supported the inclusion of the following quality measures and improvement activities: Q487: Screening for Social Drivers of Health, IA_AHE_3: Promote Use of Patient-Reported Outcome Tools, IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, and IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. Another commenter expressed appreciation for inclusion of quality measures, cost measures, and improvement activities applicable to the schizophrenia population. Several commenters supported the inclusion of this MVP in the MIPS program.

Response: We thank the commenters for their support.

Comment: Several commenters noted this MVP includes a wide range of measures and improvement activities, which is helpful in that it gives clinicians the opportunity to select the measures most appropriate for their practices, but it doesn't constitute an approach that is meaningfully different from the traditional MIPS program. In addition, the commenters noted the selection of measures in the MIPS program remains limited and inadequate to cover the major areas of practice for psychologists that are required reporters. The commenters noted this MVP would likely be feasible for only mental/behavioral health providers in certain settings, such as long-term care, or for certain subspecialty providers, such as neuropsychologists. In addition, the commenters believe MVPs like Quality Care in Mental Health and Substance Use Disorders are unlikely to be workable for psychologists in generalist practices who see between 30 – 40 patients per week, presenting with a variety diagnoses (for example, depression, anxiety, PTSD, psychosis, etc.), and include patients across the lifespan. The commenters don't agree one core measure set, or MVP, would be able to account for the level of heterogeneity of patients whom a generalist psychologist provides treatment, and having to implement multiple different MVPs would increase the burden that eligible clinicians currently experience with traditional MIPS. The commenters noted this would result in the development of separate MVPs for more focused settings/specialties like long-term care or neuropsychology, as opposed to the generalist model represented in the Quality Care in Mental Health and Substance Use Disorders MVP.

Response: This MVP has a broad clinical focus and captures performance driving positive clinical outcomes by providing fundamental treatment and management of mental health and substance use disorder. While we understand this MVP may not be applicable to all mental/behavioral health and psychiatry clinicians and NPPs, the goal of this MVP is to focus on different aspects of care that are important for patients with mental health and/or substance use disorders. Therefore, it includes measures focused on treatment and outcomes for conditions such as depression, substance use disorder, anxiety, and PTSD, which are appropriate for those clinicians specializing in mental/behavioral health. As we work through the transition from traditional MIPS to MVPs, we anticipate MIPS eligible clinicians/groups will continue to utilize traditional MIPS in the absence of an appropriate and applicable MVP; however, by utilizing reporting trends and focusing on more specialty-specific quality measures, the MVP works to capture more meaningful data to the clinician's scope of care. Moreover, it would not be expected for every aspect of a clinician's scope of care to be assessed, as the clinician would have choice in which quality measures they find most meaningful and appropriate for their case-mix and scope of care. Please note it is not expected that submission of each quality measure will be required for reporting this MVP. Rather, the intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP. As MVPs continue from year to year, the MVP Maintenance Process can be utilized to update MVPs to ensure they represent priorities in care for the MVP topic and align with care being delivered by the clinicians reporting. We agree our current inventory is limited in areas that are important to mental/behavioral health and psychiatry, thus encourage the commenter to reach out to measure developers/stewards to develop additional measures ensuring all important aspects of care are being assessed for submission to the Call for Measures for possible future implementation. The MVPs are intentionally broad to allow for broad reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting, as this would create an unattainable MVP inventory state, these nuances would be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all subspecialties and settings will be covered within the current MVP; however, this represents the foundation from which to build the most meaningful MVP for behavioral/mental health and psychology.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider to this MVP. Another commenter recommended the addition of IA_PM_16: Medication Management. A couple commenters noted this MVP lacks three to four of the quality measures commonly reported by psychiatrists from 2019-2021 (data from PsychPro registry, 2022).

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that all collection types for each MIPS quality measure finalized through rulemaking will be available for use within the MVP.

Comment: One commenter stated there are several measurement gap areas for ensuring quality for schizophrenia care, including measures of schizophrenia-focused patient-reported outcomes, relapse occurrence/ time to relapse, symptom monitoring, assessment for cognitive impairment and negative symptoms, cost/resource utilization specific to schizophrenia, and evaluation of caregiver support. They stated filling these measure gaps may bolster future versions of this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking; however, current policy only allows use of current MIPS quality and QCDR measures that meet all requirements within an MVP. We encourage the commenter to reach out to measure developers/stewards to develop new mental/behavioral health specialty focused measures for submission to the Call for Measures for possible future implementation.

Comment: Several commenters recommended postponing the adoption of this MVP until a relevant cost measure exists. One commenter noted the Medicare Spending Per Beneficiary (MSPB) measure will continue to be inapplicable to the vast majority of psychologists and other mental health clinicians. The commenter noted the measure is not specific to behavioral health and is focused on episodes triggered only by an inpatient stay. The commenter also noted the majority of psychologists participating in MIPS do not deliver services in an inpatient setting and that episode- based cost measures are triggered by Evaluation and Management (E/M) codes that psychologists do not have access to.

Response: The MSPB Clinician global cost measure and the Psychoses and Related Conditions episode-based cost measure are appropriate for use in this MVP as they assess costs associated with inpatient hospitalizations for mental health conditions and substance use disorder. The Depression episode-based cost measure is applicable to mental health clinicians who do not practice in an inpatient setting. The Depression episode-based cost measure is not limited to being triggered by E/M codes, but can also be triggered through other services specific to psychologists and other mental health clinicians, such as behavioral health visits, collaborative care management, chronic care management, among others. More information about the MSPB Clinician is available in CY 2022 PFS final rule (86 FR 66001) and CY 2023 PFS final rule (87 FR 70038). More information about the Psychoses and Related Conditions measure is in section IV.A.4.f.(2) of this final rule.

Clinicians are only scored on the cost measures within their selected MVP for which they meet the established case minimum. If a clinician cannot be scored on any of the cost measures within an MVP, the cost performance category will be reweighted in alignment with existing MIPS scoring policies under 42 CFR 414.1380(b)(2) and the clinician will not be penalized if there is not a cost measure applicable to their practice.

Comment: A couple of commenters questioned whether the cost measures included within this MVP are applicable to most psychologists and other mental health clinicians. The commenters stated MSPB Clinician is only applicable to clinicians practicing in inpatient settings, and questioned whether episode-based cost measures could be triggered by non-Evaluation and Management service codes billed by mental health clinicians. The commenters suggested postponing the adoption of the Quality Care in Mental Health and Substance Use Disorders MVP until there is exists a relevant cost measure.

Response: We disagree that there is not cost measure relevant to psychologists and other mental health clinicians. The Depression episode-based cost measure is applicable to mental health clinicians who do not practice in an inpatient setting. Additionally, the Depression episode-based cost measure is not limited to being triggered by E/M codes and can also be triggered through other services specific to psychologists and other mental health clinicians, such as behavioral health visits, collaborative care management, chronic care management, among others.

Comment: One commenter recommended either expanding the associated cost measures such that occupational therapy practitioners could report this MVP or develop additional cost measures for mental health that do not expressly restrict occupational therapy engagement.

Response: At this time, no additional episode-based cost measures beyond the Depression and Psychoses and Related Conditions cost measures are available for use in MVPs. Should additional applicable cost measures become available for use in MVPs, interested parties are welcome to submit recommended changes to the MVP through the MVP Maintenance Process. Until such time, occupational therapists can still choose to report this MVP. If a clinician cannot be scored on any of the cost measures within an MVP, the cost performance category will be reweighted in alignment with existing MIPS scoring policies under 42 CFR 414.1380(b)(2) and the clinician will not be penalized if there is not a cost measure applicable to their practice.

Comment: A couple commenters opposed the inclusion of the Psychoses and Related Conditions cost measure in this MVP, as they believe will have the undesired effect of creating a disincentive for psychiatrists to participate in the Medicare program.

Response: We maintain the proposed Psychoses and Related Conditions episode-based cost measure is appropriate for use in this MVP, as it assesses costs associated with inpatient hospitalizations for psychoses or related conditions, which aligns with the intended purpose of this MVP. We thank the commenters for their feedback on the use of the Psychoses and Related Conditions episode-based cost measure in MIPS and have addressed this feedback under section IV.A.4.f.(2) of this final rule.

After consideration of public comments, we are finalizing the *Quality Care in Mental Health and Substance Use Disorders MVP* with modifications in Table A.4 for the CY 2024 performance period/2026 MIPS payment year and future years. Due to QCDR measure MBHR15: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment not meeting the testing data requirements it is being removed from the Quality in Mental Health and Substance Use Disorders MVP.

Rehabilitative Support for Musculoskeletal Care MVP

In the CY 2024 PFS proposed rule (88 FR 55162 through 53166), we proposed and solicited comments on Rehabilitative Support for Musculoskeletal Care MVP The proposed Rehabilitative Support for Musculoskeletal Care MVP focuses on the clinical theme of promoting quality care for patients. This MVP would be most applicable to clinicians and NPPs who specialize in providing rehabilitative support for musculoskeletal care such as chiropractic, physiatry, physical therapy and occupational therapy, as well as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are embedded within Table A.5.

Quality Measures

We proposed to include 10 MIPS quality measures within the quality performance category of this MVP, which promote rehabilitative support for patients. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing rehabilitative support for musculoskeletal care:

- Q217: Functional Status Change for Patients with Knee Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the knee. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q218: Functional Status Change for Patients with Hip Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the hip. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the lower leg, foot or ankle. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q220: Functional Status Change for Patients with Low Back Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the low back. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q221: Functional Status Change for Patients with Shoulder Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the shoulder. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the elbow, wrist or hand. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q478: Functional Status Change: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the neck. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.

In addition, we proposed to include the following broadly applicable MIPS quality measures that are relevant to rehabilitative support for musculoskeletal care. The quality measures below address preventive screenings and care plan for falls:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q155: Falls: Plan of Care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 17 improvement activities that reflect actions and processes undertaken by clinicians who provide rehabilitative support for musculoskeletal care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing rehabilitative support for musculoskeletal care. We proposed the following improvement activities for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_12: Promoting Clinician Well-Being
- IA_BMH_15: Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_8: Implementation of documentation improvements for practice/process improvements
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_EPA_3: Collection and use of patient experience and satisfaction data on access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PSPA_16: Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of rehabilitative support for musculoskeletal care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in rehabilitative support for musculoskeletal care and aligns with the other measures and activities included within this MVP:

- Low Back Pain: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat low back pain. This aligns with Q220: Functional Status Change for Patients with Low Back Impairments. This measure is a new measure that will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.

TABLE A.5: Rehabilitative Support for Musculoskeletal Care MVP

Table A.5 serves to represent the measures and activities that are finalized within the Rehabilitative Support for Musculoskeletal Care MVP.

Symbol Key:
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with revisions
Double asterisk (**): quality measures can be submitted only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(**) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q155:** Falls: Plan of Care (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!!) Q217**: Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q218:** Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q219:** Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q220:** Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q221:** Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQMs Specifications) **(!!) Q478:** Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQMs Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BMH_12:** Promoting Clinician Well-Being (High) **(^) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults (High) **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_8:** Implementation of documentation improvements for practice/process improvements (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(~) IA_EPA_3:** Collection and use of patient experience and satisfaction data on access (Medium) **(^) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways	**(^) Low Back Pain**

	(High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

Comment: Various commenters supported the inclusion of the following measures and improvement activities: Q487: Screening for Social Drivers of Health this MVP, IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment, IA_PSPA_21: Implementation of fall screening and assessment programs, IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways, and the Low Back Pain cost measure. Several commenters expressed support for the inclusion of this MVP in the MIPS program with a couple commenters specifically noting it's the first of its kind, one that will allow a subset of physical therapists to meaningfully participate in the Quality Payment Program and be compared with their clinical peers.

Response: We thank the commenters for their support.

Comment: A few commenters recommended this MVP not be finalized until 2025, when harmonized Limber/IROMS measures can be proposed, permitting a wider range of available quality measures. They stated 7 of the 10 quality measures available are Focus on Therapeutic Outcomes (FOTO) measures and while free for manual/paper use there is a charge for the electronic survey. Another commenter expressed concern that the FOTO measures included in this MVP are proprietary and not readily available to most physical therapists. The commenter noted that the measures in this MVP should be available to all clinicians without incurring additional costs. Another commenter recommended the inclusion of the IROMS QCDR measures in this MVP given the widespread adoption of the measures in the physical therapy space to measure outcomes.

Response: We may consider the inclusion of applicable QCDR measures that meet the inclusion criteria and address a measurement gap through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. While QCDR measures may be considered in the future, MVP participation cannot rely soley on QCDR measures as they can only be reported via the QCDR measure owner or borrower of the measures. As this MVP is both feasible and meaningful as proposed, in addition to being voluntary, we do not agree with delaying finalization for potential future changes to QCDR measure inventory. This allows the identified clinician types the opportunity to participate in MVPs as applicable to them. We will evaluate the

recommendations received and determine if they are appropriate and align with the broader vision for the MVP. The process measures are included in this MVP to provide flexibility of clinician choice and to encompass the comprehensive care provided by clinicians caring for this patient population. Addressing these previously raised concerns, the measure steward updated the FOTO measures for PY2023 to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROMs for reporting of these quality measures. Additionally, the measure steward indicates the FOTO's Public Access Survey provides a computer adaptive test (CAT) administration of the survey with scoring results provided on the last screen of the assessment without a fee.

Comment: A couple commenters expressed concern that the three quality measures included in this MVP that are not FOTO measures are process based measures with one of the three, Q155: Falls: Plan of Care, topped out.

Response: The process measures are included in this MVP to provide flexibility of clinician choice and to encompass the comprehensive care provided by clinicians caring for this patient population. While we endeavor to include measures that allow for maximum points, we want to ensure important aspects of care within the MVP topic are represented. However, as MVPs are optional and there is still clinician choice allowed in quality measures reporting, we would encourage clinicians to review each MVP and the measures and activities within to ensure it is appropriate and applicable to report.

Comment: A few commenters noted the limited number of improvement activities for physical therapists and recommended the inclusion of IA_BMH_12: Promoting Clinician Well-Being, IA_EPA_3: Collection and use of patient experience and satisfaction data on access, and IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients.

Response: We may consider the inclusion of IA_BMH_12: Promoting Clinician Well-Being, IA_EPA_3: Collection and use of patient experience and satisfaction data on access, and IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple commenters noted that having a cost measure limited to only Low Back impairment is too focused and not broad enough for general participation.

Response: We maintain the Low Back Pain episode-based cost measure is appropriate for use in this MVP. The Low Back Pain episode-based cost measure includes the costs of services provided by physical therapists and occupational therapists, which aligns with the intended purpose of this MVP. Clinicians are only scored on the cost measures within their selected MVP for which they meet the established case minimum. If a clinician cannot be scored on any of the cost measures within an MVP, the cost performance category will be reweighted in alignment with existing MIPS scoring policies under 42 CFR 414.1380(b)(2), which allows for broader participation in the MVP.

Comment: A couple commenters recommended adding measures to address fracture-related care such as Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older and Q418: Osteoporosis Management in Women Who Had a Fracture. One commenter recommended the addition of Q498: Connection to Community Service Provider. An additional commenter recommended expanding the population health measures available in this MVP.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter doesn't agree this MVP is clinically appropriate to physiatry and recommends development of an additional MVP that would be directly relevant to physiatry. Another commenter is concerned this MVP is specific to only one type of rehabilitative support.

Response: The MVPs are intentionally broad to allow for broad reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting, as this would create an unattainable MVP inventory state, these nuances would be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand not all quality measures would be applicable to all clinicians who would submit this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing rehabilitative care and allows for clinician choice in choosing quality measures that best represent their scope of care. While we agree specialists who manage chronic pain and physical impairment conditions are distinctive providers, we would encourage those clinicians to choose measures that are more aligned with their scope of care. However, as there may not be specific individual measures that represent every specialty, this consolidated MVP can be reported when appropriate and applicable to the clinician/group. We encourage the commenter to reach out to measure developers/stewards to develop additional measures for submission to the MVP Maintenance process for possible future implementation.

Comment: One commenter requested the clinical applicability of this MVP be expanded to be more relevant to spine surgeons. The commenter recommended updating the title by removing the reference to "rehabilitative support". A couple of commenters recommended the addition of measures Q039: Screening for osteoporosis, Q126: Diabetic peripheral neuropathy – neurological evaluation, Q134: Screening for depression and follow-up plan, Q178: Functional status assessment for RA patients, Q226: Tobacco screening and cessation, Q418: Osteoporosis management in women with fracture, Q461: Leg pain after lumbar surgery, and Q471: Functional status after lumbar surgery. Another commenter recommended the addition of Q182: Functional Outcome Assessment and Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling in order to promote meaningful participation for physical therapists and other nonphysicians.

Response: The scope of this MVP is intended for use by professionals who specialize in providing rehabilitative support for musculoskeletal conditions, such as chiropractic, physiatry, physical therapy, and occupational therapy, as well as nurse practitioners and physician assistants. We may consider the inclusion of additional MIPS quality measures that align with the intent of this MVP through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters recommended the first iteration of this MVP include PROMIS measures associated with physical function, pain interference, and Global Health 10 or 29. The commenter believes including PROMIS measures offers critical options that are not represented in the measures offered in the Rehabilitative Support for Musculoskeletal Care MVP.

Response: The current MIPS quality measure inventory does not include any measures that use the PROMIS tool to assess physical function or pain interference. We encourage the commenter to reach out to measure developers/stewards to develop additional measures utilizing the PROMIS tool for submission to the Call for Measures for possible future implementation. We may consider the inclusion of QCDR measures that meet the inclusion criteria and address a measurement gap through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter expressed concern with the inclusion of the Low Back Pain cost measure in this MVP. The commenter requested that orthopedic surgeons be removed from the list of eligible specialties for attribution to evaluate non-operative, chronic care. The commenter further recommended the creation of longitudinal care episodes specific to orthopedic surgeons and non-operative management of chronic musculoskeletal conditions.

Response: We appreciate the commenter's concerns; however, it is appropriate to include the Low Back Pain episode-based measure in this MVP because it assesses the cost of patients receiving care to manage low back pain and aligns with Q220: Functional Status Change for Pateints with Low Back Impairments. Additionally, we maintain it is appropriate to attribute this measure to surgeons, as recommended by the Clinical Expert Workgroup that helped to develop this measure. We have addressed this feedback under section IV.A.4.f.(2) of this final rule in further detail. If additional cost measures applicable to musculoskeletal conditions and orthopedic surgeons become available for use in MIPS, we may consider the addition of such measures through future MVP maintenance and rulemaking processes.

Comment: A few commenters expressed concerns that having a cost measure limited to only Low Back impairment would be too focused and not broad enough for general participation in the MVP.

Response: The Low Back Pain episode-based cost measure is appropriate for use in this MVP because it assesses the cost of patients receiving care to manage low back pain and aligns with Q220: Functional Status Change for Pateints with Low Back Impairments At this time, there are no additional applicable cost measures in the MIPS cost measure inventory that would capture a broader scope of care. Should additional applicable cost measures be implemented in MIPS in the future, we may consider the addition of these measures through the MVP Maintenance Process and future rulemaking. We also note that clinicians are only scored on the cost measures within their selected MVP for which they meet the established case minimum. If a clinician cannot be scored on any of the cost measures within an MVP, the cost performance category will be reweighted in alignment with existing MIPS scoring policies under 42 CFR 414.1380(b)(2), which allows for broader participation in the MVP.

Comment: One commenter noted their support for the Low Back Pain cost measure because it allows for chiropractors to be attributed episodes and receive a cost measure score. However, the commenter expressed concerns with chiropractors using E&M codes that are not payable under Medicare, which would limit these clinicians' abilities to demonstrate the true value of their care in the proposed MVP.

Response: We appreciate the commenter's support of the Low Back Pain cost measure and its use in the Musculoskeletal MVP. The Low Back Pain episode-based cost measure attributes episodes to clinicians who bill outpatient E&M codes as well as other clinically relevant outpatient services, such as therapy evaluation, chiropractic manipulation, osteopathic manipulation, or therapy services. Additionally, these services are included within the cost measure score calculation as part of assessing the value of care provided for musculoskeletal conditions.

Comment: One commenter expressed concerns about the Low Back Pain cost measure included in this MVP, and stated it focuses exclusively on cost without any consideration for the impact of spending or cost reduction on patient outcomes or other measures of quality.

Response: We agree with the commenter that it is important to consider quality performance alongside cost performance. The Low Back Pain cost measure and Functional Status Change for Patients with Low Back Pain quality measure use similar service and diagnoses codes to identify the patient populations. The MVP also includes additional quality measures and improvement activities to collectively assess the overall value of musculoskeletal care. Additionally, cost measures aim to promote care coordination and can capture clinicians' cost savings through reduction of poor patient outcomes associated with high costs, such as avoidable hospitalizations or complications.

After consideration of public comments, we are finalizing the *Rehabilitative Support for Musculoskeletal Care MVP* as proposed in Table A.5 for the CY 2024 performance period/2026 MIPS payment year and future years.

Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

Advancing Cancer Care MVP

In the CY 2024 PFS proposed rule (88 FR 53167 through 53169), we proposed and solicited comments on the previously finalized Advancing Cancer Care MVP. Table B.1 represents the measures and activities that were finalized within the Advancing Cancer Care MVP in (87 FR 70653 through 70659) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.1.

Quality Measures

We proposed to modify the previously finalized Advancing Cancer Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one additional QCDR measure that address appropriate cancer care treatment. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians providing cancer care to patients:

- Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors: This MIPS quality measure identifies patients diagnosed with cancer who are on immune checkpoint inhibitor therapy and develop grade 2 or above diarrhea and/or colitis to assess for appropriate intervention of managing immune-related diarrhea and colitis.
- PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy: This QCDR measure assesses the use of mutation testing for all actionable biomarkers with appropriate mutation-directed therapy, in accordance with current National Comprehensive Cancer Network (NCCN) guidelines for stage IV non-small cell lung cancer.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we proposed to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving cancer care and their understanding of their health care treatment journey:

- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in their ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add six additional improvement activities that address maintenance requests from the public, and that address priority areas including clinician well-being, interoperability, patient safety, and expanding use of telehealth:

- IA_BMH_12: Promoting Clinician Well-Being
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan
- IA_PSPA_13: Participation in Joint Commission Evaluation Initiative
- IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program

TABLE B.1: Advancing Cancer Care MVP

Table B.1 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Advancing Cancer Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures

Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q144:** Oncology: Medical and Radiation – Plan of Care for Pain (Collection Type: MIPS CQMs Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(!) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q452:** Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies (Collection Type: MIPS CQMs Specifications) **(!) Q453:** Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) **(!!) Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+) Q490:** Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **(+) IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **(+) IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **IA_CC_17:** Patient Navigator Program (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(+)(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(+) IA_ERP_4:** Implementation of a Personal Protective Equipment (PPE) Plan (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Total Per Capita Cost (TPCC)**

(^)(+)(!!) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **(!) PIMSH2:** Oncology: Utilization of GCSF in Metastatic Colorectal Cancer (Collection Type: QCDR) **(+)(!) PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy (Collection Type: QCDR)	**IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **(+) IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium) **(+) IA_PSPA_28**: Completion of an Accredited Safety or Quality Improvement Program (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in this MVP. A few commenters supported the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months and a couple of commenters supported the inclusion of PIMSH13: Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy in this MVP. One commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be added to this MVP. A couple commenters recommended the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended replacing Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months in this MVP with an alternate activation survey that is accessible to any ePROM vendor or platform.

Response: The current MIPS quality measure inventory doesn't include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

Comment: One commenter recommended considering and incorporating future quality measures advancing biomarker testing in cancer care and measures advancing genetic testing for an inherited mutation, or germline testing, in cancer patients.

Response: We are finalizing the inclusion of PIMSH13: Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy. However, we encourage the commenter to reach out to measure developers/stewards to develop additional measures addressing advancing genetic testing and biomarker testing for cancer patients for submission to the Call for Measures for possible future implementation.

Comment: One commenter opposed the TPCC cost measure being included in this MVP. The commenter noted that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We maintain the TPCC measure is appropriate for use in in MVPs, as we outlined in the CY 2023 PFS final rule (87 FR 70653 through 70659). This is because the TPCC measure captures the overall costs of care after establishing a primary care-type relationship, including the care provided to patients by medical, hematological, and gynecological oncologists. The broad focus of the measure, which includes total costs of care for patients with cancer, supports the intent of this MVP to apply to cancer care. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future. We also clarify that the TPCC measure undergoes annual maintenance, where CMS and the measure developer determine whether to make updates to the measure specifications based on new, revised, or deleted CPT codes. The Measure Codes Lists that detail the specific codes used to construct the measures are also updated annually and made publicly available. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Cancer Care MVP* as proposed in Table B.1 for the CY 2024 performance period/2026 MIPS payment year and future years.

Optimal Care for Kidney Health MVP

In the CY 2024 PFS proposed rule (88 FR 53170 through 53172), we proposed and solicited comments on the previously finalized Optimal Care for Kidney Health MVP. Table B.2 represents the measures and activities that were finalized within the Optimal Care for Kidney Health MVP in (87 FR 70660 through 70664) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.2.

Quality Measures

We proposed to modify the previously finalized Optimal Care for Kidney Health MVP within the quality performance category of this MVP to include to include six additional MIPS quality measures that encompass the appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP encompass appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist:

- Q488: Kidney Health Evaluation: This MIPS quality measure ensures patients with diabetes receive a kidney health evaluation including both an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR).
- N/A: First Year Standardized Waitlist Ratio (FYSWR): This proposed MIPS quality measure ensures patients with end-stage renal disease (ESRD) are placed on the kidney or kidney-pancreas transplant list or that the patient received a living donor transplant in the first year after initiation of dialysis.
- N/A: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): This proposed MIPS quality measure captures the adjusted count of patient months for dialysis patients on the kidney and kidney-pancreas transplant waitlist and patients on the kidney or kidney -pancreas transplant waitlist in active status.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we proposed to add the following two broadly applicable MIPS quality measures which address patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We also proposed to modify the previously finalized Optimal Care for Kidney Health MVP to remove two MIPS quality measures that would be replaced by MIPS quality measure Q493 Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measures would be captured in the composite measure:

- Q110: Preventive Care and Screening: Influenza Immunization
- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and population health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients

We also proposed to remove the following improvement activity in response to maintenance requested from the public and interested-party feedback and agree with the recommendation that IA_PM_13: Chronic Care and

Preventative Care Management for Empaneled Patients better targets the MVP population while still advancing care coordination:

- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients

TABLE B.2: Optimal Care for Kidney Health MVP

Table B.2 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Optimal Care for Kidney Health MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category.

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+)(*) Q488:** Kidney Health Evaluation (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications) **(*)(+) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^)(+)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **Total Per Capita Cost (TPCC)**

	(Medium) **(+) IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

Comment: A couple commenters supported the inclusion of the following quality measures: Q487: Screening for Social Drivers of Health, Q488: Kidney Health Evaluation, Q493: Adult Immunization Status, the proposed First Year Standardized Waitlist Ratio (FYSWR) measure, and the proposed Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure in this MVP. One commenter supported the Patient Activation Measure given its use in the Center for Medicare and Medicaid Innovation's (CMMI) Kidney Care Choices Model to promote alignment with the MVP and advanced alternative payment models. Another commenter supported all proposed changes to the Improvement Activities measures in this MVP. One commenter generally supported all measures aimed at preventing or slowing progression of kidney disease among individuals with CKD, as well as screening for CKD in high risk individuals with diabetes, hypertension, heart disease, and other risk factors. A few commenters supported the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP. Another commenter supported the inclusion of IA_AHE_9 in this MVP. One commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure and a couple of commenters recommended quality measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure be added to this MVP. Another commenter recommended the inclusion of IA_AHE_9 in this MVP.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended replacing Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP with an alternate activation survey that is accessible to any ePROM vendor or platform.

Response: The current MIPS quality measure inventory doesn't include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

Comment: One commenter asked for clarification as to why the eCQM ID CMS95v1 version of the Kidney Health Evaluation quality measure is not included in this MVP when the MIPS CQM ID Q488 version is available. The commenter believes both should be included.

Response: This was an inadvertent omission and Table B.2 has been updated to reflect the eCQM specifications collection type (CMS951v2).

Comment: One commenter stated there are several measurement gap areas for ensuring quality for CKD care, including measures of CKD stage at diagnosis, medication adherence, readmissions and hospitalizations, quality of life and symptom burden, patient preparedness, kidney failure/renal replacement therapy planning, and prescription of key medications. They stated filling these measures may bolster future versions of this MVP.

Response: We encourage the commenter to reach out to measure developers/stewards to develop additional CKD measures that may fill these gap areas for submission to the Call for Measures for possible future implementation.

Comment: A few commenters requested clarification regarding the proposed First Year Standardized Waitlist Ratio (FYSWR) measure and the proposed Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure and encouraged development and implementation of measures that support medications such as sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy and other measures to delay CKD progression in this MVP.

Response: The intent of the proposed First Year Standardized Waitlist Ratio (FYSWR) measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant, within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. The intent of the proposed Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure is to assess monthly wait listing in active status of patients as well as evaluates and encourages maintenance of patients on the waitlist. We encourage the commenters to reach out to measure developers/stewards to develop additional CKD measures that may fill the gap areas identified for submission to the Call for Measures for possible future implementation. However, due to potential implementation concerns regarding timing and application of the risk adjustment methodology, these measure will not be finalized for the CY 2024 performance period/2026 MIPS payment year.

Comment: One commenter opposed the TPCC cost measure being included in this MVP. The commenter noted that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We maintain the TPCC measure is appropriate for use in MVPs. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Optimal Care for Kidney Health MVP* with. As described in Appendix 1: MIPS Quality Measures Tables A.4 and Table A.5, we are not finalizing the proposed quality measures:First Year Standardized Waitlist Ratio (FYSWR), and Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW). As a result, we are not finalizing the inclusion of these measures in the Optimal Care for Kidney Health MVP. We refer readers to Appendix 1: MIPS Quality Measures Table A.4 and A.5 for details..

Optimal Care for Patients with Episodic Neurological Conditions MVP

In the CY 2024 PFS proposed rule (88 FR 53173 through 53175), we proposed and solicited comments on the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP. Table B.3 represents the measures and activities that were finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP in (87 FR 70665 through 70668) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.3.

Quality Measures

We proposed to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP within the quality performance category of this MVP to include to include two additional MIPS quality measures that address health equity and the patient's understanding of their health care journey. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we proposed to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving care for episodic neurological conditions. The quality measure below addresses the patient's understanding of their health care journey:

- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We also proposed to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP to remove one QCDR measure as it is a process measure with no follow-up or link to a health outcome as doesn't ensure preventive therapies were successful.

- AAN30: Migraine Preventive Therapy Management

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add one additional improvement activity that addresses a maintenance request from the public and that addresses the priority area of including the patient voice in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

TABLE B.3: Optimal Care for Patients with Episodic Neurological Conditions MVP

Table B.3 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Optimal Care for Patients with Episodic Neurological Conditions MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(^)(+)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

AAN5: Treatment Prescribed For Acute Migraine Attacks (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **AAN31**: Acute Treatment Prescribed for Cluster Headache (Collection Type: QCDR) **AAN32:** Preventive Treatment Prescribed for Cluster Headache (Collection Type: QCDR)	**IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

	ONC Direct Review Attestation

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. Another commenter agreed with the removal of AAN30: Migraine Preventative Therapy Management from this MVP. One commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. A few commenters supported the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure be added to this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended replacing Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP with an alternate activation survey that is accessible to any ePROM vendor or platform.

Response: The current MIPS quality measure inventory doesn't include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

Comment: One commenter noted that AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy will no longer be available beginning January 1, 2024.

Response: We acknowledge that AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy will no longer be available beginning January 1, 2024, and will have no impact on the voluntary reporting of this MVP. As such, this QCDR measure will be removed from the finalized MVP for PY 2024. We may consider the inclusion of additional measures through the MVP Maintenance Process and future rulemaking; however, current policy only allows use of current MIPS quality and QCDR measures that meet all requirements to be included within an MVP.

Comment: One commenter didn't agree with the inclusion of Q487: Screening for Social Drivers of Health in this MVP as the measure is a process measure without any follow-up or outcome. The commenter noted that in the past these types of measures for neurology-specific items have been declined. The commenter also noted the measure could be demotivational to the neurology community and is more appropriate for a patient's primary care provider or medical home team as they coordinate care. In addition, the commenter expressed concern with the burden that this measure may place on institutional quality improvement efforts and on Qualified Clinical Data Registries (QCDRs).

Response: We maintain this is an important process measure that supports the collection of DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure purely focuses on the completion of screening for DOH patient information and is consistent with the priority to advance health equity. We note the information a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Because clinicians have the flexibility to choose measures to report, it would be at their discretion whether to report this measure as requirements only include reporting of 4 quality measures. Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, and improve a patient's overall health and well-being. [585, 586]

After consideration of public comments, we are finalizing the *Optimal Care for Patients with Episodic Neurological Conditions MVP* with modifications in Table B.3 for the CY 2024 performance period/2026 MIPS payment year and future years. Due to QCDR measure AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy no longer be available beginning January 1, 2024, it is being removed from the Optimal Care for Patients with Episodic Neurological Conditions MVP.

[585] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. Annals of Internal Medicine, 168(8), 577–578. https://doi.org/10.7326/M17-2441.

[586] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at https://doi.org/10.31478/201705b.

Supportive Care for Neurodegenerative Conditions MVP

In the CY 2024 PFS proposed rule (88 FR 53176 through 53177), we proposed and solicited comments on the previously finalized Supportive Care for Neurodegenerative Conditions MVP. Table B.4 represents the measures and activities that were finalized within the Supportive Care for Neurodegenerative Conditions MVP in (87 FR 70669 through 70672) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.4.

Quality Measures

We proposed to modify the previously finalized Supportive Care for Neurodegenerative Conditions MVP within the quality performance category of this MVP to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of including patient voices in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

TABLE B.4: Supportive Care for Neurodegenerative Conditions MVP

Table B.4 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Supportive Care for Neurodegenerative Conditions MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(!) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **AAN9:** Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **(!!) AAN34:** Patient reported falls and plan of care (Collection Type: QCDR)	(Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional)	

	Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: One commenter stated the QCDR measure steward will not permit borrowing of their QCDR measures included in this MVP. They noted this could lead to provider frustration/burden and the selection of only the process measures and/or regular MIPS measures available within the MVP.

Response: We acknowledge the commenter's concerns. We note the reporting requirements include reporting four quality measures from the MVP, including one outcome measure. If the only outcome measures available to the clinician are cost burdensome, the clinician may report a high priority measure (86 FR 65417). This MVP as proposed contains seven high priority measures, allowing some flexibility and choice to clinicians in reporting a subset of measures and activities within this MVP. We may consider the inclusion of additional measures through the MVP Maintenance Process and future rulemaking; however, current policy only allows use of current MIPS quality measures and QCDR measures that meet all requirements for inclusion within an MVP. Additionally, we encourage the commenter to reach out to measure developers/stewards to develop new neurodegenerative supportive care measures for submission to the Call for Measures for possible future implementation.

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. One commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways.

Response: We thank the commenter for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure be added to this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter didn't agree with the inclusion of Q487: Screening for Social Drivers of Health in this MVP as the measure is a process measure without any follow-up or outcome. The commenter noted that in the past these types of measures for neurology-specific items have been declined. The commenter also noted the measure could be demotivational to the neurology community and is more appropriate for a patient's primary care provider or medical home team as they coordinate care. In addition, the commenter expressed concern with the burden that this measure may place on institutional quality improvement efforts and on Qualified Clinical Data Registries (QCDRs).

Response: We maintain this is an important process measure that supports the collection of DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure purely focuses on the completion of screening for DOH patient information and is consistent with the priority to advance health equity. We note the information a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Because clinicians have the flexibility to choose measures to report, it would be at their discretion whether to report this measure as requirements only include reporting of 4 quality measures. Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, and improve a patient's overall health and well-being. [587, 588]

After consideration of public comments, we are finalizing the *Supportive Care for Neurodegenerative Conditions MVP* as proposed in Table B.4 for the CY 2024 performance period/2026 MIPS payment year and future years.

[587] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. Annals of Internal Medicine, 168(8), 577–578. https://doi.org/10.7326/M17-2441.

[588] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at https://doi.org/10.31478/201705b.

Advancing Care for Heart Disease MVP

In the CY 2024 PFS proposed rule (88 FR 53178 through 53181), we proposed and solicited comments on the previously finalized Advancing Care for Heart Disease MVP. Table B.5 represents the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (87 FR 70679 through 70683) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.5.

Quality Measures

We proposed to modify the previously finalized Advancing Care for Heart Disease MVP within the quality performance category of this MVP to include four additional MIPS quality that are relevant to patients receiving care for heart disease. We reviewed the quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP are relevant to patients receiving care for heart disease. The quality measures below address appropriate medications for patients with coronary artery disease (CAD):

- Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy: This MIPS quality measure assesses that patients diagnosed with CAD are prescribed aspirin or clopidogrel.
- Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF $\leq$ 40%): This MIPS quality measure assesses patients diagnosed with CAD, in addition to a prior myocardial infarction or current or prior LVEF $\leq$ 40%, are prescribed a beta-blocker therapy.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we proposed to add one additional broadly applicable MIPS quality measure that is relevant to patients receiving care for heart disease. The quality measure below addresses the patient's understanding of their health care journey:

- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Cost Measures

We also proposed to add two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including cardiac care. An interested party recommended that the MSPB Clinician measure replace the TPCC measure. We agree that it is appropriate to include MSPB Clinician within this MVP. However, TPCC is appropriate to include in this MVP for the reasons stated when the measure was initially finalized for use in this MVP (86 FR 66012 through 66103).
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure. The addition of this measure aligns with included quality measures, such as Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) and Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD). This is a new measure that

will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.

TABLE B.5: Advancing Care for Heart Disease MVP

Table B.5 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Advancing Care for Heart Disease MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(+)(*) Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(+)(*) Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQMs Specifications) **(**) Q128**: Preventive care and screening: Body Mass Index (BMI) screening and follow-up plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use of evidence-based tools to support shared decision making (Medium) **IA_BE_15:** Engagement of Patients, Families, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)** **(^)(+) Heart Failure** **(+) Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(*)(!) Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) **(!!) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) **(!!) Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) **(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) Q492:** Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims) **(^)(+)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	(Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional)

	Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: A couple commenters supported the inclusion of Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. Another commenter supported the inclusion of IA_AHE_9 in this MVP. Another commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. And a few commenters supported the addition of quality measures Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy and Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%). A few commenters supported the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP. One commenter supported the inclusion of the Heart Failure cost measure in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure be added to this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended replacing Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP with an alternate activation survey that is accessible to any ePROM vendor or platform.

Response: The current MIPS quality measure inventory doesn't include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

Comment: One commenter stated there are several measurement gap areas for ensuring quality for heart failure care, measures of risk assessment, screening, health-related quality of life (beyond functional status), treatment, and medication adherence. They stated filling these measures may bolster future versions of this MVP.

Response: We encourage the commenter to reach out to measure developers/stewards to develop additional measures. Interested parties are welcome to submit recommended changes to finalized MVPs on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter opposed the TPCC cost measure being included in this MVP. The commenter noted that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We thank the commenter for raising these concerns and maintain the TPCC measure is appropriate for use in MVPs. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* as proposed in Table B.5 for the CY 2024 performance period/2026 MIPS payment year and future years.

Advancing Rheumatology Patient Care MVP

In the CY 2024 PFS proposed rule (88 FR 53182 through 53184), we proposed and solicited comments on the previously finalized Advancing Rheumatology Patient Care MVP. Table B.6 represents the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (87 FR 70687 through 70689) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.6.

Quality Measures

We proposed to modify the previously finalized Advancing Rheumatology Patient Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving rheumatology care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measure proposed within this MVP addresses appropriate clinical care for patients with

rheumatological conditions:

- UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function: This QCDR outcome measure ensures assessment of disease control or improvement based on Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score in patients with ankylosing spondylitis.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we proposed to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving care for rheumatological conditions. The quality measures below address immunization status and the patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We also proposed to modify the previously finalized Advancing Rheumatology Patient Care MVP to remove one MIPS quality measure that would be replaced by MIPS quality measure Q493: Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measure would be captured in the composite measure:

- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including incorporating the patient voice into health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_24: Financial Navigation Program
- IA_BE_25: Drug Cost Transparency

TABLE B.6: Advancing Rheumatology Patient Care MVP

Table B.6 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Advancing Rheumatology Patient Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q130: Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal	**Total Per Capita Cost (TPCC)**

Q176: Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)(+) Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^)(+)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurement for Patients with PsA (Collection Type: QCDR) **(!!) ACR14:** Gout: Serum Urate Target (Collection Type: QCDR) **(!) ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR) **(+)(!!) UREQA10:** Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	(Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **(+) IA_BE_24:** Financial Navigation Program (Medium) **(+) IA_BE_25**: Drug Cost Transparency (High) **IA_BMH_2:** Tobacco use (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional)	

	Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health and another supported the inclusion of Q493: Adult Immunization Status in this MVP. A few commenters supported the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months measure in this MVP. Another commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. A couple commenters support the inclusion of IA_BE_24: Financial Navigation Program and IA_BE_25: Drug Cost Transparency improvement activities in this MVP.

Response: We thank the commenters for their support.

Comment: Commenters recommended additional quality measures be considered for this MVP. Recommendations included adding measures to address fracture-related care such as Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older and Q418: Osteoporosis Management in Women Who Had a Fracture. One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure to MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP

Comment: One commenter recommended replacing Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months in this MVP with an alternate activation survey that is accessible to any ePROM vendor or platform.

Response: The current MIPS quality measure inventory doesn't include an alternate measure based upon an activation survey. We encourage the commenter to reach out to measure developers/stewards to develop additional measures allowing for the use of alternate activation surveys that are accessible to any ePROM vendor or platform for submission to the Call for Measures for possible future implementation.

Comment: One commenter expressed concerns with the topped out quality measures included in this MVP. They noted this will make it difficult to obtain a full quality score. A couple of commenters recommended additional quality measures be added to this MVP. They noted the current selection of measures limits eligible clinicians to achieve optimal scoring in the quality performance category. The measures recommended included the following; Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age, Q418 Osteoporosis Management in Women Who Had a Fracture, UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved, UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older, UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy, ACR10: Hepatitis B Safety Screening, ACR16: Rheumatoid Arthritis Patients with Low Disease Activity or Remission, and Q318: Falls: Screening for Future Fall Risk. Another commenter recommended expanding the population health measures available in this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.
The process measures are included in this MVP to provide flexibility of clinician choice and to encompass the comprehensive care provided by clinicians caring for this patient population. While we endeavor to include measures that allow for maximum points, we want to ensure important aspects of care within the MVP topic are represented. However, as MVPs are optional and there is still clinician choice allowed in quality measures reporting, we would encourage clinicians to review each MVP and the measures and activities within to ensure it is appropriate and applicable to report.

Comment: One commenter didn't support the inclusion of Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months in this MVP. They also recommended delaying the addition of UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function until further information about its potential for unintended consequences is available. In addition, the commenter recommended delaying the removal of Q111: Pneumococcal Vaccination Status for Older Adults and replacing it with Q493: Adult Immunization Status until care teams are more comfortable with the test and development experience using the tradition MIPS pathway measure Q493.

Response: The reliability and validity of the PAM® survey has been demonstrated across patient populations, sociodemographic segments, mode of administration, and across multiple languages. Across all patient populations, lower activation has been shown to be predictive of poor self-management, higher healthcare utilization, and higher costs. The evidence suggests that factors such as education, income, ethnicity, and gender account for less than 5% of the variance in PAM® scores. Furthermore, evidence shows that all patients can improve in activation and when appropriately supported, patients at the lower levels of activation actually improve more quickly than other patients.[589, 590, 591, 592, 593]

Currently, there have been no identified unintended consequences during review of measure UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function as the measure is looking at improvement in disease control. Measure Q493: Adult Immunization Status

[589] PAM® Survey: *https://www.phreesia.com/patient-activation-measure/ ?utm_source=google&utm_ medium=paid_ search&utm_ destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&utm_audience1=payer&utm_co ntent=648172611574&utm_destinati.*

[590] Mitchell, S. E., Gardiner, P. M., Sadikova, E., Martin, J. M., Jack, B. W., Hibbard, J. H., & Paasche-Orlow, M. K. (2014). Patient Activation and 30-day Post-discharge Hospital Utilization. Journal of General Internal Medicine, 29(2), 349–355. *https://doi.org/10.1007/s11606-013-2647-2.*

[591] Sacks, R. M., Greene, J., Hibbard, J. H., & Overton, V. (2014). How Well Do Patient Activation Scores Predict Depression Outcomes One Year Later? Journal of Affective Disorders, 169, 1-6. *https://doi.org/10.1016/j.jad.2014.07.030.*

[592] Hibbard, J. H., Greene, J., Sacks, R. M., Overton, V., & Parrotta, C. (2017). Improving Population Health Management Strategies: Identifying Patients Who Are More Likely to Be Users of Avoidable Costly Care and Those More Likely to Develop a New Chronic Disease. Health Services Research, 52(4), 1297–1309. *https://doi.org/10.1111/1475-6773.12545.*

[593] Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Services Research, 39(4 Pt 1), 1005–1026. *https://doi.org/10.1111/j.1475-6773.2004.00269.x.*

will capture a more robust representation of vaccination status than the individual components and drives complete vaccination rates for patients. As a result, measure Q111 is being removed as it will be duplicative to measure Q493. Additionally, the clinician maintains choice in which quality measures to choose and we encourage reporting of those measures that are the most meaningful and appropriate to their scope of care.

Comment: One commenter opposed the TPCC cost measure being included in this MVP. The commenter noted that TPCC does not account for the benefit of preventive services in reducing costs in the long term, which would unfairly penalize physicians. The commenter also expressed concerns with the measure's use of outdated CPT coding specifications, which would impact the reliability and validity of the measure and lead to inaccurate results and unintended consequences for physicians and groups.

Response: We maintain the TPCC measure is appropriate for use in this MVP, as we outlined in the CY 2023 PFS final rule (87 FR 70687 through 70689), because it captures the overall costs of care after establishing a primary care relationship, including the care provided by rheumatologists. The TPCC measure assesses ongoing management of rheumatology conditions and aligns with the intent of this MVP. We may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters expressed concerns with the use of TPCC in this MVP. One commenter questioned whether the TPCC measure appropriately assess the costs of medications, as the measure includes the cost of Part B medications but not Part D medications. The commenters suggested CMS improve cost measurement for rheumatologists so that clinicians are not penalized if their patient population requires more Part B drugs than Part D drugs.

Response: We maintain the TPCC measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about previously finalized MVPs including the TPCC cost measure. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Rheumatology Patient Care MVP* as proposed in Table B.6 for the CY 2024 performance period/2026 MIPS payment year and future years.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

In the CY 2024 PFS proposed rule (88 FR 53185 through 53187), we proposed and solicited comments on the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. Table B.7 represents the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (87 FR 70690 through 70692) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.7.

Quality Measures

We proposed to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving emergency medical care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP address appropriate use of medication and diagnostic testing:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years: This appropriate use MIPS quality measure evaluates the appropriate use of head computed tomography (CT) in pediatric patients presenting with minor blunt head trauma.
- HCPR24: Appropriate Utilization of Vancomycin for Cellulitis: This appropriate use QCDR measure evaluates for appropriate antibiotic ordering for patients diagnosed with cellulitis.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We proposed to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- ACEP21: Coagulation Studies in Patients Presenting with Chest Pain with No Coagulopathy or Bleeding

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of clinician well-being:

- IA_BMH_12: Promoting Clinician Well-Being

We also proposed to remove the following improvement activities after consideration of feedback received from the public through the MVP maintenance process:

- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

In addition, we proposed to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of emergency medicine. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in emergency medicine and aligns with the other measures and activities included within this MVP:

- Emergency Medicine: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who have an emergency department (ED) visit during the performance period. This measure includes costs of Part A and B services during each episode from the start of the ED visit that opens, or "triggers," the episode through 14 days after the trigger, excluding a defined list of services for each ED visit type that are unrelated to the ED care. This is a new measure that will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.

We also proposed to remove the following cost measure because the Emergency Medicine episode-based cost measure more closely aligns with the measures and activities included in this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician

TABLE B.7: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.7 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(+)(*) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium)	**(^)(+) Emergency Medicine**

(*) Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Collection Type: MIPS CQMs Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) **(+)(!) Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) **(!) ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) **(!) ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR) **(+)(!) HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **(+) IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

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Comment: One commenter supported the addition of Q65: Appropriate Treatment for Upper Respiratory Infection (URI) and Q416: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2-17 Years. A couple of commenters supported the inclusion of Q487: Screening for Social Drivers of Health. Another commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways in this MVP. One commenter supported the addition of the Emergency Medicine cost measure.

Response: We thank the commenter for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure to each of the new and previously finalized MVPs. Another commenter recommended the addition of Q066: Appropriate Testing for Pharyngitis, Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy, and Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis to this MVP. The commenter noted to incentivize movement towards MVPs, the scope of quality measures offered under this MVP must be broadened. The commenter noted providing emergency physicians with a more diverse set of CQMs will help ensure practices of all sizes and levels of resource can take advantage of this new, more streamlined reporting pathway.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter didn't support the removal of ACEP21 from this MVP. They noted the historic escalation of the benchmark was primarily due to COVID-19 and as emergency departments have very little post-COVID experience, more information should be gathered before removal of the measure.

Response: We endeavor to include measures that allow for the achievement of maximum points and continue to drive quality improvement, establishing meaningful benchmarks. Additionally, this measure has included a denominator exception for COVID-19 since PY2022 and as such this patient population would be a null towards measure performance.

Comment: One commenter recommended the MSPB Clinician measure be maintained in this MVP alongside the Emergency Medicine episode-based cost measure until emergency physicians have experience with the new episode-based cost measure. The commenter also recommended that CMS only include the higher of the two measure scores in when calculating clinicians' cost performance category scores.

Response: We disagree with the commenter that the MSPB Clinician cost measure should be retained in this MVP. While the MSPB Clinician measure may capture Emergency Medicine clinicians, the measure intent is to assess care provided during inpatient hospitalizations The Emergency Medicine episode-based cost measure more closely aligns with the intent of the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine. For this reason, it is appropriate to only include the Emergency Medicine episode-based cost measure within this MVP. Additionally, the current MIPS scoring policy is to include all cost measures within an MVP in the cost performance category score calculation. As such, clinicians could be scored on the Emergency Medicine and MSPB Clinician cost measures if both measures were included within the MVP.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP* as proposed in Table B.7 for the CY 2024 performance period/2026 MIPS payment year and future years.

Improving Care for Lower Extremity Joint Repair MVP

In the CY 2024 PFS proposed rule (88 FR 53188 through 53189), we proposed and solicited comments on the previously finalized Improving Care for Lower Extremity Joint Repair MVP. Table B.8 represents the measures and activities that were finalized within the Improving Care for Lower Extremity Joint Repair MVP in (87 FR 70693through 70695) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.8.

Quality Measures

We proposed to modify the previously finalized Improving Care for Lower Extremity Joint Repair MVP to include one additional MIPS quality measure that is relevant to patients receiving care for lower extremity joint repair. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

TABLE B.8: Improving Care for Lower Extremity Joint Repair MVP

Table B.8 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Improving Care for Lower Extremity Joint Repair MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*)(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350**: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351**: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3**: Promote use of Patient-Reported Outcome Tools (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9**: Implementation of practices/processes for developing regular individual care plans (Medium)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

(*)(!) Q376: Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_15:** PSH Care Coordination (High) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27**: Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in this MVP. Another commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways.

Response: We thank the commenter for their support.

Comment: Commenters recommended additional quality measures be considered for this MVP. Recommendations included adding measures to address fracture-related care such as Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older and Q418: Osteoporosis Management in Women Who Had a Fracture. One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure while a couple commenters recommended the addition of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols to this MVP.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP

Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter requested clarification regarding Q487: Screening for Social Drivers of Health in this MVP. The commenter questioned if this measure is considered specialty specific to orthopedics and therefore the QCDR will be required to support the measure. If Q487 is considered specialty specific, the commenter requested the inclusion of Q487 as well as any future measures be delayed allowing time for the QCDR to update their data capture capacity and IT resources to capture quality data.

Response: This is an important process measure that supports the collection of DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure purely focuses on the completion of screening for DOH patient information and is consistent with the priority to advance health equity. We note the information a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Because clinicians have the flexibility to choose measures to report, it would be at their discretion whether to report this measure as requirements only include reporting of 4 quality measures; allowing clinicians to delay implementation of measures until their systems and workflows allow for complete data capture. Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, and improve a patient's overall health and well-being. [594, 595]

Comment: One commenter stated this MVP is specific to just one portion of an orthopedic provider's scope. They noted it would be helpful if this MVP were broader and included all areas in an orthopedic provider's scope to reduce the administrative burden placed on the health system.

Response: We may consider the inclusion of other quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* as proposed in Table B.8 for the CY 2024 performance period/2026 MIPS payment year and future years.

[594] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. Annals of Internal Medicine, 168(8), 577–578. https://doi.org/10.7326/M17-2441.

[595] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at https://doi.org/10.31478/201705b.

Patient Safety and Support of Positive Experiences with Anesthesia MVP

In the CY 2024 PFS proposed rule (88 FR 53190 through 53191), we proposed and solicited comments on the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP. Table B.9 represents the measures and activities that were finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP in (87 FR 70695 through 70697) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.9.

Quality Measures

We proposed to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to include one additional MIPS quality measure and two additional QCDR measures that are relevant to patients receiving anesthesia care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measures proposed within this MVP address appropriate utilization of general anesthesia and rates of intraoperative hypotension:

- ABG44: Low Flow Inhalational General Anesthesia: This QCDR measure identifies adult patients undergoing elective procedures, lasting at minimum 30 minutes, that require inhalational general anesthesia to assess for appropriate total fresh gas flow during the maintenance phase of the anesthetic.
- EPREOP31: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases: This outcome QCDR measure identifies adult patients undergoing noncardiac, non-emergency surgery requiring general, neuraxial, or regional anesthesia care to evaluate if the patient had a mean arterial pressure (MAP) below 65 mmHg exceeding a cumulative length of 15 minutes.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We also proposed to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- AQI69: Intraoperative Antibiotic Redosing

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

TABLE B.9: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.9 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Patient Safety and Support of Positive Experiences with Anesthesia MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost

(!!) Q404: Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) **(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q463**: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(+)(!) ABG44:** Low Flow Inhalational General Anesthesia (Collection Type: QCDR) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) **(+)(!!) EPREOP31**: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_15:** PSH Care Coordination (High) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs(Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting	

	Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: A few commenters supported the inclusion of ePreop31: Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases in this MVP. One commenter also supported the inclusion of ABG44: Low Flow Inhalational General Anesthesia measure. Another commenter supported the inclusion of Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. And one commenter supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider to this MVP.

Response: We may consider the inclusion of Q498: Connection to Community Service Provider measure through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter noted that with the proposal to include Q487: Screening for Social Drivers of Health in the anesthesia MVP, it would be appropriate that CRNAs be recognized for providing this service in practice. Therefor the commenter is requesting that CRNAs be allowed to Use Stand Alone G Code for Preanesthesia Patient Assessment and Evaluation and as Part of Evaluation and Management for Pain Management Practices.

Response: We thank the commenter for supporting the addition of measure Q487 to this MVP and feedback regarding coding.

Comment: One commenter opposed the removal of AQI69: Intraoperative Antibiotic Redosing from this MVP as this measure has implications for preventing surgical site infections and other complications and can lead to wider quality improvement activities locally and across specialties.

Response: We endeavor to include measures that allow for the achievement of maximum points and continue to drive quality improvement, establishing meaningful benchmarks. Removal of this measure does not preclude clinicians from completing this quality action and clinicians should continue to maintain current standards for quality care.

Comment: One commenter recommended delaying implementation of Q487: Screening for Social Drivers of Health in this MVP until at least 2025. They are concerned the Q487 measure specifications do not reflect anesthesia workflows and do not include codes that the vast majority of anesthesiologists report.

Response: This is an important process measure that supports the collection of DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure purely focuses on the completion of screening for DOH patient information and is consistent with the priority to advance health equity. We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures within an MVP will be applicable or appropriate to all clinicians who may choose to report. However, no quality measures within the MVP are required. We allow for clinician choice to account for these nuances, while ensuring clinicians are able to choose measures that are most meaningful to their scope of care and patient case-mix. The goal is to ensure we have a comprehensive set of measures to drive positive health outcomes as well as allow flexibility in clinician choice when determining the appropriateness of each measure.We note the information a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, and improve a patient's overall health and well-being. We will take this feedback into consideration during the annual update process for potential future revisions.

After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* as proposed in Table B.9 for the CY 2024 performance period/2026 MIPS payment year and future years.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

In the CY 2024 PFS proposed rule (88 FR 53192 through 53193), we proposed and solicited comments on the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. Table B.10 represents the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in (87 FR 70698 through 70700) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are embedded within Table B.10.

Quality Measures

We proposed to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we proposed to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity, incorporating patient voices into health care decision making, and behavioral and mental health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_15: Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults

TABLE B.10: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.10 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium)	**Intracranial Hemorrhage or Cerebral Infarction**

(*) Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q409:** Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_24:** Financial Navigation Program (Medium) **(^)(+) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

	ONC Direct Review Attestation
Comment: One commenter supported the inclusion of Q487: Screening for Social Drivers of Health in this MVP. A couple of commenters supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols. Another commenter agreed with the addition of IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings, and IA_BMH_15: Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults in this MVP. A couple of commenters supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. **Response:** We thank the commenters for their support. **Comment:** One commenter recommended the addition of Q498: Connection to Community Service Provider and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be added to this MVP. **Response:** We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. **Comment:** One commenter opposed the inclusion of Q487: Screening for Social Drivers of Health in this MVP as the measure is a process measure without any follow-up or outcome. The commenter noted that in the past these types of measures for neurology-specific items have been declined. The commenter also noted the measure could be demotivational to the neurology community and is more appropriate for a patient's primary care provider or medical home team as they coordinate care. In addition, the commenter is concerned with the burden that this measure may place on institutional quality improvement efforts and on Qualified Clinical Data Registries (QCDRs). **Response:** This is an important process measure that supports the collection of DOH data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. This measure purely focuses on the completion of screening for DOH patient information and is consistent with the priority to advance health equity. We note the information a clinician collects during a DOH screening may be clinically relevant and may not have otherwise been collected by the clinician absent the screening. As such, better scores on this measure are still indicators of the quality of care provided to patients. Because clinicians have the flexibility to choose measures to report, it would be at their discretion whether to report this measure as requirements only include reporting of 4 quality measures. Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, and improve a patient's overall health and well-being. [596, 597] After consideration of public comments, we are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* as proposed in Table B.10 for the CY 2024 performance period/2026 MIPS payment year and future years.	

[596] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. Annals of Internal Medicine, 168(8), 577–578. https://doi.org/10.7326/M17-2441.

[597] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at https://doi.org/10.31478/201705b.

Value in Primary Care MVP

In the CY 2024 PFS proposed rule (88 FR 53193 through 53197), we proposed and solicited comments on the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Table B.11 represents the measures and activities that were finalized within the Promoting Wellness MVP (87 FR 70673 through 70678) and the Optimizing Chronic Disease Management MVP (87 FR 70684 through 70686) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years. This MVP also aligns with the Adult Universal Core Set/Patient Care First CMMI Model primary care measures. The summary of the public comments received and our responses for this MVP are embedded within Table B.11.

Quality Measures

We proposed to modify the previously finalized Promoting Wellness MVP to include six additional MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address appropriate clinical care for patients receiving primary or preventive care including well visits or condition specific visits in the auspices of primary care:

- Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): This inverse outcome MIPS quality measure assesses diabetic patients for poor control of their HbA1c.
- Q236: Controlling High Blood Pressure: This outcome MIPS quality measure assesses patient diagnosed with hypertension for adequately controlled blood pressure.
- Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new substance use disorder (SUD) episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.
- Q497: Preventive Care and Wellness (composite): This composite MIPS quality measure combines 7 current preventive care measures with age and sex appropriate preventive screenings and wellness services, creating a robust, broadly encompassing preventive care assessment. The measure would set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care, and ensuring more all-inclusive preventive care.
- Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.

We proposed to modify the previously finalized Promoting Wellness MVP to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address health equity, immunization status, and the patient's wishes:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker for patients aged 65 years and older.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

We also proposed to modify the previously finalized Promoting Wellness MVP to remove four MIPS quality measures that would be replaced by MIPS quality measure Q497: Preventive Care and Wellness (composite), which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult preventive care, improving quality care and preventing/controlling disease for the general patient population. The quality actions represented in the measures below would be captured in the composite measure:

- Q112: Breast Cancer Screening
- Q113: Colorectal Cancer Screening
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Additionally, the following five measures are being proposed for removal to streamline the clinical concepts within the Value in Primary Care MVP to align with the clinical concepts of preventive care, quality chronic disease

management, and alignment with the Adult Universal Foundation measures.[598] The below MIPS quality measures represent important preventive screening and patient voice measures clinical concepts and as such, the measure or concept can be found in other MVPs:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
- Q309: Cervical Cancer Screening
- Q310: Chlamydia Screening in Women
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Improvement Activities

For the reasons stated in the introduction of this appendix, we proposed to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we proposed to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including equity, food insecurity, and clinical decision support (CDS):

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_22: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- IA_PM_23: Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

We also proposed to remove the following two improvement activities in response to interested-party feedback:

- IA_BMH_9: Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

We proposed to add four MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. The additional cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Asthma/COPD: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat asthma or COPD.
- Diabetes: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat diabetes.
- Depression: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression.
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure. This is a new measure that will be used in MIPS beginning in CY 2024 performance period/ 2026 MIPS payment year, as finalized in section IV.A.4.f.(2) of this final rule.

TABLE B.11: Value in Primary Care MVP

Table B.11 serves to represent the measures and activities that are additions or modifications to the previously finalized measures and activities within the Value in Primary Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

[598] D.B. Jacobs, M. Schreiber, M. Seshamani, D. Tsai, E. Fowler, L.A. Fleisher. Aligning quality measures across CMS—The universal foundation: N Engl J Med (2023).

Quality	Improvement Activities	Cost
(+)(*)(!!) Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+)(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(+)(!) Q305:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (Collection Type: eCQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(+)(*) Q438:** Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*) Q493**: Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^)(+) Q497:** Preventive Care and Wellness (composite) (Collection Type: MIPS CQMs Specifications) **(+)(!) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(+)(~) IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^)(+) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(^)(+) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **(^)(+) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines (Medium)	**(+) Asthma/COPD** **(+) Diabetes** **(^)(+) Depression** **(^)(+) Heart Failure** **Total Per Capita Cost (TPCC)**
Foundational Layer		

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Comment: A few commenters expressed support for the following quality measures: Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), Q236: Controlling High Blood Pressure, Q475: HIV Screening, Q487: Screening for Social Drivers of Health, Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM), and Q493: Adult Immunization Status. A few commenters also supported the addition of IA_PM_22: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services improvement activity in this MVP. A couple commenters supported the inclusion of Q497: Preventive Care and Wellness (composite) measure. One commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols while another supported the inclusion of IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways. A couple commenters supported inclusion of the following three cost measures: Asthma/COPD, Diabetes, and Heart Failure. Several commenters supported the consolidation of the previously finalized Optimizing Chronic Disease Management and Promoting Wellness MVPs into this primary care MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended the addition of Q498: Connection to Community Service Provider quality measure and a couple of commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure be added to this MVP. One commenter recommended the addition of several quality measures including Q238: Use of High-Risk Medications in Older Adults, Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture, Q065: Appropriate Treatment for Upper Respiratory Infection (URI), and Q130: Documentation of Current Medications in the Medical Record. Another commenter recommended the inclusion of Q488: Kidney Health Evaluation to this MVP. The commenter noted Q488 would encourage physicians to ensure that individuals with diabetes receive an annual kidney health evaluation. An additional commenter recommended adding measures to address fracture-related care such as Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older and Q418: Osteoporosis Management in Women Who Had a Fracture.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: Several commenters opposed the inclusion of Q497: Preventive Care and Wellness (composite) measure in this MVP. The commenters noted the measure is not included in the Universal Foundation. In addition, they noted the BMI screening component of the composite measure is outdated, no longer endorsed by a consensus-based entity, and may not be appropriate for elderly patients. The commenters believe there will be interoperability challenges that could prevent primary care physicians from reliably receiving data on patients' screening mammograms, which could negatively impact performance on the composite measure. Furthermore, the commenters shared that reporting the composite measure only counts as one quality measure when it represents the delivery of multiple high-value services. Therefore a physician who elects to report this measure would need to collect and report a total of 10 measures to satisfy the quality requirements for the MVP, which is higher than traditional MIPS and serves as a disincentive to select it. The commenters recommended maintaining the following quality measures in place of Q497: Preventive Care and Wellness (composite) measure; Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q226: Preventive Care and Screening: Tobacco Use Screening and

Cessation Intervention. Other commenters that were not opposed to the inclusion of Q497: Preventive Care and Wellness (composite) measure recommended retaining the following quality measures because they provide additional collection types:
Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, and Q309: Cervical Cancer Screening.

Response: This measure combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services, to create a robust, broadly encompassing preventive care assessment. Many of the individual components within this composite are either included in the Universal Foundation or are considered core measure concepts that align with the Core Quality Measure Collaborative (CQMC) core measure set(s), thus have been determined to be an important part of patient health and support healthy outcomes. This includes documenting a patient's BMI and a follow-up plan when the BMI is outside of normal parameters as BMI correlates with health outcomes and cause-specific mortality[599], however we recognize that there are clinical limitations of BMI and as such it should not be used as a diagnostic tools, but as an initial screening.[600] As it relates to concerns with system interoperability, the composite measure allows clinicians to capture this information via patient reported outcomes for some components. For example, patient reported mammograms, when recorded in the medical record, are acceptable for meeting the numerator.

We recognize this measure sets a more stringent performance standard than the component measures by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we will gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/*). Additionally, clinicians have the flexibility to choose measures to report within an MVP, performance isn't based solely on the reporting outcome of a single measure.

Comment: A couple commenters opposed the inclusion of Q493: Adult Immunization Status in this MVP. The commenters noted immunization registry challenges create significant administrative burden for primary care physicians reporting Q493, which can result in suboptimal performance on the measure at no fault to the physician. In addition the commenters stated that the use of immunization information systems (IIS), vaccination data from other settings is not consistently or reliably reported back to the primary care physician. The commenters urge CMS to partner with the Centers for Disease Control and Prevention, the Office of the National Coordinator for Health IT, and other federal partners to advance reliable, interoperable sharing of immunization data across the health care system.

Response: Because clinicians have the flexibility to choose measures to report within an MVP and this measure's performance is based on a weighted average of those measures, this measure provides a comprehensive adult immunization assessment. Each component measure allows patient reported vaccination to be documented in the medical record to meet performance. MIPS measures collect data on all payer sources and therefore captures a robust representation of performance. Data abstraction for calculation of this measure can be collected from multiple medical resources and isn't necessarily reliant on immunization registries. The measure contains denominator criteria that is specific to the targeted patient population for the vaccination represented in the component measures. Additionally, this composite measure contains denominator exceptions, applicable to all four submission criteria, that assist with identifying patients that may not be appropriate for vaccination.

Comment: A couple commenters opposed the inclusion of Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment and Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk in this MVP. The commenters agreed these are important priorities and recognizes their clinical significance. However, the commenters noted the data needed to report on these measures is not discretely captured in EHR systems without a significant investment of time and money which results in administrative and financial burden if the measures are reported.

Response: While we understand there may be challenges when opting to report a certain measure, the expectation is your system is able to accurately and securely capture and store patient data. We note clinicians have the flexibility to choose which measures to report within an MVP. If implementation challenges result in the inability to report the measures in question, clinicians may select other measures within the MVP. Given the clinical importance of the quality actions being assessed, we want to allow those clinicians that are able to report these quality measures that opportunity as they are aligned with the MVP clinical topic.

Comment: A few commenters opposed the consolidation of the Promoting Wellness MVP and the Optimizing Chronic Disease Management MVP into a single Value in Primary Care MVP. One commenter believes the Optimizing Chronic Disease Management MVP can accommodate other clinician types besides primary care, and that participation in a chronic care management MVP should not be limited to only primary care physicians. The commenter recommends that the Optimizing Chronic Disease Management MVP be maintained to allow specialists who manage chronic conditions to report under this MVP. Another commenter believes there is a distinction between these two critical aspects of a primary care clinician's practice and consolidating the two existing MVPs is untenable.

Response: The modified Primary Value in Primary Care MVP isn't limited to a particular specialty and represents measures and activities that were finalized within the Promoting Wellness MVP and the Optimizing Chronic Disease Management MVP. An MVP may be reported by any clinician type if MVP submission requirements can be met. While we agree specialists who manage chronic conditions are distinct from primary care providers, we would encourage those clinicians to choose an MVP that is more aligned with their scope of care. However, as there aren't individual MVPs that represent each specialty, this consolidated MVP can be reported when appropriate and applicable to the clinician/group.

Comment: One commenter recommended broader HIV testing due to the growing number of older individuals with HIV/AIDS.

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[599] Khanna D, Peltzer C, Kahar P, Parmar MS. Body Mass Index (BMI): A Screening Tool Analysis. Cureus. 2022 Feb 11;14(2):e22119. doi: 10.7759/cureus.22119. PMID: 35308730; PMCID: PMC8920809.

[600] https://www.cdc.gov/healthyweight/assessing/bmi/index.html.

Response: We agree that HIV screening and treatment are important clinical topics, and we encourage the commenter to reach out to the measure steward for potential measure revisions for potential future implementation through rulemaking.

Comment: Several commenters supported the episode-based cost measures included in this MVP. However, the commenters didn't support the inclusion of the TPCC cost measure and stated it is not designed to capture the long-term cost savings that primary care is known to achieve. The commenters also noted there are numerous variables that can affect cost, many of which primary care physicians cannot control even when providing the best possible care. Additionally, the commenters expressed concerns with potential double counting of costs for participants in this MVP, which is currently proposed to include episode-based cost measures and the TPCC measure.

Response: We agree it is appropriate to include episode-based cost measures within this MVP. We maintain the TPCC measure is appropriate for use in this MVP, as we have outlined in the CY 2023 PFS final rule (87 FR 70673 through 70678), because it assesses the cost of care provided for a primary care. We refer readers to the CY 2023 PFS proposed rule (87 FR 46825 through 46828) and the CY 2023 PFS final rule (87 FR 70038) for more information about the use of TPCC in this MVP, which was previously titled Promoting Wellness. Additionally, we may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Value in Primary Care MVP* as proposed in Table B.11 for the CY 2024 performance period/2026 MIPS payment year and future years.

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Part III

Nuclear Regulatory Commission

10 CFR Parts 50, 52, and 72
Emergency Preparedness for Small Modular Reactors and Other New Technologies; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 52, and 72

[NRC–2015–0225]

RIN 3150–AJ68

Emergency Preparedness for Small Modular Reactors and Other New Technologies

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include new alternative emergency preparedness requirements for small modular reactors and other new technologies. This final rule acknowledges technological advancements and other differences from large light-water reactors that are inherent in small modular reactors and other new technologies. The NRC is concurrently issuing Regulatory Guide 1.242, ''Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities.''

DATES: This final rule is effective on December 18, 2023.

ADDRESSES: Please refer to Docket ID NRC–2015–0225 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2015–0225. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–3874, email: *Robert.Beall@nrc.gov* and Eric Schrader, Office of Nuclear Security and Incident Response, telephone: 301–287–3789, email: *Eric.Schrader@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

Certain existing requirements and guidance are focused on large light-water reactors (LWRs) and currently operating non-power reactors (also referred to as research and test reactors), as defined in part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities.'' Through this final rule, the NRC is amending its regulations to create an alternative emergency preparedness (EP) framework for small modular reactors (SMRs) and other new technologies (ONTs). These new alternative EP requirements and implementing guidance in Regulatory Guide 1.242 adopt a performance-based, technology-inclusive, risk-informed, and consequence-oriented approach. The new alternative EP requirements (1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by an SMR or ONT licensee; (2) promote regulatory stability, predictability, and clarity; (3) reduce the need for requests for exemptions from EP requirements; (4) recognize advances in design and technological advancements embedded in design features; (5) credit safety enhancements in evolutionary and passive systems; and (6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This final rule and guidance could affect existing SMR and non-LWR applicants and licensees as well as SMRs, non-LWRs, and non-power production or utilization facilities that would be licensed after the effective date of this final rule. Those applicants and licensees have the option to develop a performance-based EP program as an alternative to using the existing, deterministic EP requirements in 10 CFR part 50. This final rule does not include within its scope emergency planning, preparation, or response for large LWRs, fuel cycle facilities,[1] or currently operating non-power reactors. For the purposes of this final rule, large LWRs are reactors that are licensed to produce greater than 1,000 megawatts thermal power.

B. Major Provisions

Major provisions of this final rule and guidance include the addition of:

- A new alternative performance-based EP framework, including requirements for demonstrating effective response in drills and exercises for emergency and accident conditions;
- A requirement for a hazard analysis of any facility contiguous to or near an SMR or ONT, that considers any hazard that would adversely impact the implementation of emergency plans developed under this framework;
- A scalable approach for determining the size of the plume exposure pathway emergency planning zone; and
- A requirement to describe ingestion response planning in the emergency plan, including the offsite capabilities and resources available to prevent contaminated food and water from entering the ingestion pathway.

C. Costs and Benefits

The NRC prepared a final regulatory analysis of the expected quantitative costs and benefits of this final rule and associated guidance as well as the qualitative factors considered in the NRC's rulemaking decision. The conclusion from the analysis is that this final rule and associated guidance result in net averted costs to the industry and the NRC ranging from $7.98 million using a 7-percent discount rate to $14.9 million using a 3-percent discount rate.

The regulatory analysis considered qualitative aspects, such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits result from applicants and licensees not needing to use the exemption process to establish EP criteria commensurate with design- and site-specific considerations. Another

[1] Emergency planning requirements for facilities licensed under 10 CFR part 70, ''Domestic Licensing of Special Nuclear Material,'' are set forth in § 70.22(i).

qualitative consideration is promoting a performance-based regulatory framework that specifies requirements to be met and provides flexibility to an applicant or licensee regarding the information or approach needed to satisfy those requirements.

For more information, the final regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document.

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I. Background

In December 2016, the NRC developed and published ''NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness,'' with a goal to further develop the NRC's non-light-water reactor (non-LWR) regulatory, technical, and policy infrastructure to be ready to review potential licensing applications for non-LWR technologies. This final rule contributes to the NRC's efforts to optimize non-LWR regulatory readiness. In particular, the NRC's objective for this final rule is to create alternative emergency preparedness (EP) requirements that: (1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by a small modular reactor (SMR) or other new technology (ONT) licensee; (2) promote regulatory stability, predictability, and clarity; (3) reduce the need for requests for exemptions from EP requirements; (4) recognize advances in design and technology advancements embedded in design features; (5) credit safety enhancements in evolutionary and passive systems; and (6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products.

Within the **SUPPLEMENTARY INFORMATION** section of this document, the NRC uses the term ''ONTs'' to refer to new technologies, such as non-LWRs and medical radioisotope facilities licensed under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR). Further, within this document, the NRC uses the term ''existing'' or ''current'' in the context of the NRC's regulations to mean the requirements in § 50.47, ''Emergency plans,'' and appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' before December 18, 2023 and, when referring to applicants or licensees for an SMR or ONT facility, to mean applicants or licensees for an SMR or ONT facility as of December 18, 2023.

This final rule also defines ''non-power production or utilization facility'' (NPUF) to clarify the applicability of the performance-based EP framework. The definition includes production or utilization facilities, licensed under § 50.21(a), § 50.21(c), or § 50.22, as applicable, that are not nuclear power reactors or production facilities as defined under paragraphs (1) and (2) of the definition of *Production facility* in § 50.2. In the context of this final rule, medical radioisotope facilities licensed under 10 CFR part 50 are included within this definition of NPUF. The term ''non-power production or utilization facility'' is used in this final rule to distinguish between those medical radioisotope facilities licensed as production or utilization facilities under 10 CFR part 50 and other facilities to be used for the production of medical radioisotopes licensed under the regulations in 10 CFR parts 30, ''Rules of General Applicability to Domestic Licensing of Byproduct Material,'' 40, ''Domestic Licensing of Source Material,'' and 70, ''Domestic Licensing of Special Nuclear Material.'' Those facilities licensed under 10 CFR parts 30, 40, or 70 are subject to existing emergency planning requirements in those parts. Relevant 10 CFR part 70 fuel facility emergency planning considerations (*e.g.,* inadvertent criticality accidents and hazardous chemical exposures) applicable to 10 CFR part 50 production facilities have been incorporated into this final rule and associated guidance. As such, the scope of this final rule is limited to those ONT facilities (*e.g.,* non-LWRs licensed as power reactors, new non-power reactors, and medical radioisotope facilities) for which the NRC expects to receive license applications under 10 CFR parts 50 or 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' Those NPUFs that are not considered ONTs (*i.e.,* currently operating non-power reactors) are not within the scope of this final rule. Currently operating non-power reactors continue to implement existing emergency planning requirements and guidance.

A. Existing Emergency Preparedness Framework for Nuclear Power Reactors

Appendix E to 10 CFR part 50 identifies the specific items currently required to be included in emergency plans. Additionally, § 50.47 provides EP requirements for nuclear power reactors, including planning standards for onsite and offsite emergency response plans. Other relevant regulations include paragraphs (q), (s), and (t) of § 50.54, ''Conditions of licenses.''

For large LWRs, the most notable guidance documents for the development and maintenance of emergency plans are: NUREG–0654/FEMA–REP–1, Revision 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' dated November 1980, which provides guidance and evaluation criteria for the development and evaluation of operating power reactors' and offsite response organizations' (OROs) radiological emergency response plans; NUREG–0654/FEMA–REP–1, Revision 2, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' dated December 2019, which reflects changes to NRC regulations, guidance, and policies, as well as advances in technology and best practices that occurred since issuance of the 1980 version; Regulatory Guide (RG) 1.219, Revision 1, ''Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors,'' dated July 2016, which provides guidance for operating power reactor licensees implementing requirements in § 50.54(q) for evaluating and making changes to emergency plans; NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Section 13.3, ''Emergency Planning,'' dated March 2007, which provides the criteria that the NRC uses in reviewing applicants' emergency plans as described in the applications' safety analysis reports; and NUREG–0800, Section 14.3.10, ''Emergency Planning—Inspections, Tests, Analyses, and Acceptance Criteria,'' dated March 2007, which provides the criteria that the NRC uses in reviewing 10 CFR part 52 applicants' proposed inspections, tests, and analyses applicable to emergency planning that the licensee performs, and the associated acceptance

criteria. This regulatory framework has defined the EP programs for the current operating fleet of power reactors for several decades. These standards have been effectively used in practice and provided a basis to draw from in developing this EP regulatory framework for SMRs and ONTs.

Currently, applicants for light-water SMR licenses can use the guidance used by large LWRs described in the preceding paragraph. Applicants for non-LWR licenses can use NUREG–0654/FEMA–REP–1, Revision 1 or 2; RG 1.219, Revision 1; and RG 1.233, Revision 0, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' which provides guidance on the selection of licensing-basis events; classification and special treatments of structures, systems, and components; and assessment of defense in depth.

B. Existing Emergency Preparedness Framework for Non-Power Production or Utilization Facilities

The EP requirements applicable to a particular applicant or licensee can vary depending on the type of facility. In the August 19, 1980, final rule, ''Emergency Planning'' (45 FR 55402) (referred to herein as the ''1980 Final Rule''), the NRC established in appendix E to 10 CFR part 50 emergency planning requirements for research and test reactors (RTRs) that reflected the lower potential radiological hazards associated with these facilities. The RTRs and other NPUFs must meet the emergency planning requirements of §§ 50.34(a)(10), 50.34(b)(6)(v), and 50.54(q) and appendix E to 10 CFR part 50. The requirements of § 50.47 do not apply to RTRs and other NPUFs. Additionally, in section I.3. of appendix E to 10 CFR part 50, the NRC differentiates between emergency planning requirements for nuclear power reactors and those for other facilities, stating that the size of emergency planning zones (EPZs) and the degree to which compliance with sections I through V of appendix E to 10 CFR part 50 is necessary are determined on a case-by-case basis for facilities other than power reactors.

Further, footnote 2 of appendix E to 10 CFR part 50 provides that RG 2.6, ''Emergency Planning for Research and Test Reactors,'' is used as guidance for the acceptability of RTR emergency response plans. Regulatory Guide 2.6 was initially issued in January 1979 and most recently updated to Revision 2, ''Emergency Planning for Research and Test Reactors and Other Non-power Production and Utilization Facilities,'' in September 2017. Consistent with the radiological risks associated with operating power levels between 5 watts thermal and 20 megawatts thermal (MWt) for currently operating RTRs, RG 2.6, Revision 2 endorses the use of the emergency planning guidance based on source term and power level contained in American National Standards Institute (ANSI) and American Nuclear Society (ANS) standard ANSI/ANS–15.16–2015, ''Emergency Planning for Research Reactors.'' Similarly, RG 2.6, Revision 2 endorses the use of ANSI/ANS–15.16–2015 for other NPUFs. The ANSI/ANS–15.16, originally developed in 1982, and updated in 2008 and 2015, provides specific criteria and guidance for RTRs to comply with the applicable requirements set forth in §§ 50.34, ''Contents of applications; technical information,'' and 50.54, and appendix E to 10 CFR part 50.

In October 1983, the NRC issued NUREG–0849, ''Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors.'' Consistent with ANSI/ANS–15.16, NUREG–0849 provides areas of review, planning standards, and evaluation items for the NRC to evaluate compliance with the applicable emergency planning requirements, previously described. Notably, the guidance contained in both ANSI/ANI–15.16 and NUREG–0849 addresses EPZs for RTRs ranging from the operations boundary [2] to 800 meters from the operations boundary for facilities up to 50 MWt. Both guidance documents state that the EPZs for facilities operating above 50 MWt are to be considered on a case-by-case basis. Section 12.7, ''Emergency Planning,'' of the non-power reactor standard review plan, NUREG–1537, Parts 1 and 2, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-power Reactors'' and the Interim Staff Guidance augmenting NUREG–1537, Parts 1 and 2, for the licensing of radioisotope production facilities and aqueous homogeneous reactors provide additional emergency planning considerations for NPUFs. For example, this additional guidance includes relevant radioisotope production facility emergency planning considerations (*e.g.,* hazardous chemicals) contained in the Interim Staff Guidance augmenting NUREG–1537 based on NUREG–1520, Revision 1, ''Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.''

These criteria and guidance provide a basis for NPUF applicants and licensees to develop acceptable emergency response plans for their facilities. This existing regulatory framework for EP at NPUFs provides the planning necessary to reflect the lower potential radiological hazards associated with the operation of these facilities compared to large LWRs. These EP standards provide additional information for developing the consequence-oriented approach to establishing EPZs and the planning commensurate with the radiological risk for SMRs and ONTs.

C. Evolution of the Emergency Preparedness Regulatory Framework for Small Modular Reactors and Other New Technologies

The use and regulation of small reactors and other advanced reactor designs have been active topics of discussion between the NRC and the nuclear reactor industry for more than 30 years. The NRC has worked with stakeholders to develop an initial framework for the implementation of performance-based EP regulations and licensing of non-LWR designs, culminating in the current EP rulemaking activities. This section describes the history of small and advanced reactor designs that led to this final rule.

1. Emerging Interest in Advanced Nuclear Reactor Technology

Concurrent with large LWR deployment and design evolution, the United States and other countries have developed and promoted several different reactor designs that are either light-water SMRs with passive safety features or reactors that do not use light-water as a coolant. This latter category is commonly referred to as non-LWR technology. Advanced designs using non-LWR technology include liquid-metal-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. These advanced designs could have a rated thermal power ranging from low to very high and may apply modular construction concepts.

As advanced reactor technology evolved in the 1980s and early 1990s, the NRC considered the prospect of a regulatory regime for these emerging technologies. On July 8, 1986, the Commission issued a policy statement, ''Regulation of Advanced Nuclear Power Plants, Statement of Policy'' (51 FR

[2] As defined in ANSI/ANS–15.16–2015, ''operations boundary'' refers to the area within the site boundary such as the reactor building (or the nearest physical personnel barrier in cases where the reactor building is not a principal physical personnel barrier) where the reactor chief administrator has direct authority over all activities.

24643), outlining the Commission's early thoughts on the regulation of advanced reactor designs. In the policy statement, the Commission provided a high-level framework for the review and consideration of advanced reactor designs. Following issuance of the policy statement, the NRC published NUREG–1226, ''Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants'' in June 1988 to provide guidance on implementing and utilizing the policy statement. With the issuance of this initial guidance came questions concerning EP requirements for such designs.

In response, the NRC staff proposed in SECY–93–092, ''Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements,'' [3] dated April 8, 1993, that no change to existing EP regulations for advanced reactors was then needed. The NRC staff noted that regulatory direction would be given at or before the start of the design certification phase of advanced reactors so that design implications for EP could be addressed in the licensing process.

The Commission agreed and stated in the Staff Requirements Memorandum (SRM) for SECY–93–092, dated July 30, 1993, that it was premature to reach a conclusion on EP for advanced reactors and that existing regulatory requirements should be used for ongoing review processes. However, the Commission directed that:

> [T]he staff should remain open to suggestions to simplify the emergency planning requirements for reactors that are designed with greater safety margins. To that end, the staff should submit to the Commission recommendations for proposed technical criteria and methods to use to justify simplification of existing emergency planning requirements.

In response to the Commission's direction, the NRC performed an evaluation to develop technical criteria and methods for EP for evolutionary and advanced reactor designs. The evaluation focused on evolutionary and passive advanced LWR designs due to the availability of design and risk assessment data and because applicants were pursuing certification of these designs. In SECY–97–020, ''Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors,'' dated January 27, 1997, the staff determined that the rationale upon which EP for current reactor designs is based, that is, potential consequences from a spectrum of accidents, is appropriate for use as the basis for EP for evolutionary and passive advanced LWR designs and is consistent with the Commission's defense-in-depth safety philosophy.

In the early 2000s, performance-based EP became an important component of LWR licensing and relicensing discussions. As part of an EP exemption request review, in SECY–04–0236, ''Southern Nuclear Operating Company's Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters,'' dated December 23, 2004, the staff noted the following:

> [A]s part of the top-down review of Emergency Preparedness, the staff has identified 10 CFR 50 Appendix E section E.8 and 10 CFR 50.47(b)(3) as opportunities to enhance the emergency preparedness regulatory structure. The staff will propose rulemaking to remove ''near-site'' from the regulations, as a more performance-based requirement is appropriate. . . .

The Commission agreed, highlighting the potential value of performance-based EP for LWRs in the SRM for SECY–04–0236, dated February 23, 2005, as follows:

> The staff should consider revising 10 CFR part 50 to make the requirements for EOFs [emergency operations facilities] more performance-based to allow other multi-plant licensees to consolidate their EOFs, if those licensees can demonstrate their emergency response strategies will adequately cope with an emergency at any of the associated plants.

In this decision, the Commission allowed for the development of a performance-based EP requirement.

In SECY–06–0200, ''Results of the Review of Emergency Preparedness Regulations and Guidance,'' dated September 20, 2006, the staff sought Commission approval to explore the feasibility of a voluntary, performance-based EP regulatory regimen. Specifically, the staff stated:

> [A]s the EP program has matured and industry performance has improved, the staff recognized the benefits of a performance-based regulatory structure. Thus, the staff is proposing a new voluntary performance-based regulatory regimen. The staff has conceptualized the basis for a voluntary performance-based EP regulatory regimen. . . . This regimen could be adopted in lieu of the existing EP regulations contained in 10 CFR part 50. The current regimen tends to emphasize compliance with, and control over, emergency plans and facilities. The performance-based regimen would focus licensee efforts on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight would focus on licensee performance, instead of licensee processes and procedures. Creating a performance-based EP regulatory regimen could achieve a higher level of preparedness, as the regimen would focus on results and abilities rather than on means. The performance-based regimen would provide the NRC with enhanced oversight of the actual competencies important to protection of public health and safety while allowing licensees increased flexibility.

In SECY–06–0200, the staff also outlined several high-level performance-based concepts for large LWRs related to performance goals, staffing, and performance indicators (PIs). In the SRM for SECY–06–0200, dated January 8, 2007, the Commission approved several staff recommendations, including the staff's request to begin activities to explore a voluntary performance-based EP regulatory concept.

During the early development of a performance-based EP regulatory concept, the NRC published a ''Policy Statement on the Regulation of Advanced Reactors,'' dated October 14, 2008 (73 FR 60612). The policy statement expressed the Commission's expectation that advanced reactor designers would ensure that security and emergency response are considered alongside safety during the early stages of plant design.

By 2014, the NRC had finalized its study and review of the potential to enhance the oversight of performance-based nuclear power plant EP programs as directed in the SRM for SECY–06–0200. In SECY–14–0038, ''Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight,'' dated April 4, 2014, the staff stated:

> A systematic review and revision of EP requirements to employ a more performance-based oversight regimen (regulation, inspection, and enforcement) has the potential to enhance many aspects of emergency response and oversight. A performance-based oversight regimen could simplify EP regulations and focus inspection more fully on response-related performance rather than the current focus on plan maintenance and compliance.

Although the staff asserted that the performance-based framework would simplify EP regulations and focus inspections more on response-related performance, the staff recommended that the existing framework continue to be used with operating plants because changing the EP approach for those plants would require significant resources and could introduce regulatory uncertainty. Additionally, the staff recognized that existing EP programs provided reasonable assurance of adequate protection of public health

[3] ''PRISM,'' ''MHTGR,'' ''PIUS,'' and ''CANDU'' are abbreviations for Power Reactor Innovative Small Module, Modular High-Temperature Gas-Cooled Reactor, Process Inherent Ultimate Safety, and CANadian Deuterium-Uranium, respectively.

and safety and therefore recommended maintaining the current EP regimen.

In the SRM to SECY–14–0038, dated September 16, 2014, the Commission directed that:

> The staff should be vigilant in continuing to assess the NRC's emergency preparedness program and should not rule out the possibility of moving to a performance-based framework in the future. The Commission notes the potential benefit of a performance-based emergency preparedness regimen for small modular reactors, and the staff should return to the Commission if it finds that conditions warrant rulemaking.

2. Approach to Emergency Preparedness for Small Modular Reactors and Other New Technologies

In the late 2000s, the discussion of modernizing EP and developing alternative performance-based requirements for LWRs merged with the NRC's ongoing discussions of advanced reactor designs. By this time, several advanced reactor designs were under discussion in the U.S., including the U.S. Department of Energy's (DOE's) Next Generation Nuclear Plant and SMR programs, and by private sector companies seeking to introduce an alternative to large LWRs. By 2010, the NRC began considering the possibility of developing a performance-based approach to EP for SMRs and ONTs. In SECY–10–0034, ''Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs,'' issued on March 28, 2010, the staff identified EP as a key technical issue for the licensing of SMRs and other advanced reactor designs. The enclosure to the SECY stated that resolution of offsite EP requirements would be of interest to the Federal Emergency Management Agency (FEMA) and the public, as well as to applicants trying to support their business case at the design certification stage.

Contemporaneous with the issuance of SECY–10–0034, the NRC held a series of public meetings with other Federal agencies, industry leaders, and key stakeholders to discuss potential policy, licensing, and technical issues associated with advanced reactor designs. Summaries of the October 8–9, 2009, and July 28, 2010, meetings are available in ADAMS, as provided in the ''Availability of Documents'' section of this document. Discussions included the proposed framework of potential EP requirements. Emergency preparedness was a significant policy issue for SMR designers because SMR designs may have reduced accident consequences offsite per reactor module, potentially forming the basis for smaller EPZs relative to large LWRs.

The staff discussed the public's input from those meetings in SECY–11–0152, ''Development of an Emergency Planning and Preparedness Framework for Small Modular Reactors'' on October 28, 2011. The paper informed the Commission of the staff's proposed actions to develop an emergency planning and preparedness framework for SMR facilities. In the document, the staff stated its intent to develop a technology-neutral (now technology-inclusive), dose-based, consequence-oriented EP framework for SMR sites that would take into account the various designs, modularity, and co-location of these facilities with other NRC-licensed facilities and industrial facilities not licensed by the NRC, as well as the size of the EPZs. The staff also stated that ''[t]he staff will work with stakeholders to develop general guidance on calculating the offsite dose, and is anticipating that the industry will develop and implement the detailed calculation method for review and approval by the staff.''

In response to SECY–11–0152, the Nuclear Energy Institute (NEI) prepared a white paper to provide perspective to the NRC and SMR developers in establishing EPZs for SMRs. In the ''White Paper on Proposed Methodology and Criteria for Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone,'' submitted in December 2013, NEI noted the NRC expectation in SECY–11–0152 that SMR license applicants will provide a well-justified technical basis for NRC's review and consideration. The 2013 White Paper was designed to ''discuss a generic methodology and criteria that can be adopted and used by the SMR developers and plant operating license applicants for establishing the design-specific and site-specific technical basis for SMR-appropriate EPZs.'' In the paper, NEI stated that the intent of the paper was to ''serve as a vehicle to support the continuing dialogue with the staff that should result in a mutually agreeable methodology and criteria, and thus provide the SMR developers and applicants sufficient guidance as they proceed to develop their design-specific and site-specific technical basis.'' As stated in the paper, NEI's approach was rooted in the following:

> (1) the expectation of enhanced safety inherent in the design of SMRs (*e.g.,* increased safety margin, reduced risk, smaller and slower fission product accident release, and reduced potential for dose consequences to population in the vicinity of the plant); (2) the applicable SECY–11–0152 concepts including utilization of existing emergency preparedness regulatory framework and dose savings criteria of NUREG–0396; and (3) the significant body of risk information available to inform the technical basis for SMR-appropriate EPZ, including severe accident information developed since NUREG–0396 was published in 1978, and information from the design-specific and plant-specific probabilistic risk assessments (PRAs) which will support SMR design and licensing.

The NEI 2013 White Paper addressed only SMRs with light-water-cooled and moderated designs and the plume exposure pathway EPZ. It did not address other designs or the ingestion pathway EPZ (IPZ). The NRC reviewed the White Paper and discussed the development of the regulatory framework with NEI and stakeholders; however, the NRC did not endorse the paper.

In the enclosure to SECY–10–0034, the staff stated, ''Should it be necessary, the staff will propose changes to existing regulatory requirements and guidance or develop new guidance concerning reduction of offsite emergency preparedness for SMRs in a timeframe consistent with the licensing schedule.'' In 2015, the NRC determined that SMR EP issues were a key concern for potential SMR and ONT applicants, and that addressing those issues would enhance regulatory predictability for both applicants and the NRC. In May 2015, the staff sought Commission approval to initiate rulemaking to revise the EP regulations and guidance for SMRs and ONTs. In SECY–15–0077, ''Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies,'' dated May 29, 2015, the staff proposed a consequence-oriented approach to establishing EP requirements commensurate with the potential consequences to public health and safety and the common defense and security at SMR and ONT facilities. The staff stated that the need for EP is based on the projected offsite dose in the unlikely occurrence of a severe accident. In SRM–SECY–15–0077, the Commission approved the staff's recommendation to proceed with rulemaking, keeping a performance-based framework in mind as previously directed in SRM–SECY–14–0038. The Commission further directed that, for any SMR reviews conducted prior to the establishment of a regulation, the staff should be prepared to adapt an approach to EPZs for SMRs under the exemption process.

In June 2015, NEI issued a White Paper supporting the NRC proposal in SECY–15–0077 and recommending the revision of EP regulations and guidance

for SMR facilities. In ''White Paper: Proposed Emergency Preparedness Regulations and Guidance for Small Modular Reactors Facilities,'' dated July 2015, NEI provided proposed revisions to the planning standards set forth in § 50.47 and appendix E to 10 CFR part 50 as well as associated EP guidance. The proposed revisions were developed by NEI to ''constructively inform the staff's deliberations concerning the development of an SMR EP framework, and serve as a basis for future public meeting engagement.'' The NRC has considered NEI's recommendations in the development of this final rule.

In addition to the NEI white papers, the NRC has had several interactions with the public concerning licensing issues related to SMRs and ONTs, including joint DOE–NRC Workshops on Advanced Non-Light-Water Reactors held on September 1–2, 2015, and June 7–8, 2016. The NRC held these workshops to obtain stakeholder feedback regarding the proposed rule and inform the public on the proposed approach. Additional information on these workshops may be found in their summaries.

3. Rulemaking Activity

In response to SRM–SECY–15–0077, on May 31, 2016, the staff submitted a rulemaking plan to the Commission (SECY–16–0069, ''Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies'') to propose rulemaking to address EP for SMRs and ONTs. In SECY–16–0069, the staff provided a proposed rulemaking schedule, outlining the need to develop EP requirements for SMRs and ONTs commensurate with the potential consequences to public health and safety posed by these facilities. On June 22, 2016, the Commission issued SRM–SECY–16–0069 approving the staff's rulemaking plan.

On August 22, 2016, the NRC held a public meeting to request feedback from stakeholders on a potential performance-based approach for EP for SMRs and ONTs. The participants supported a performance-based approach for EP, indicating that it would be more effective because it would focus on achieving desired outcomes. Participants also favored the performance-based approach because it would allow for innovation and flexibility in addressing the EP requirements. The potential need for an entire new suite of guidance documents, including the process by which licensees make changes to their emergency plans (*i.e.,* change process), was the only disadvantage identified by participants as it would require additional up-front work to reflect the new approach. A summary of this public meeting is available in ADAMS, as provided in the ''Availability of Documents'' section of this document. After considering the feedback received from the stakeholders in support of the performance-based approach to EP, the NRC developed a draft regulatory basis that included an option to proceed with rulemaking to implement this approach.

On April 13, 2017, the NRC issued a draft regulatory basis for a 75-day public comment period (82 FR 17768). In the draft regulatory basis, the NRC requested feedback from the public on questions related to the scope of the draft regulatory basis, performance-based approach, regulatory impacts, and cumulative effects of regulation (CER). In addition, the NRC held a public meeting on May 10, 2017, to discuss the draft regulatory basis with interested stakeholders. A summary of this public meeting is available in ADAMS, as provided in the ''Availability of Documents'' section of this document.

The NRC received comment submissions from 57 individuals and organizations on the draft regulatory basis and the associated regulatory analysis, including 223 individual comments related to EP. The commenters included individuals, environmental groups, industry groups, a Tribal government, States, and FEMA. The NRC reviewed all comments submitted on the draft regulatory basis, grouped the comments into categories by comment topic, and developed a resolution for each topic. Comments included topics such as: consequence-based approach, co-location, dose assessment, EPZ and offsite EP, general rulemaking approach, siting of multi-module facilities, performance-based approach, regulatory analysis, scope of the draft regulatory basis, safety, and technology-inclusive approach. The NRC considered those comments and discussions from the public meeting as it finalized the regulatory basis. The NRC published a notification in the **Federal Register** announcing the public availability of the regulatory basis on November 15, 2017 (82 FR 52862).

On May 12, 2020, the NRC published the proposed rule, ''Emergency Preparedness for Small Modular Reactors and Other New Technologies,'' for a 75-day public comment period (85 FR 28436). On May 25, 2020, the NRC published a notification to correct the definition of ''Non-power production or utilization facility'' (85 FR 32308). The NRC held a public meeting on June 24, 2020, to engage with external stakeholders on the proposed rule and associated draft guidance document. Additional information about this public meeting is detailed in the meeting summary. The NRC received several requests to extend the comment period by 6 months or more due to the Coronavirus Disease 2019 (COVID–19) public health emergency. On July 21, 2020, the NRC extended the comment period by 60 days with a closing date of September 25, 2020 (85 FR 44025). The NRC received comment submissions from 2,212 individuals and organizations, including 2,087 form letters and form letters with non-substantive additional text. The staff's analysis identified 649 unique comments on the proposed rule and associated guidance, the regulatory analysis, and the environmental assessment. The commenters included State and local governments, Tribal governments and Tribal organizations, Federal agencies, members of the nuclear power industry, non-governmental organizations, and private citizens. A summary of the comments and the NRC's responses to the comments are available as indicated in the ''Availability of Documents'' section of this document. The NRC used these comments to develop this final rule.

II. Discussion

A. Objective and Applicability

This final rule creates alternative EP requirements that: (1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by an SMR or ONT licensee; (2) promote regulatory stability, predictability, and clarity; (3) reduce the need for requests for exemptions from EP requirements; (4) recognize advances in design and technology advancements embedded in design features; (5) credit safety enhancements in evolutionary and passive systems; and (6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This final rule applies to existing and future SMR and ONT facilities. These applicants and licensees have the option to develop a performance-based EP program designed for SMRs and ONTs, as an alternative to complying with the existing, deterministic EP requirements in 10 CFR part 50.

This final rule does not include within its scope emergency planning, preparation, and response for large LWRs, which for the purposes of this final rule are those LWRs that are

licensed to produce greater than 1,000 MWt power; fuel cycle facilities; or currently operating non-power reactors. The current operating fleet of power reactors has an established EP regulatory framework under § 50.47 and appendix E to 10 CFR part 50. Emergency planning requirements for facilities licensed under 10 CFR part 70 are set forth in § 70.22(i). The NRC established in appendix E to 10 CFR part 50 emergency planning requirements for RTRs that reflect the lower potential radiological hazards associated with these facilities.

The plume exposure pathway EPZ for the current operating fleet of nuclear power reactors consists of an area about 10 miles (16 km) in radius and the IPZ for such facilities consists of an area about 50 miles (80 km) in radius. See current §§ 50.33(g) and 50.47(c). As discussed in the ''Background'' section of this document, in the early 2000s, the NRC anticipated that future SMR and ONT applications would reflect a wide range of potential designs that have smaller source terms and incorporate EP considerations as part of the design. In the Policy Statement on the Regulation of Advanced Reactors (73 FR 60612), the Commission stated that it ''expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions.'' Under the current EP framework, §§ 50.33(g) and 50.47(c)(2) provide that the size of plume exposure pathway EPZs and IPZs for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt may be determined on a case-by-case basis. Section I.3 of appendix E to 10 CFR part 50 states that the EPZs for facilities other than power reactors may also be determined on a case-by-case basis. In addition, applicants and licensees for power reactors may also request that the size of the EPZs and IPZs for their facilities be determined on a case-by-case basis by seeking an exemption under § 50.12, ''Specific exemptions,'' from the requirements in §§ 50.33(g) and 50.47(c)(2) regardless of authorized power level. Furthermore, appendix E to 10 CFR part 50, provides the flexibility to determine other emergency planning considerations, such as organization, assessment actions, activation of emergency organization, emergency facilities, and equipment, on a case-by-case basis for certain facilities.

The NRC initiated this rule to seek a wide-range of public views and increase regulatory predictability and flexibility in the development of an alternative, generic approach that designers, vendors, and applicants may use to determine the appropriate EP requirements for SMRs and ONTs, for which emergency planning may otherwise be addressed on a case-by-case basis. In particular, this final rule provides additional predictability and flexibility for advanced reactor developers that use simplified or other innovative means to accomplish their safety functions and provide enhanced margins of safety. Large LWRs were not included by the NRC in the scope of this final rule because an EP licensing framework already exists for those reactors, and licensees for those plants have not expressed a clear interest in changing that framework.

For clarity, this final rule defines the different types of affected facilities. The NRC amends § 50.2 to include the terms ''small modular reactor,'' ''non-light-water reactor,'' and ''non-power production or utilization facility.'' The NRC has included a definition of ''non-light-water reactor'' to address ONTs, including liquid-metal-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. Having a separate definition for these non-LWR technologies clarifies the applicability of the existing EP standards and requirements in 10 CFR part 50, which are specific to LWRs, and maintains consistency between this final rule and the ''Variable Annual Fee Structure for Small Modular Reactors'' final rule (81 FR 32617; May 24, 2016).

The NRC evaluated the suitability of using the existing definition of ''small modular reactor'' in § 171.5, ''Definitions'' for the purposes of this EP final rule. The § 171.5 definition of ''small modular reactor'' means, for the purpose of calculating fees, the class of light-water power reactors having a licensed thermal power rating less than or equal to 1,000 MWt per module. This rating is based on the thermal power equivalent of a light-water SMR with an electrical power generating capacity of 300 megawatts electric or less per module. Although similar, this final rule's definition of ''small modular reactor'' does not include reference to electrical power generating capacity. For the fee-related regulations in 10 CFR part 171, ''Annual Fees For Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,'' the NRC determined that using the thermal power equivalent of electric power generating capacity would be equitable because SMRs should pay annual fees that are commensurate with the economic benefit received from their license (81 FR 32617). However, because electric power generating capacity is not a criterion the NRC uses to determine EP requirements, this final rule's definition focuses on thermal power rating.

The NRC received a public comment on the proposed rule that the definition of ''small modular reactor'' should indicate that an SMR can have a licensed thermal power up to 1,000 MWt, and that this limit applies to each module in a facility rather than the total thermal power of all modules in a facility. The proposed rule's definition of ''small modular reactor'' provided that an SMR was a power reactor licensed to produce heat energy up to 1,000 MWt, which may be of modular design as defined in § 52.1, ''Definitions.'' The NRC agreed that this definition could be subject to more than one interpretation and revised the definition of ''small modular reactor'' to read: ''a power reactor, which may be of modular design as defined in § 52.1 of this chapter, licensed under § 50.21 or § 50.22 to produce heat energy up to 1,000 megawatts thermal per module.'' The ''per module'' language is also consistent with the definition of ''small modular reactor'' in § 171.5.

B. Need for Changes to Existing Regulatory Framework

As mentioned in the ''Background'' section of this document, in SECY–10–0034, the NRC identified potential policy and licensing issues for SMRs based on the preliminary design information supplied in pre-application interactions and discussions with SMR designers and the DOE. In general, these issues result from the key differences between the new designs and the current-generation large LWRs, such as rated thermal power, moderator, coolant, and fuel design. In SECY–10–0034, the NRC described designs discussed in pre-application interactions with DOE and SMR designers. The rated thermal power of these designs ranged from 30 MWt to 1,000 MWt. The designs included the use of helium gas, sodium, and light-water as coolants. While some SMR designs employ conventional LWR radiological barrier designs, some designs may employ a non-traditional containment approach.

In addition to licensing issues associated with differences in designs, some of the licensing issues resulted from industry-proposed review approaches and industry-proposed modifications to current policies and practices, including standard review plans and design-specific review

standards. The potential for smaller reactor core sizes, lower power densities, lower probability of severe accidents, slower accident progression, and smaller accident offsite consequences per module that characterize some SMR designs have led DOE, SMR designers, and potential operators to revisit the determination of the size of the EPZs, the extent of onsite and offsite emergency planning, and the number of onsite response staff needed.

Historically, licensees of small reactors have requested exemptions from EP regulations because those EP requirements would have imposed a regulatory burden on the applicants that was not necessary to protect the public health and safety due to the facilities' designs. The NRC anticipates that existing or future SMR and ONT applicants could also have designs that differ substantially from the existing fleet of large LWRs. These applicants could also request exemptions from EP requirements that are potentially unnecessary to protect the public health and safety. Although the exemption process provides the flexibility to address these existing or future applicants, regulating by exemption generally provides little opportunity for public engagement in the exemption process and can lead to undue burden and lack of predictability for applicants, licensees, and the NRC stemming from the applicant or licensee specific nature of exemption requests.

This final rule creates a transparent alternative EP regulatory framework for SMR and ONT applicants and licensees that continues to provide reasonable assurance that adequate protective measures can and will be implemented in a radiological emergency. The final alternative EP requirements consider a wide range of views, acknowledge technological advancements and other differences from large LWRs inherent in SMRs and ONTs, and reduce regulatory burden by precluding the need for exemptions from EP requirements as applicants request permits and licenses. This final rule also supports the principles of good regulation, including openness, clarity, and reliability.

1. Technical Basis

This final rule is a performance-based, technology-inclusive, risk-informed, and consequence-oriented alternative approach to EP for SMRs and ONTs. These approaches form the basis for the NRC's final rule, and the following discussion addresses the technical basis for each.

a. Performance-Based Approach to Emergency Planning

The NRC's current regulatory framework for EP in 10 CFR part 50 requires that site-specific emergency plans be developed and maintained in compliance with 16 planning standards for nuclear power reactors. This deterministic structure does not provide performance standards, but the regulations and guidance for emergency response organizations (EROs) emphasize requirements for emergency plans and facilities. The existing EP requirements for large LWRs are based on decades of research on the risks posed by these facilities. The risks for these facilities are well understood, and, as such, a deterministic approach to regulating EP is an effective method for providing reasonable assurance that protective measures can and will be taken in a radiological emergency.

The NRC anticipates that existing and future SMR and ONT applications will use a wide range of potential designs and source terms. Advances in designs could enhance the EP for these facilities. At the same time, EP itself is improving through technological innovations like FEMA's Integrated Public Alert & Warning System. Because the technology for EP and certain SMR and ONT designs are evolving, a performance-based approach could allow for more regulatory flexibility, provide a basis for appropriate EP through review of design- and site-specific accident scenarios, and minimize the need for exemption requests that would otherwise be anticipated under a prescriptive regulatory framework. In this context, a performance-based approach bases the adequacy of EP upon the NRC's identification of emergency response functions that affect the protection of public health and safety and the licensee's successful execution of those functions. The NRC's performance-based framework, inspection and enforcement program, and design-specific review process provide reasonable assurance that protective measures can and will be taken in the event of an emergency at an SMR or ONT facility. The NRC has previously explored the idea of a performance-based EP framework, as discussed in the ''Performance-Based Emergency Preparedness'' section of this document, and the Commission noted that a performance-based approach was a potential benefit to regulating EP for SMRs. The performance-based approach could simplify EP regulations and focus inspections more fully on response-related performance.

The NRC also considered a graded approach to EP that would take into account the magnitude of any credible hazard involved, the particular characteristics and status of a facility, and the balance between radiological and non-radiological hazards. A graded approach to EP has a longstanding regulatory history. The 16 EP planning standards for nuclear power reactors, outlined in § 50.47(b), and the associated evaluation criteria in NUREG–0654/FEMA–REP–1, Revision 1 and NUREG–0654/FEMA–REP–1, Revision 2, are part of a continuum of planning standards for radiological EP. The existing regulations in § 50.47(c)(2) for EPZ size determinations for gas-cooled reactors and reactors with power levels less than 250 MWt, the EP regulations for production and utilization facilities other than nuclear power reactors in appendix E to 10 CFR part 50, and the EP regulations for fuel cycle facilities in § 70.22(i) and independent spent fuel storage installations (ISFSIs) in § 72.32, ''Emergency plan,'' are also part of a graded approach to EP that is commensurate with the relative radiological risk, source term, and potential hazards, among other considerations.

b. Technology-Inclusive Approach to Emergency Planning

As previously mentioned, the NRC has licensed, reviewed, or had pre-application discussions with stakeholders supporting a range of technology types that are included in the scope of this final rule. Based on the information currently available to the NRC, unique design considerations (*e.g.,* passive safety characteristics, advanced fuel types, and chemical processes) and the potential for multi-module facilities and siting contiguous to, or near, NRC-licensed facilities or facilities not licensed by the NRC could lead to a variety of accident frequencies, progression times, and potential consequences for SMRs or ONTs. To incorporate recent and potential technology advancements and reduce the need for future EP rulemaking, this final rule offers a technology-inclusive approach to EP for SMRs and ONTs. In this context, technology-inclusive means the establishment of performance requirements for any SMR or ONT applicant or licensee to use in its emergency plan, developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies.

As described further in the ''Performance-Based Framework'' section of this document, the NRC's

final alternative framework for SMRs and ONTs consists of two major elements—an EPZ size determination process and a set of performance-based requirements. The size of an EPZ determined by this process is scalable based on factors such as accident source term, fission product release, and associated dose characteristics, and the same process can be applied to all SMR and ONT designs. Further, the performance-based requirements in § 50.160, ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,'' do not contain any technology specific language. Rather, applicants and licensees demonstrate how they meet the EP performance-based framework based on their design- and site-specific considerations through the implementation of a performance objective scheme and the conduct of drills and exercises.

c. Consequence-Oriented and Risk-Informed Approaches to Emergency Planning

This final rule offers a consequence-oriented approach to establish EP requirements for SMRs and ONTs. In this context, consequence-oriented means the principle of basing decisions regarding the scope of EP upon the potential consequences from a spectrum of accidents, including those that could result in an offsite radiological release. The decisions regarding EP should be based upon projected offsite dose from such accidents and the pre-determined plume exposure pathway EPZ for pre-planned protective measures.

The NRC reviewed the current EP requirements associated with various nuclear facilities, including large and small operating reactors, material facilities, fuel facilities, ISFSIs, NPUFs, and decommissioning large LWRs (including SECY–18–0055, ''Proposed Rule: Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning,'' dated May 22, 2018). In this review, the NRC identified that all of the existing types of NRC-licensed nuclear facilities use a consequence-oriented approach and take into account other considerations, such as the likelihood of the accident, to establish the boundary of the plume exposure pathway EPZ (or other planning area). The consequence or dose considerations are based on the U.S. Environmental Protection Agency (EPA) early-phase Protective Action Guides (PAGs) (EPA–520/1–75–001), issued in September 1975. The PAGs were revised and republished as EPA–400–R–92–001 in May 1992, and a subsequent revision, EPA400/R–17/001, was issued in January 2017.

The general considerations from the existing planning basis for EP, established in NUREG–0396/EPA 520/1–78–016, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' introduced the concept of generic EPZs as the basis for preplanned response actions. These planning distance considerations were intended to result in dose savings to members of the public in the environs of a nuclear facility when the EPA PAGs were used as the threshold to trigger the preplanned protective measures in the event of a reactor accident that would result in offsite dose consequences. Planning should also be based upon knowledge of the potential consequences, timing, and radiological release characteristics from a spectrum of accidents, including severe accidents. The joint NRC–EPA task force that developed NUREG–0396 considered several possible rationales for establishing the size of the EPZs, including risk, cost effectiveness, and the accident consequence spectrum (*e.g.,* dose and significant health effects). After reviewing these alternatives, the NRC–EPA task force concluded that the objective of emergency response plans should be to provide dose savings for a spectrum of accidents that could produce offsite doses in excess of the EPA PAGs for those members of the public who would most likely receive exposure as a result of a significant release.

In the 1980 Final Rule, based on the guidance in NUREG–0396, the NRC established plume exposure pathway and ingestion pathway EPZ requirements for large LWRs of about 10 miles (16 km) and 50 miles (80 km), respectively. The NRC also clarified that the size of the EPZ could be determined on a case-by-case basis for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt. The NRC stated that this requirement was based on the lower potential hazard from these facilities (*i.e.,* lower radionuclide inventory and longer times to release significant amounts of activity in many scenarios) and clarified that the radionuclides to be considered in planning for large LWR accident scenarios were set forth in NUREG–0396. Similarly, the NRC established in the 1980 Final Rule that the degree to which compliance with sections I through V of appendix E to 10 CFR part 50 would apply to RTRs and fuel cycle facilities would be determined on a case-by-case basis because the radiological hazards to the public associated with the operation of RTRs and fuel cycle facilities involve considerations different than those associated with nuclear power reactors.

This final rule for SMRs and ONTs continues this consequence-oriented approach for determining the size of the plume exposure pathway EPZ. The primary purpose of the plume exposure pathway EPZ is to define the area where predetermined, prompt protective measures are necessary, which results in dose savings and a reduction in early health effects. In this final rule, the NRC establishes in § 50.33(g)(2)(i) two criteria for determining a plume exposure pathway EPZ size. The first criterion is that the plume exposure pathway EPZ is the area within which public dose, as defined in § 20.1003, ''Definitions,'' is projected to exceed 10 millisieverts (mSv) (1 rem) total effective dose equivalent (TEDE) over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion is that the plume exposure pathway EPZ is the area where predetermined, prompt protective measures are necessary.

The principle of using dose versus distance to determine EPZ size has been used in the past when the NRC licensed several small reactors with a reduced EPZ size of 5 miles (8 km). These reactors include the Fort St. Vrain high-temperature gas-cooled reactor (HTGR) (842 MWt), the Big Rock Point boiling water reactor (BWR) (240 MWt), and the La Crosse BWR (165 MWt). Pre-application discussions between the NRC and SMR designers have indicated that SMRs also could have reduced offsite dose consequences in the unlikely event of an accident. With the expected safety enhancements in SMR designs and the potential for reduced accident source terms and fission product releases from SMRs and ONTs, this final rule provides an alternative EP framework that allows SMR and ONT applicants to develop EPZ sizes commensurate with their accident source terms, fission product releases, and accident dose characteristics considering site-specific meteorology.

To support this final rule, the NRC conducted research on EPZ size determinations for SMRs and ONTs. Because of the potential variations in SMR or ONT designs, the NRC cannot conduct a comprehensive evaluation of source terms and spectra of accidents as part of this final rule. Instead, the research study, ''Generalized Dose Assessment Methodology for Informing

Emergency Planning Zone Size Determinations,'' dated June 2018, reviewed the dose assessment methodologies that informed the EPZ size determinations in NUREG–0396 and developed a general methodology for determining plume exposure pathway EPZ size based on NUREG–0396. Information from that review and a subsequent set of recommended analyses documented in ''Required Analyses for Informing Emergency Planning Zone Size Determinations,'' dated June 2018, was used to develop the methodology described in Appendix A, ''General Methodology for Establishing Plume Exposure Pathway EPZ Size,'' of RG 1.242.

This final rule requires applicants that choose to comply with § 50.160 to submit an analysis under § 50.33(g)(2) to provide the technical basis justifying the proposed plume exposure pathway EPZ size. The NRC evaluates each application on a case-specific basis. The ''Emergency Planning Zones'' section in this document contains additional discussion on the NRC's consequence-oriented approach to EPZ size determinations for an SMR or ONT facility.

The proposed rule included a plume exposure pathway EPZ in which public dose is projected to be above 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials, resulting from a spectrum of credible accidents for the facility. The NRC received public comments concerning the need for clarification on the plume exposure pathway EPZ determination requirements, including the 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials and the definition of ''spectrum of credible accidents.'' The NRC removed the phrase ''spectrum of credible accidents'' in this final rule. The determination of whether accidents are credible for a facility is a part of the applicant's safety analysis required for its application. As part of the NRC's safety review of the application, the NRC reviews the applicant's assessment of licensing basis events, event likelihood, and public dose consequences. The NRC's determination of the acceptability of the applicant's assessment supports the agency's separate review of the applicant's emergency plan.

As a result of these comments on the proposed rule, the NRC revised the requirements by listing in § 50.33(g)(2)(i)(A) the major considerations for the radiological consequence analysis to be used in determining the plume exposure pathway EPZ size for the facility: accident likelihood and source term, timing of the accident sequence, and meteorology. Consideration of accident likelihood in combination with event sequences makes it possible to arrive at the spectrum of accidents used to develop the basis for the applicant's site-specific plume exposure pathway EPZ. Source terms are used to determine dose consequences. Timing of the accident sequence facilitates determining if prompt protective measures are warranted. Meteorology input is essential in determining the weather conditions that impact dose consequences due to atmospheric transport and dispersion of the radioactive plume. Meteorological inputs should consider, but not be limited to, wind speeds, wind directions, atmospheric stability, precipitation, and mixing height, for temporal and geographical representativeness. Regulatory Guide 1.242 provides guidance on these considerations and developing the dose-consequence analysis.

The NRC also added a second criterion to the plume exposure pathway EPZ size determination in § 50.33(g)(2)(i)(B): the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. This rule provision adds a functional criterion to the EPZ to be consistent with the planning basis approach in NUREG–0396 and Federal guidance contained in the EPA PAG Manual.

The risk-informed planning basis for EP, established in NUREG–0396, was endorsed in the Commission policy statement, ''Planning Basis for Emergency Responses to Nuclear Power Reactor Accidents,'' dated October 23, 1979 (44 FR 61123), and incorporated in the 1980 Final Rule. In the policy statement, the Commission said, ''Predetermined protective action plans are needed for the EPZs.'' As described in NUREG–0396, for very serious accidents, predetermined, prompt protective actions would be taken if projected doses, at any place and time during an actual accident, appeared to be at or above the applicable proposed PAGs, based on information readily available in the reactor control room (*i.e.,* at predetermined emergency action levels).

The planning basis established in NUREG–0396 determined that the scope of the planning effort needs to include: (1) the distance to which detailed planning for predetermined protective actions is warranted, (2) the time dependent characteristics of potential releases and exposures, and (3) the radioactive materials potentially released. The specified planning distance ensures that the locations of at-risk populations are identified, the responsible authorities who would carry out these actions will be notified, and the means of communication to these authorities are included in the detailed planning. The time available between recognition of the initiation of a serious accident and the beginning of the radioactive release to the environment is critical in determining what predetermined protective actions would be appropriate.

The planning basis in NUREG–0396 used the accident analyses and assumptions of NUREG–75/014, ''Reactor Safety Study—An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants,'' (WASH–1400), Appendices III and IV; Appendix V; Appendix VI; and Appendices VII–X, dated October 1975. These analyses assume that the range of times for the onset of radiological accident conditions and the start of a major radiological release could be from less than an hour to several hours. The potential for a major atmospheric release would necessitate consideration of predetermined, prompt protective measures. The length of time from the initiation of an event to the time of release in relation to the ability for OROs to determine and initiate protective measures is key to reducing dose and providing for public health and safety. If OROs have sufficient time to determine what protective measures, if any, are necessary to take for releases occurring after a delay from the initiating event (*e.g.,* several hours), then predetermined, prompt protective measures may not be necessary. As an example of an analysis of timing considerations, the Low-Power Rule (''Emergency Planning and Preparedness Requirements for Nuclear Power Plant Fuel Loading and Low-Power Testing,'' Final Rule, 53 FR 36955; September 23, 1988) included an analysis on the need for predetermined, prompt protective measures. Due to the substantial reduction in the likelihood of an accident and potential accident consequences for low power testing as compared to continuous full power operation, the analysis for this example identified a time period of 10 hours from the start time of the initiating event to the start time of a potential major release as a reasonable amount of time for OROs to take appropriate response actions that provide for public health and safety without the need for predetermined, prompt protective measures.

This timing of a potential major release is the basis for requiring predetermined, prompt protective

measures triggered by plant conditions or dose projections in response to a General Emergency declaration. Because SMRs and ONTs are expected to have accident timing characteristics different from large light-water reactor technologies considered in NUREG–0396, and because technology important to emergency planning and response continues to improve, the NRC added a functional criterion to this final rule to ensure that the need for predetermined, prompt protective measures is evaluated in the planning considerations.

This final rule requires applicants and licensees choosing to comply with § 50.160 to describe in their emergency plan the information that demonstrates compliance with the elements set forth in § 50.160(b). This includes the capability to assess and classify emergency events, establish and maintain effective communications, assess radiological conditions in and around the facility, and recommend protective measures to offsite authorities as conditions warrant. If an applicant or licensee determines under § 50.33(g)(2)(i)(B) that pre-determined, prompt protective measures are warranted, which would occur only if § 50.33(g)(2)(i)(A) is also met, then an EPZ is required. The need for pre-determined, prompt protective measures is assumed to exist unless an applicant can demonstrate that the timing of accidents in relation to the proposed capabilities for assessment and notification are such that predetermined, prompt protective measures are not warranted. That is, the applicant must demonstrate that plant condition-based, predetermined, prompt protective measures are not required because sufficient time is available, and the capability exists, to initiate appropriate response actions offsite as conditions warrant. RG 1.242 provides guidance for the EPZ functional criterion.

The capability for taking protective measures is not dependent upon an established EPZ. The EPZ is a planning tool to ensure predetermined, prompt protective measures can and will be taken if accident conditions warrant. If both § 50.33(g)(2)(i) criteria are met, then an EPZ is required. However, if there is no need for predetermined, prompt protective measures, then the final rule still requires licensees to develop and maintain capabilities to assess, classify, notify, and recommend protective measures as conditions warrant. In all cases, the NRC will not issue an initial operating license (OL) or combined license (COL) unless the NRC finds that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

This final rule does not provide for a specific IPZ. This final rule includes ingestion response planning requirements instead of an IPZ at a set distance as part of the performance-based framework. Ingestion response planning focuses planning efforts on identification of major exposure pathways for ingestion of contaminated food and water. This final rule requires applicants and licensees who comply with § 50.160 to describe in their emergency plan the licensee, Federal, State, and local resources for ingestion emergency response capabilities available to sample, assess, and implement a quarantine or embargo of food and water to protect against contaminated food and water entering the ingestion pathway. For those applicants and licensees using § 50.47(b) and appendix E to 10 CFR part 50, the IPZ requirements remain unchanged.

These ingestion emergency response capabilities are implemented either by the licensee within the site boundary or by Federal, State, and local authorities in the intermediate or later-stage response to an accident involving the release of radioactive material. The sampling, assessing, and imposing of a quarantine or embargo are longer-term issues. Federal and State authorities frequently issue precautionary actions or implement quarantines or embargos for non-radiological contamination of foods. Further, Federal resources are available upon request to State, local, and Tribal response to any nuclear or radiological incident. Current State and local plans include sampling, assessing, and implementing precautionary actions prior to exceeding dose thresholds or PAGs.

2. Performance-Based Framework

This final rule creates a new section, § 50.160, that provides a performance-based EP framework for SMRs and ONTs as an alternative to the current regulations. Under § 50.54(q)(2)(ii) in this final rule, licensees are required to follow and maintain either an emergency plan that meets the requirements in § 50.160 or an emergency plan that meets the requirements in appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards of § 50.47(b). Sections 50.34 and 52.79, ''Contents of applications; technical information in final safety analysis report,'' stipulate that SMR and ONT applicants have the option to choose either approach. Section 50.160 includes: (1) emergency response functions that must be demonstrated through the regular development and maintenance of performance objectives and periodic drills and exercises, (2) onsite and offsite planning activities to be met by applicants and licensees to which the provision applies, (3) requirements for considering credible hazards associated with contiguous or nearby NRC-licensed facilities and industrial facilities not licensed by the NRC, and (4) a requirement for applicants and licensees to determine and describe in the emergency plan the boundary and physical characteristics of the plume exposure pathway EPZ and ingestion response planning capabilities. Licensees complying with § 50.160 are required under § 50.160(b)(1) to demonstrate effective response in drills and exercises and describe in their emergency plans how they will maintain preparedness. To comply, emergency plans must include a description of how the emergency response functions in § 50.160(b)(1)(iii) and the planning activities in § 50.160(b)(1)(iv), if applicable, will be met.

The NRC has a long history of successful implementation of performance-based EP requirements (*e.g.,* performance-based requirements for emergency facilities and staffing, and the Reactor Oversight Process).[4] Under this final rule's performance-based approach to EP, performance and results are the primary basis for regulatory decisionmaking, and the applicant or licensee has the flexibility to determine how to meet the established performance criteria for an effective EP program. The performance-based regimen focuses on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight focuses on performance, instead of processes and procedures. The performance-based regimen provides the NRC with enhanced oversight of the actual competencies important to the protection of public health and safety while allowing applicants and licensees increased flexibility.

The performance-based requirements in § 50.160 address the most risk-significant aspects of EP (*e.g.,* classification, notification, protective action recommendation, mitigation), as well as several planning activities currently required under appendix E to 10 CFR part 50. Compliance with § 50.160 is demonstrated by performance during drills or exercises

[4] For further information on the Reactor Oversight Process, see: *https://www.nrc.gov/reactors/operating/oversight.html.*

and the NRC's review of performance objectives and corrective actions. The NRC, in consultation with FEMA when an EPZ extends beyond the site boundary, ensures that reasonable assurance is maintained based on demonstrations of required emergency response functions through drills and exercises and NRC inspections. Between drills and exercises, licensees maintain a set of performance objectives to measure emergency response performance. See the ''Reasonable Assurance'' section of this document for a discussion of how this final rule maintains reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

In responding to a public comment related to risks associated with the loading and storage of irradiated fuel, the NRC determined that a conforming change is needed to 10 CFR part 72, ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater that Class C Waste.'' A 10 CFR part 72 specific license ISFSI must comply with the EP requirements in § 72.32. Most power reactor licensees have 10 CFR part 72 general licenses for their ISFSIs. For these ISFSIs, § 72.32(c) provides that the emergency plan required by § 50.47 satisfies the EP requirements of § 72.32. This provision means that an emergency plan that meets the requirements of § 50.47 satisfies the EP requirements of § 72.32. This same policy applies to an ISFSI on the site of a power reactor whose licensee is complying with § 50.160. To allow for this, the NRC revised § 72.32(c) to clarify that the emergency plan that meets either the requirements in § 50.160 or the requirements in appendix E to part 50 and § 50.47(b) satisfies the EP requirements of § 72.32.

a. Application Process

Current applicants for a construction permit (CP), early site permit (ESP), OL, or COL are required to provide emergency planning information as described in § 50.33, § 50.34, § 52.17, ''Contents of applications; technical information,'' and § 52.79. In particular, § 50.34(a)(10) requires applicants for CPs to describe within the preliminary safety analysis report (PSAR) their preliminary plans for coping with emergencies. Under § 52.17(b), ESP applicants must identify within their site safety analysis report physical characteristics of the proposed site that could pose a significant impediment to the development of emergency plans and, as applicable, measures for mitigating or eliminating the significant impediments. Within the site safety analysis report, ESP applicants also have the option of proposing either major features of emergency plans (under § 52.17(b)(2)(i)) or complete and integrated emergency plans (under § 52.17(b)(2)(ii)) for NRC review and approval. Applicants for OLs and COLs, as well as ESP applicants choosing to provide emergency plans under § 52.17(b)(2)(ii), must submit radiological emergency response plans of State and local governments wholly or partially within the plume exposure pathway EPZ and State governments wholly or partially within the IPZ under § 50.33(g). Under §§ 50.34(b)(6)(v) and 52.79, OL and COL applicants also must include in their final safety analysis report (FSAR) their plans for coping with emergencies.

Because SMR and ONT licensees are given a choice between complying with either § 50.160 or complying with the requirements in appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards in § 50.47, this final rule includes a number of conforming changes to clarify application requirements for applicants choosing the performance-based requirements.

- Construction permit and OL applicants must include emergency planning information in their PSARs and FSARs, respectively, and § 50.34(a)(10) and (b)(6)(v) require that the information describe how the applicant complies with either appendix E to 10 CFR part 50 or § 50.160.
- In order to maintain applicability to applicants and licensees choosing to comply with § 50.160, the NRC has added references to § 50.160 in § 50.47(c)(1), § 50.47(c)(1)(i), and § 50.47(e).
- Combined license and ESP applicants must continue to include emergency planning information in their site safety analysis report and FSAR; §§ 52.17(b)(2), 52.18, and 52.79(a)(21) require that the information describe how the applicant complies with either the applicable requirements in § 50.47 and appendix E to 10 CFR part 50, or the requirements in § 50.160.
- Applicants choosing to comply with § 50.160 must describe how their emergency plans meet the requirements in § 50.160(b). A revision to § 52.1 clarifies that, for applicants choosing the performance-based approach, the definition for ''major feature of the emergency plans'' includes aspects of plans necessary to address the requirements of § 50.160(b).
- Section 50.33(g)(2)(ii)(A) clarifies requirements to submit State, local, and participating Tribal emergency response plans for SMR, non-LWR, and NPUF applicants. Namely, if the application is for an OL or COL, or for an ESP that contains plans for coping with emergencies, and the plume exposure pathway EPZ extends beyond the site boundary (as defined in § 20.1003), the applicant must submit State, local, and participating Tribal emergency response plans. For purposes of this final rule, the term ''participating Tribal'' government means a Federally recognized Tribal government that has decided to participate in FEMA's offsite radiological emergency preparedness (REP) program and act as an independent entity with its own radiological emergency plan. The NRC included participating Tribal emergency response plans in this requirement to reflect the Commission's January 9, 2017 ''Tribal Policy Statement'' (82 FR 2402) and the 2019 issuance of NUREG–0654/FEMA–REP–1, Revision 2, which encourages the involvement of Tribal governments in NRC activities, and to reflect that Tribes have the option to participate in emergency planning in the communities where they are located. A Tribal government that has its own radiological emergency response plan can participate in State or local emergency response planning as an independent entity. A Tribe also has the option of being part of a State or local emergency response plan without participating in exercises or other community emergency response planning. To the extent that the Tribe elects to be included in State and local plans or does not participate in community emergency planning, FEMA will evaluate the adequacy of the State or local emergency response plan to provide for adequate protection of the members of the Tribal nation.

The requirements in § 50.33(g)(2) also include submission of an analysis for determining the plume exposure pathway EPZ, which is discussed in the ''Emergency Planning Zones'' section of this document.

b. Performance Objectives

Applicants and licensees adopting the alternative performance-based regulations must describe how they intend to maintain the effectiveness of their emergency plans to meet the performance-based requirements, which includes the implementation of a performance objective scheme that reflects the emergency response functions under § 50.160(b)(1)(iii). The NRC anticipates that performance objectives needed to demonstrate

compliance with performance-based requirements will vary by design. Therefore, the NRC or industry may develop additional guidance related to performance objectives for specific designs or classes of designs.

Section 50.160(b)(1)(ii) requires applicants and licensees using § 50.160 to describe in the emergency plan an approach to develop and maintain at the beginning of each calendar quarter a list of performance objectives for that calendar quarter. Each licensee also must maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters. The NRC monitors the performance objectives and metrics to ensure that licensees are maintaining adequate emergency planning and preparedness. During evaluated exercises, the NRC assesses the performance of the licensee and reviews the ability of the licensee to take corrective actions in a timely manner.

c. Drills and Exercises

A key feature of this final rule is the use of drills and exercises to demonstrate that the applicant or licensee can implement the emergency plan to carry out an effective response to emergency and accident conditions. Current regulations in appendix E to 10 CFR part 50, section IV.F include a requirement for periodic drills and exercises for nuclear power reactor licensees to be conducted during an eight-year drill and exercise cycle. The eight-year cycle requirement affords sufficient time for a licensee to vary exercise scenario content to provide ERO members the opportunity to demonstrate proficiency in the key skills necessary to respond to several specific scenario elements. Similarly, § 50.160(b)(1)(iii) requires the use of drills and exercises to demonstrate the licensee's capabilities in the enumerated emergency response functions listed in § 50.160(b)(1)(iii)(A)–(H). Additionally, maintenance of these capabilities is demonstrated through continued drills and exercises. And, unlike the exercise cycle requirements in appendix E to 10 CFR part 50, this final rule's performance-based requirements do not define the required frequency of drills and exercises or their scenarios. However, the exercise cycle frequency adopted by applicants and licensees should afford sufficient time during which ERO members will be provided ample opportunities to demonstrate their emergency response function capabilities listed in § 50.160(b)(1)(iii)(A)–(H). Applicants and licensees are required to describe exercise scenario elements necessary to demonstrate the emergency response functions in their emergency plans.

For facilities with EPZs that do not extend beyond the site boundary, OROs are not required to participate in radiological drills and exercises. Participation is not required because State, local, and Tribal government organizations do not need to provide for predetermined, prompt protective measures or take specialized actions in response to an event, other than providing onsite firefighting, law enforcement, and ambulance/medical services. Applicants and licensees may consider allowing State, local, or Tribal government organizations to participate in drills when requested by the offsite authorities. The ''Offsite Radiological Emergency Preparedness Planning Activities'' section of this document addresses ORO participation for facilities with EPZs that extend beyond the site boundary.

Under § 50.160(b)(1)(iii), the applicant's or licensee's emergency response team needs to have sufficient capability to demonstrate the following emergency response functions:

- *Event classification and mitigation.* The applicant or licensee needs to establish an emergency classification and action level scheme with established criteria for determining the need for notification of State, local, and Tribal governments, and participation of those governments in emergency response such that demonstration of the scheme can be achieved through the performance of drills or exercises within a performance-based framework. Applicants and licensees need to demonstrate the ability to assess, classify, monitor, and repair facility malfunctions and return the facility to safe conditions. The term ''safe conditions'' means that the facility has been restored to a radiologically safe and stable condition.
- *Protective actions.* The drill and exercise program needs to demonstrate the capability to implement and maintain protective actions for onsite personnel, as warranted. Applicants and licensees need to demonstrate the ability to recommend protective actions to offsite authorities as conditions warrant.
- *Communications.* The drill and exercise program needs to demonstrate that control room staff are capable of making effective communications to the ERO, including personnel and organizations who may have responsibilities for responding during emergencies. Control room staff and the emergency response team must have a means for maintaining communication with the NRC as needed, and with OROs based on prior arrangements. For example, the applicant or licensee may need to notify and maintain communications with the onsite fire brigade; offsite fire departments, rescue squad, or medical dispatch; and local law enforcement according to established agreements. As EP programs are developed, applicants and licensees need to determine if notification to OROs is appropriate. If notification to OROs is necessary, then drills and exercises need to demonstrate notifying the appropriate Federal, State, local, and Tribal officials of an emergency.
- *Command and control.* The drill or exercise needs to demonstrate continuity of operations through one or more shift changes of emergency response personnel, including the augmentation of the ERO. The supporting organizational structure needs to have defined roles, responsibilities, and authorities, and the drill or exercise needs to show how key ERO functions (*e.g.,* communications, command and control of operations, notification of OROs, accident/incident assessment, information dissemination to OROs and media, radiological monitoring, protective response, security) will be maintained around the clock throughout the emergency.
- *Staffing and operations.* The drills or exercises need to demonstrate effective emergency response with the level of staffing at the SMR or ONT as described in the emergency plan. There needs to be sufficient on-shift staff to perform all necessary tasks until augmenting staff arrive to provide assistance. This is of particular interest to the NRC because of the potential for reduced staffing levels at SMRs and ONTs, as compared to large LWRs. For example, some SMR and ONT designs may use multiple modules at one site with a single, centralized control room. Designers have indicated that they are considering designs that can operate with a staffing complement that is less than what is currently required of large LWRs by § 50.54(m), which sets forth the minimum licensed operator staffing requirements. Under this final rule, drills and exercises provide the NRC the opportunity to consider the sufficiency of emergency response staffing to implement the roles and responsibilities described in the emergency plan. The performance opportunities allow applicant and licensee staff to develop, maintain, or demonstrate key skills and provide applicants, licensees, and the NRC the opportunity to identify and correct any weaknesses or deficiencies.
- *Radiological Assessment.* During the drills or exercises, control room

staff, on-shift personnel, and the emergency response team need to demonstrate the ability to assess radiological conditions, including the ability to: monitor and assess dose to personnel resulting from radiological releases and inadvertent criticality accidents; conduct radiological surveys; assess and report information to the ERO such as early indications of loss of adequate core cooling and radiological releases, including the release of hazardous chemicals produced from licensed material; and use protective equipment to implement protective action strategies. The NRC received a public comment suggesting a revision to § 50.160(b)(1)(iii)(F)(*1*), ''Radiological conditions,'' § 50.160(b)(1)(iii)(F)(*3*), ''Core or vessel damage,'' and § 50.160(b)(1)(iii)(F)(*4*), ''Releases.'' The commenter recommended the NRC change the phrase ''and report radiological conditions to the response organization'' to read ''and report radiological conditions to the onsite and offsite response organizations.'' In the proposed rule, the NRC explained that the information to be reported under § 50.160(b)(1)(iii)(F)(*1*), (F)(*3*) and (F)(*4*) (*i.e.,* radiological conditions; the extent and magnitude of damage to the core or other vessel containing irradiated special nuclear material; and the extent and magnitude of all radiological releases, including releases of hazardous chemicals produced from licensed material, respectively) would be reported to the ERO. However, considering the public comment, the NRC determined that that information would need to be reported to only certain personnel within the ERO. Therefore, the NRC changed these rule provisions, so the information is reported to the ''applicable response personnel.''

• *Reentry.* Reentry is the temporary movement of people into an area of actual or potential hazard. The applicant or licensee also needs to demonstrate general plans for reentry after an emergency through drills or exercises. The applicant or licensee needs to demonstrate reentry plans for the site boundary, including determining when facility conditions are acceptable to justify reentry (*e.g.,* based on air and soil sampling and analysis to determine levels of radiological contamination and projected dose). Certain individuals who have been evacuated or relocated from a restricted area may be allowed to reenter under controlled conditions to perform specified activities.

• *Critique and corrective actions.* The performance of emergency response functions in drills and exercises (or responses to actual emergencies) is evaluated to identify weaknesses or deficiencies in ERO performance and the EP program. The applicant or licensee needs to use a corrective action program to evaluate, track, and correct EP weaknesses and deficiencies identified in drills and exercises (or responses to actual emergencies). Weaknesses and deficiencies may include items such as errors in the emergency plan or implementing procedures, ERO performance weaknesses, or degraded conditions in emergency response facilities, systems, and equipment resulting in a performance objective not being met. Corrective actions include remedial exercises to demonstrate that the deficiencies have been fully addressed.

d. Planning Activities

In addition to an applicant's or licensee's performance demonstrations through drills and exercises, this final rule includes a set of required planning activities in § 50.160(b)(1)(iv) to account for certain EP-related activities that are not readily observable or effectively measured through drills and exercises. This final rule includes two sets of planning activities: § 50.160(b)(1)(iv)(A) establishes planning activities for all applicants and licensees complying with § 50.160; and § 50.160(b)(1)(iv)(B) establishes planning activities that apply to applicants and licensees with a plume exposure pathway EPZ that extends beyond the site boundary.

Currently, § 50.47(b) requires licensees to be capable of maintaining prompt communication among the response organizations and the public. In § 50.160(b)(1)(iv)(A)(*1*), SMR and ONT applicants and licensees are required to be capable of preparing and issuing information to the public during emergencies to protect public health and safety. The NRC is establishing in § 50.160(b)(1)(iv)(A)(*2*) that applicants and licensees also must be capable of implementing the NRC-approved emergency response plan in conjunction with the Licensee Safeguards Contingency Plan. In implementing the emergency response plan, licensees should coordinate security-related and emergency response activities to ensure an adequate and efficient response to a radiological event. The regulations in § 50.160(b)(1)(iv)(A)(*3*) require the capability to establish voice and data communications with the NRC for use during emergencies. Voice communication through the Emergency Notification System (ENS) and data communication through an electronic data link provide timely updates to the NRC on the implementation of the emergency plan during and after an emergency. Section 50.160(b)(1)(iv)(A)(*4*) requires the capability to establish emergency response facilities to support the emergency response functions required in § 50.160(b). Applicants and licensees need to establish a facility from which effective direction can be given and effective control can be executed for the duration of an emergency. Depending on design- and site-specific considerations, applicants and licensees may need to establish multiple emergency response facilities to demonstrate the capability to support emergency response functions. Emergency plans need to include descriptions of the facilities' functional capabilities, activation times, staffing, and communication systems.

In this final rule, the NRC moved the proposed requirement in § 50.160(b)(1)(iv)(B)(*4*) to new § 50.160(b)(1)(iv)(A)(*5*). This provision requires applicants and licensees to provide site familiarization training to individuals whose assistance may be needed in the event of a radiological emergency, including personnel from offsite response organizations. The NRC moved this provision to ensure that all applicants and licensees complying with § 50.160 provide this offsite organization training, notwithstanding whether an applicant's or licensee's plume exposure pathway EPZ extends beyond the site boundary.

Finally, the NRC moved the proposed requirement in § 50.160(b)(1)(iv)(B)(*11*) to new § 50.160(b)(1)(iv)(A)(*6*). This provision requires applicants and licensees to maintain up to date the emergency plan, contacts and arrangements with OROs, procedures, and evacuation time estimates (ETEs). Emergency plans need to include a description of the periodic coordination with OROs. The NRC moved this provision to ensure that all applicants and licensees complying with § 50.160 maintain their emergency plans, notwithstanding whether the plume exposure pathway EPZ extends beyond the site boundary.

e. Offsite Radiological Emergency Preparedness Planning Activities

Current requirements for offsite radiological emergency response plans are included in § 50.47 and appendix E to 10 CFR part 50. In select cases, the NRC has granted exemptions from these requirements to licensees based partially on a demonstration that an offsite radiological release would not exceed the EPA PAGs at the site boundary. For SMR and ONT applicants and licensees complying with § 50.160

that have no plume exposure pathway EPZ or establish a plume exposure pathway EPZ at the site boundary, the NRC does not mandate offsite radiological emergency planning activities. Section 50.160(b)(1)(iv)(B) establishes offsite planning activities that must be described in the emergency plan for applicants and licensees with plume exposure pathway EPZs extending beyond the site boundary. These activities include:

- *Contacts/arrangements with governmental agencies.* Applicants and licensees need to describe in emergency plans their contacts and arrangements with OROs for offsite radiological emergency response. Applicants and licensees need to ensure regular coordination with these organizations, including review of emergency plan changes.
- *Notification of OROs.* Applicants and licensees need to establish primary and backup means of notifying OROs and a message authentication scheme. The emergency plan needs to include the proposed time period within which notifications to OROs would be made.
- *Protective measures.* Applicants and licensees need to maintain the capability to issue offsite protective action recommendations to OROs (*e.g.,* evacuation, sheltering). The emergency plan needs to describe the procedures by which protective measures are implemented, maintained, and discontinued in their emergency plans.
- *Evacuation time estimate study.* Applicants and licensees need to conduct an evacuation time estimate (ETE) study and maintain the ETE up to date. The ETE is primarily used in the development of protective action strategies and to inform offsite protective action decisionmaking. In the proposed rule, § 50.160(b)(1)(iv)(B)(*5*) would have required an ETE ''of the areas beyond the site boundary and within the EPZ.'' The NRC received comments that the phrase, ''areas beyond the site boundary'' could be interpreted to exclude, rather than include, the area within the site boundary. As a result, in this final rule, the NRC removed the phrase ''beyond the site boundary and'' to clarify that an ETE is intended to estimate the time to evacuate various sectors and distances within a licensee's plume exposure pathway EPZ, which includes the area within the plant site boundary. However, for a site boundary EPZ, the NRC is not requiring an ETE because predetermined, prompt offsite protective actions are not required. In addition, in this final rule § 50.160(b)(1)(iv)(B)(*5*) is renumbered to § 50.160(b)(1)(iv)(B)(*4*).
- *Emergency response facilities.* Applicants and licensees need to describe in their emergency plans an offsite facility and any backup facilities for coordination of the response with OROs.
- *Offsite dose projections.* Applicants and licensees need to be capable of making offsite dose assessments and communicating their results to OROs. The emergency plan needs to describe the methods and instruments available for conducting these assessments.
- *Dissemination of public information.* Applicants and licensees need to describe in their emergency plans the means of providing initial and updated information to the public during an emergency (*e.g.,* communication with the news media, coordination with OROs). Applicants and licensees need to describe the public alert and notification system.
- *Reentry.* Applicants and licensees need to describe in their emergency plans coordination with OROs on offsite reentry plans including the conditions necessary to allow reentry into the EPZ during and after an emergency. Some conditions may include: (1) use of access control points to issue dosimetry and train reentering individuals on its use; (2) use of stay times (as used here, the amount of time a person can safely stay in a restricted zone without exceeding their exposure limit), depending on the location of the reentry destination; (3) use of a health physicist escort or other personnel escort trained in the use of dosimetry; and (4) provision of monitoring and decontamination for exiting individuals. Reentry plans cover private citizens. For example, reentry plans may cover scenarios such as farmers being permitted to reenter the affected area to provide essential care for livestock.
- *Offsite drills and exercises.* Applicants and licensees need to describe in their emergency plans how offsite radiological emergency response is incorporated into their drills and exercises without mandatory public participation. Drill and exercise programs need to incorporate offsite response, and applicants and licensees need to coordinate with offsite response organizations, including FEMA, for their participation in drills and exercises and implementation of corrective actions.

In carrying out its responsibility under the Atomic Energy Act of 1954, as amended (AEA), the NRC establishes regulatory standards for onsite and offsite radiological emergency planning. If an applicant's or licensee's emergency plan meets the NRC's regulations, then the NRC has reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. In the case of existing EP regulations for NPUFs, fuel cycle facilities, and ISFSIs, there are no regulatory requirements for dedicated offsite radiological emergency plans as part of the NRC license. Accordingly, NRC guidance for such facilities states that FEMA findings and determinations are not needed to support NRC licensing decisions. Similarly, for SMRs and ONTs within the scope of this final rule, FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) are only needed for a facility where a plume exposure pathway EPZ extends beyond the site boundary requiring dedicated offsite radiological EP plans for the facility.

This final rule, which does not require offsite planning activities for facilities without plume exposure pathway EPZs or with plume exposure pathway EPZs at the site boundary, does not affect the authority that FEMA has under its regulations in Chapter I, ''Federal Emergency Management Agency, Department of Homeland Security,'' of 44 CFR, ''Emergency Management and Assistance,'' for overall emergency management and assistance to State and local response organizations, nor does it affect the responsibilities of State and local governments to establish and maintain comprehensive emergency management plans. Under its role as described in the National Response Framework, the NRC remains ready to provide FEMA and State, local, and Tribal governments with technical advice related to the safety and security of any proposed SMR or ONT facility.

In cases where a plume exposure pathway EPZ does not extend beyond the site boundary, even in the absence of NRC requirements for offsite radiological emergency planning, the responsible OROs would continue to take actions to protect the health and safety of the public. Each of the States has established an emergency management organization to facilitate the safeguarding of the life and property of its citizens.[5]

The NRC has confidence in the ability of OROs to implement appropriate response actions when necessary, using comprehensive ''all-hazards'' emergency planning. The OROs' general emergency response capabilities are not unique to radiological emergency response. The NRC's confidence is expressed in the NRC's regulations in § 50.47(c)(1)(iii) and further strengthened by the NRC's

[5] See FEMA's Emergency Management Agencies website *https://www.fema.gov/emergency-management-agencies.*

recognition of national-level efforts (*e.g.,* National Incident Management System,[6] National Preparedness Goal,[7] Core Capabilities,[8] National Preparedness System,[9] National Planning Frameworks [10]), in which the NRC participates, to improve the state of emergency planning at all levels of government and within the whole community.[11] Consequently, for SMR and ONT facilities without plume exposure pathway EPZs or with plume exposure pathway EPZs at the site boundary, there is reasonable assurance that appropriate response actions can and will be taken in the event of a radiological emergency, without the need for regulatory standards for offsite radiological emergency response plans and the associated FEMA findings and determinations that offsite plans are adequate and can be implemented.

The requirements in this final rule do not alter exemptions from EP regulations previously granted to power reactor licensees that have transitioned to decommissioning. In particular, the changes to § 50.47 in this rule clarify when § 50.47(b) does not apply to offsite emergency plans once certain conditions are met, consistent with the exemptions.

f. Changes to Emergency Plans

Section 50.54(q) currently establishes the process for evaluation, submission, and review of changes to emergency plans. The NRC is establishing that SMRs and ONTs continue to follow the existing process for changes to emergency plans, whether the facilities are following the performance-based approach to EP under § 50.160 or the approach to EP under § 50.47(b) and appendix E to 10 CFR part 50. This final rule includes conforming changes to § 50.54(q).

Existing § 50.54(q)(2) requires licensees to follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to 10 CFR part 50 and, for power reactor licensees, the planning standards in § 50.47(b), and existing § 50.54(q)(3) and (4) describe the process for analyzing, submitting, and making changes to emergency plans. The NRC is revising § 50.54(q)(2) through (4) to include cross-references to the requirements under § 50.160 for licensees choosing the performance-based approach and to clarify that licensees must follow and maintain an emergency plan that meets either the applicable requirements of § 50.160 or the requirements of appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards of § 50.47(b). The NRC is not making any changes to the emergency plan change process. Licensees choosing the performance-based approach to EP must evaluate changes to their emergency plans against the performance-based requirements under § 50.160 using the same reduction in effectiveness criteria as current licensees and submit changes that reduce the effectiveness of the plan to the NRC for approval prior to implementation. The NRC is revising the definition of ''emergency planning function'' under § 50.54(q)(1) to remove references to appendix E to 10 CFR part 50 and § 50.47(b) because emergency planning functions are addressed under both these sections and under § 50.160, and the NRC does not consider the references essential to the definition.

For any existing or future holder of an OL or COL for an SMR or non-LWR, or any future holder of an OL for an NPUF, § 50.54(q)(7) stipulates that a licensee desiring to change its emergency plan to comply with the performance-based approach to EP needs to submit a license amendment request with the proposed changes to its emergency plan. The request needs to include an explanation of the schedule and analyses supporting the implementation of a performance-based EP program.

g. Emergency Response Data System

Appendix E to 10 CFR part 50, section VI, ''Emergency Response Data System,'' outlines a set of system, testing, and implementation requirements for the emergency response data system (ERDS) for operating nuclear power reactor licensees, and § 50.72, ''Immediate notification requirements for operating nuclear power reactors,'' includes requirements for activation of ERDS. In contrast, the 10 CFR part 50, appendix E ERDS requirement and § 50.72 ERDS activation requirement are not applicable to applicants and licensees choosing to comply with § 50.160. Applicants and licensees choosing § 50.160 need to describe in their emergency plans the data links with the NRC for use in emergencies. Specific parameters to be reported are determined for the specific technology during the license application process under 10 CFR part 50 or part 52. The NRC must review each applicant's data transmission capabilities on a case-specific basis. The NRC is not making any changes to its ERDS regulations.

3. Hazard Analysis of Contiguous or Nearby Facilities

The NRC anticipates that SMRs and ONTs may be located on the same site or close to large LWRs or other types of reactors; industrial, military, or transportation facilities; or a combination of these or other facilities. The presence of such facilities requires additional EP considerations relative to an independently sited facility. For example, SMRs or ONTs may need to be prepared for events associated with contiguous or nearby facilities' hazards.

Although the NRC's regulations do not extend to the licensing, operations, or oversight of non-nuclear facilities, the NRC has authority over the activities of NRC applicants and licensees that are located on or close to an industrial site or other facility not licensed by the NRC. For example, a nuclear power facility could be sited contiguous to or near an industrial facility to supply process heat or electrical power, or an SMR could be used to power a desalination facility located on the same site. There are many potential examples of licensees that may be located contiguous to or near a facility not licensed by the NRC; under each scenario, the hazards of the facility not licensed by the NRC must be factored into the EP program of the nuclear facility to ensure the protection of public health and safety.

For SMR or ONT applicants and licensees located contiguous to or near another facility, § 50.160(b)(2) requires the applicant or licensee to perform a hazard analysis to assess any credible hazards that would adversely impact the implementation of emergency plans at the SMR or ONT facility. The analysis needs to identify site-specific, credible hazards from other, non-nuclear facilities that require the applicant's or licensee's emergency plan to include arrangements that would otherwise not be needed in the absence of the facility. For example, these arrangements might include notifying contiguous or nearby facilities regarding emergencies, classifying a hazard from another facility that may negatively impact the safe operation of the nuclear facility, and providing for protective actions for the other facility's personnel or other on-site individuals, such as visitors. A credible hazard could include any event at another facility's site that would lead

[6] For further information on the National Incident Management System, see: *https://www.fema.gov/pdf/emergency/nims/nimsfaqs.pdf.*

[7] For further information on the National Preparedness Goal, see: *https://www.fema.gov/national-preparedness-goal.*

[8] For further information on Core Capabilities, see: *https://www.fema.gov/core-capabilities.*

[9] For further information on the National Preparedness System, see: *https://www.fema.gov/national-preparedness-system.*

[10] For further information on the National Planning Frameworks, see: *https://www.fema.gov/national-planning-frameworks.*

[11] For more information on the definition of ''whole community,'' see: *https://www.fema.gov/whole-community#.*

to an emergency response at the SMR or ONT facility. It may be appropriate for SMRs or ONTs with contiguous or nearby facilities to consider a quantitative or qualitative assessment of all postulated accident scenarios at the other facilities. The applicant's or licensee's EP program must reflect these credible hazards and the planning activities needed to address the hazards. For example, the location of facilities on the same site or close to an SMR or ONT may affect the applicant's or licensee's determinations about the EPZ size. Looking across all facilities, the applicant or licensee must assess the combined radiological and industrial hazards at the site.

The NRC is issuing RG 1.242 with this final rule, which includes guidance on hazard analyses for contiguous or nearby facilities.

4. Emergency Planning Zones

The NRC is establishing a consequence-oriented, technology-inclusive approach to EPZ size determinations for SMRs and ONTs. This approach is similar to the dose/distance rationale historically used by the NRC, in part, to determine EPZ size for production or utilization facilities. Under the existing regulations, SMRs or ONTs, depending on their capacity and technology, are either required to establish a 10-mile (16-km) plume exposure pathway EPZ and a 50-mile (80-km) IPZ or follow the case-by-case EPZ size determination process under §§ 50.33(g), 50.47(c)(2), and section I.3. of appendix E to 10 CFR part 50. Preapplication discussions and previous applications for EP exemption requests from SMRs and ONTs have indicated that these technologies could have reduced offsite dose consequences in the unlikely event of an accident, and the standard 10-mile (16-km) EPZ and 50-mile (80-km) IPZ may not be necessary to ensure public health and safety for these facilities. Because of the range of potential source terms and designs for SMRs or ONTs, the NRC is establishing an alternative scalable methodology for determining EPZ size on a case-specific basis. This methodology is established in guidance (RG 1.242) generically without design- or site-specific information regarding source term, fission products, or projected offsite dose. Applicants must provide the design- and site-specific information regarding source term, fission products, or projected offsite dose for NRC review in an application.

As mentioned in the ''Technical Basis'' section of this document, NUREG–0396 established the planning basis for EP and established EPZs for large LWRs based on the conclusion that the objective of emergency response plans should be to provide dose savings for a spectrum of accidents that could produce offsite doses in excess of the EPA PAGs. This final rule is offering an EPZ size determination process that is consistent with this philosophy. Section 50.33(g)(2) establishes EPZ size determination requirements for SMR, non-LWR, and NPUF applicants complying with § 50.160. Small modular reactor and non-LWR applicants for an OL, COL, CP, or ESP and NPUF applicants for a CP or OL must submit the analysis used to establish their proposed plume exposure pathway EPZ size. Applicants need to establish their EPZ as the area within which public dose, as defined in § 20.1003, is projected to exceed 10 mSv (or 1 rem) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. In addition, applicants need to show that the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. If the plume exposure pathway EPZ extends beyond the site boundary and if the application is for an SMR or non-LWR OL, COL, an ESP that contains plans for coping with emergencies under § 52.17(b)(2)(ii), or an ESP that proposes major features of the emergency plans and describes the EPZ, then § 50.33(g)(2) requires that the exact configuration of the plume exposure pathway EPZ be determined in relation to local emergency response needs and capabilities, as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Section 50.160(b)(3) requires applicants to describe in their emergency plans the boundary and physical characteristics of the EPZ.

Upon receiving an OL, COL, ESP, or CP applicant's technical basis for proposed site-specific plume exposure pathway EPZ size, the NRC must review the design and licensing information to ensure that the information that the applicant provides on the offsite dose consequences is commensurate with the requested EPZ size and that the applicable performance-based requirements are met to ensure adequate protection of public health and safety. Some of this information may have already been provided as part of a certified design referenced in an application or in a topical report related to the design. The NRC also must assess the need to provide site-specific guidance concerning the accident scenarios being considered.

The plume exposure pathway EPZ determination requirements could result in an applicant having no plume exposure pathway EPZ. For this result to occur, the applicant's analysis required by § 50.33(g)(2) would need to show that one or both of the criteria in § 50.33(g)(2)(i) are not met. For purposes of complying with § 50.160, this applicant would be similar to an applicant with a site boundary plume exposure pathway EPZ. Both applicants would need to have an emergency plan that meets the requirements of § 50.160(a), (b)(1)(i)–(iv)(A), (b)(2), (b)(4) and (c). An applicant with a site boundary plume exposure pathway EPZ would also need to comply with § 50.160(b)(3), which requires the applicant to determine and describe in its emergency plan the boundary and physical characteristics of the EPZ.

In addition to the plume exposure pathway EPZ size determination process, the NRC is including ingestion response planning requirements under § 50.160(b)(4). Applicants and licensees complying with § 50.160 are required to describe in their emergency plans the capabilities to prevent contaminated food and water from entering the ingestion pathway. The proposed rule would have required applicants and licensees to describe in their emergency plans the capabilities to protect contaminated food and water from entering the ingestion pathway. Although the goal is to protect the public from contaminated food and water, this goal can be achieved by preventing contaminated food and water from entering the ingestion pathway. Therefore, in the final rule, the NRC revised § 50.160(b)(4) to require applicants and licensees to describe in their emergency plans the capabilities to prevent contaminated food and water from entering the ingestion pathway.

The capabilities described in the emergency plan need to address major exposure pathways associated with the ingestion of contaminated food and water. The duration of any exposure to contaminated food or water could range from weeks to months and represents a long-term response need. Even in cases where the facility's plume exposure pathway EPZ is bounded by the site boundary, the applicant or licensee must reference capabilities of Federal, State, and local authorities.

Examples of demonstrated capabilities in response to ingestion of contaminated food or water include three notable large-scale quarantines documented by the Centers for Disease Control and Prevention: the multi-state

outbreaks of E. Coli O157:H7 infections from spinach (September–October 2006); the multi-state outbreak of human *salmonella enteritis* infections associated with shell eggs (July–December 2010); and, the multi-state outbreak of fungal meningitis and other infections (October 2012). In each case, the successful quarantine and removal from public access of contaminated food and water products in response to biological contamination demonstrates that a response to prevent ingestion of contaminated foods and water could be performed in an expeditious manner without a predetermined ingestion planning zone.

5. Implementation

This final rule includes implementation schedules for existing and future applicants and licensees of facilities choosing to comply with § 50.160. The NRC received public comments on the proposed requirement for applicants to conduct an initial exercise to demonstrate effectiveness of the EP program no later than 18 months before the issuance of an OL or the scheduled date for initial loading of fuel for a part 52 COL holder. The comments suggested that an initial exercise ''no later than 18 months before'' the issuance of an OL for a part 50 applicant or the scheduled date for initial loading of fuel for a part 52 COL holder is not the appropriate time frame. In reviewing these comments, the NRC determined that the wording in the proposed rule needed revision. Specifically, in § 50.160(c)(1), the NRC is revising the rule language to require an applicant for an OL issued under 10 CFR part 50 after the effective date of this final rule that desires to comply with the performance-based approach to EP to establish, implement, and maintain an EP program that meets the requirements of § 50.160(b), as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the issuance of an OL for the first unit described in the license application. Similarly, in § 50.160(c)(2), a holder of a COL issued under 10 CFR part 52 desiring to comply with the performance-based approach to EP before the Commission has made the finding under § 52.103(g) is required to establish, implement, and maintain an EP program that meets the requirements of § 50.160(b), as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the scheduled date for initial loading of fuel. These changes allow greater flexibility in demonstrating regulatory compliance and ensure consistency with appendix E to 10 CFR part 50, which requires an applicant to conduct a full-participation emergency planning exercise within 2 years before the issuance of an OL for a part 50 applicant or the scheduled date for initial loading of fuel for a part 52 COL holder.

As discussed in the ''Changes to Emergency Plans'' section of this document, for existing or future SMRs or ONTs that hold OLs or COLs, § 50.54(q)(7) stipulates that facilities desiring to change their emergency plans to comply with the performance-based approach to EP, shall submit a license amendment request with these changes.

a. Reasonable Assurance

The NRC's authority to regulate the use of radioactive materials is set forth in the AEA. The AEA confers broad regulatory powers to the Commission and specifically authorizes it to issue regulations it deems necessary to fulfill its responsibilities under that statute. Section 161.b of the AEA authorizes the Commission to establish by rule, regulation, or order such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Under Section 161.i of the AEA, the Commission may prescribe such regulations or orders, as it may deem necessary, to protect health and to minimize danger to life or property.

The NRC's regulations include standards for both onsite and offsite emergency response plans. The Commission, based on its authority under the AEA, determined that these standards are necessary for operating power reactors to provide for public health and safety. The regulations in §§ 50.47 and 50.54 prescribe how the NRC makes licensing decisions or takes appropriate enforcement action by using findings of reasonable assurance that adequate protective measures can and will be taken to protect public health and safety in the event of a radiological emergency. The NRC bases reasonable assurance findings on: (1) the NRC's assessment of the adequacy of the applicant's or licensee's onsite emergency plan and whether there is reasonable assurance the plan can be implemented, and (2) the NRC's review of FEMA findings and determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented.

The performance-based approach to EP under § 50.160 provides an adequate basis for an acceptable state of EP and ensures that coordination and applicable arrangements with offsite agencies are maintained (*e.g.,* notification and assistance resources). Reasonable assurance is maintained under the performance-based approach through: (1) submission and case-specific review of design- and site-specific analyses to support the proposed plume exposure pathway EPZ size; (2) review of site-specific emergency plans to ensure compliance with the performance-based requirements; (3) demonstration of emergency response functions through drills and exercises; (4) regular tracking of performance objective information; (5) analysis of potential hazards associated with contiguous or nearby NRC-licensed facilities or facilities not licensed by the NRC; and (6) the NRC's inspection and enforcement program.

For applicants and licensees with plume exposure pathway EPZs beyond the site boundary, the NRC, in consultation with FEMA, continues to ensure that reasonable assurance is maintained based on the performance-based requirements, as demonstrated through drills and exercises. As described in the ''Offsite Radiological Emergency Preparedness Planning Activities'' section of this document, FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) are not needed for SMRs or ONTs without plume exposure pathway EPZs or with plume exposure pathway EPZs that do not extend beyond the site boundary. The NRC makes reasonable assurance determinations regarding onsite EP requirements for these facilities, and every licensee must follow and maintain the effectiveness of its emergency plan if the NRC is to continue to find, under § 50.54(s)(2)(ii), that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at that site.

In this final rule, the NRC revised § 50.160(b) from the proposed rule to state that the reasonable assurance finding made under § 50.47(a)(1) necessary to issue an OL, COL, or ESP to an applicant complying with § 50.47 and appendix E to part 50 is also necessary to issue an OL, COL, or ESP to a power reactor applicant complying with § 50.160. The NRC also revised § 50.47(a)(1)(iv) to reflect that an applicant for an ESP that proposes major features of the emergency plan

under § 52.17(b)(2)(i) can choose to comply with § 50.160.

b. Administrative and Clarifying Changes to the Regulations

The NRC is making clarifying changes to the following paragraphs.

1. Section 50.54(q)(4), which required after February 21, 2012, any changes to a licensee's emergency plan that reduce the effectiveness of the plan as defined in paragraph (q)(1)(iv) to be submitted to the NRC for approval before implementation. As the date of the provision has expired, the NRC is deleting ''after February 21, 2012'' and retaining the remainder of the provision.

2. Section 50.54(q)(5), which required licensees to submit a report of each change made without prior NRC approval, as allowed under § 50.54(q)(3), after February 21, 2012, including a summary of its analysis, within 30 days after the change is put into effect. The NRC is deleting ''after February 21, 2012'' from this provision, as the date has expired, and retaining the remainder of the provision.

3. Section 50.54(s)(2)(ii), which allows the NRC to take enforcement action to shut down power reactors that do not provide reasonable assurance that adequate protective measures would be taken in the event of a radiological emergency after April 1, 1981. There is no longer a need for the date requirement of this provision because any future determinations made under § 50.54(s) will occur after April 1, 1981. The NRC is deleting ''after April 1, 1981'' and retaining the remainder of the provision.

The NRC is revising these requirements in the interest of regulatory clarity. Eliminating or revising these requirements does not relax currently effective regulatory requirements or cause any regulatory burden for existing or future licensees.

III. Opportunities for Public Participation

The NRC published the proposed rule on May 12, 2020 (85 FR 28436), and the comment period was open until July 27, 2020. On July 21, 2020 (85 FRN 44025), the NRC extended the public comment period by an additional 60 days to September 25, 2020, to allow more time for members of the public and other stakeholders to develop and submit their comments.

The NRC hosted one public meeting to engage with external stakeholders on the proposed rule and associated draft guidance document during the public comment period. This public meeting was held on June 24, 2020. A summary of the public meeting is available in ADAMS, as provided in the ''Availability of Documents'' section. The feedback from this public meeting informed the development of this final rule.

IV. Public Comment Analysis

The NRC prepared a summary and analysis of public comments received on the 2020 proposed rule and draft regulatory guide, as referenced in the ''Availability of Documents'' section. In response to the proposed rule and draft regulatory guide, the NRC received 2,212 comment submissions.

The public comment submittals are available from the Federal e-Rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2015–0225. Responses to the public comments, including a summary of how this final rule or the guidance changed as a result of the public comments, can be found in the public comment analysis document as indicated in the ''Availability of Documents'' section of this document.

For more information about the associated guidance document, see the ''Availability of Guidance'' section of this document.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes within this final rule.

Section 50.2 Definitions

In § 50.2, this final rule adds the definitions for *Non-light-water reactor, Non-power production or utilization facility,* and *Small modular reactor.*

Section 50.8 Information Collection Requirements; OMB Approval

In § 50.8, this final rule adds new § 50.160 to the list of approved information collection requirements contained in 10 CFR part 50.

Section 50.10 License Required; Limited Work Authorization

In § 50.10, this final rule revises paragraph (a)(1)(vii) to include onsite emergency facilities necessary to comply with new § 50.160 requirements within the scope of items for which a CP or limited work authorization is necessary to commence construction.

Section 50.33 Contents of Applications; General Information

In § 50.33, this final rule revises paragraph (g) to create new subparagraphs (g)(1) and (2). Paragraph (g)(1) contains the original text of paragraph (g) and adds the qualifier ''Except as provided in paragraph (g)(2) of this section.''

Paragraph (g)(2) establishes EPZ size determination requirements for SMR, non-LWR, and NPUF applicants complying with § 50.160.

Section 50.34 Contents of Applications; Technical Information

In § 50.34, this final rule revises paragraph (a)(10) to require SMR, non-LWR, or NPUF CP applicants to describe in their PSARs the preliminary plans for coping with emergencies based on the requirements in either § 50.160 or appendix E to 10 CFR part 50.

This final rule also revises paragraph (b)(6)(v) to require SMR, non-LWR, and NPUF applicants for an OL to include in their FSARs their plans for coping with emergencies based on the requirements in either § 50.160 or appendix E to 10 CFR part 50.

Section 50.47 Emergency Plans

In § 50.47, this final rule makes conforming changes to paragraphs (a)(1)(iv), (b) introductory text, (c)(1) introductory text, (c)(1)(i), and (e) and adds new paragraph (f) denoting when the offsite emergency response plan requirements in § 50.47(a)(2), (b), and (c)(2) do not apply.

Section 50.54 Conditions of Licenses

In § 50.54, this final rule revises paragraph (q)(1)(iii) to remove the references to appendix E to 10 CFR part 50 and § 50.47(b).

This final rule revises paragraph (q)(2) to include new subparagraphs (q)(2)(i) and (ii). Paragraph (q)(2)(i) contains the original text of paragraph (q)(2) and adds the qualifier ''except as provided in paragraph (q)(2)(ii) of this section,'' and paragraph (q)(2)(ii) allows SMR, non-LWR, and NPUF licensees to follow and maintain the effectiveness of an emergency plan that meets the requirements of § 50.160 or appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, § 50.47(b).

This final rule also revises paragraph (q)(3) to include new subparagraphs (q)(3)(i) and (ii). Paragraph (q)(3)(i) contains the original text of paragraph (q)(3) and adds the qualifier ''except as provided in paragraph (q)(3)(ii) of this section'' and paragraph (q)(3)(ii) specifies when an SMR, non-LWR, or NPUF licensee choosing to comply with the performance-based EP regulations could make changes to its emergency plan without prior NRC approval.

Paragraphs (q)(4) and (5) are amended to remove the date February 21, 2012, and paragraph (q)(4) is further revised to specify that licensees that choose to comply with the new requirements of § 50.160, when making an emergency plan change that reduces plan effectiveness, need to specify the basis for concluding how their revised

emergency plans continue to meet the requirements of that section.

This final rule adds new paragraph (q)(7) that contains the details for submitting license amendment requests for SMR, non-LWR, or NPUF licensees implementing EP programs with the associated plan modifications necessary to meet the requirements of new § 50.160.

Paragraph (s)(2)(ii) is amended to remove the date April 1, 1981, and to replace the word ''reactor'' with the word ''facility.''

This final rule revises paragraph (s)(3) by adding clarification at the beginning of the sentence that if the standards apply to offsite emergency response plans, or if the planning activities in new § 50.160(b)(1)(iv)(B) apply, then the NRC bases its findings on a review of FEMA's findings and determinations.

This final rule also revises paragraph (gg)(1) introductory text to include the option for SMR, non-LWR, or NPUF applicants to use new § 50.160, as applicable.

Section 50.160 Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities

This final rule adds a new subpart, ''Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities,'' after § 50.155 and new § 50.160, which contains alternative EP requirements for SMRs, non-LWRs, and NPUFs.

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

This final rule revises paragraph I.3 and footnote 2 to clarify that the potential radiological hazards to the public associated with the operation of NPUFs and fuel facilities involve considerations different than those associated with power reactors. This paragraph is also amended to replace ''as necessary'' with ''is necessary,''.

Section 52.1 Definitions

This final rule revises the definition of *Major feature of the emergency plans* to include new § 50.160, as applicable.

Section 52.17 Contents of Applications; Technical Information

This final rule revises paragraphs (b)(2)(i) and (ii) to include new § 50.160, as applicable.

Section 52.18 Standards for Review of Applications

This final rule revises § 52.18 to make editorial changes and to include references to new § 50.160, as applicable.

Section 52.79 Contents of Applications; Technical Information in Final Safety Analysis Report

This final rule revises paragraph (a)(21) to require applicants for SMRs or non-LWRs to comply with either the requirements in § 50.160 or the requirements in appendix E to 10 CFR part 50 and § 50.47(b).

Section 72.32 Emergency Plans

In § 72.32, this final rule revises paragraph (c)(2) to replace the words ''required by'' with ''that meets either the requirements in'' and to add a reference to new § 50.160.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power facilities and NPUFs. The companies, universities, and government agencies that own these facilities do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

VII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The conclusion from the analysis is that this final rule and associated guidance results in net savings to the industry and the NRC of $7.98 million using a 7-percent discount rate and $14.9 million using a 3-percent discount rate. The final regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document.

VIII. Backfitting and Issue Finality

This final rule contains new alternative requirements for SMR and ONT applicants and licensees. Because these alternative requirements are not imposed upon applicants and licensees and do not prohibit applicants and licensees from following existing requirements, the requirements do not constitute backfitting under 10 CFR part 50 or part 72 or affect the issue finality of any approval issued under 10 CFR part 52.

As described in Section XVI, ''Availability of Guidance,'' in this document, the NRC is issuing RG 1.242, which provides guidance on methods acceptable to the NRC for complying with this final rule. Issuance of the RG does not constitute backfitting under §§ 50.109 and 72.62 and does not affect the issue finality of any approval issued under 10 CFR part 52. As discussed in the ''Implementation'' section of the RG, the NRC has no current intention to impose the RG on holders of an OL, ESP, or COL. If, in the future, the NRC seeks to impose positions stated in the RG in a manner that would constitute backfitting or affect the issue finality of an approval under 10 CFR part 52, the NRC would need to make the showing as set forth in § 50.109 or address the regulatory criteria set forth in the applicable issue finality provision, as applicable, that would allow the NRC to impose the position.

IX. Cumulative Effects of Regulation

Cumulative Effects of Regulation (CER) consists of the challenges licensees may face in addressing the implementation of new regulatory positions, programs, and requirements (*e.g.,* rulemaking, guidance, generic letters, backfits, inspections). The CER may manifest in several ways, including the total burden imposed on licensees by the NRC from simultaneous or consecutive regulatory actions that can adversely affect the licensee's capability to implement those requirements, while continuing to operate or construct its facility in a safe and secure manner.

The goals of the NRC's CER effort were met throughout the development of this final rule. The NRC engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. The NRC held a public meeting on June 24, 2020, to discuss the proposed rule. A summary of the public meeting is available in ADAMS, as provided in the ''Availability of Documents'' section of this document.

Although the new alternative EP requirements for SMRs and ONT are voluntary, the NRC included in the **Federal Register** notice for the proposed rule a request for feedback related to CER. Specifically, the NRC requested feedback on the implementation and potential unintended consequences of the proposed rule. The NRC received two comments in response to the CER questions in the proposed rule, but neither required a change to the rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has

written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

XI. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this final rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis of this determination reads as follows: The majority of the provisions in this final rule are administrative or procedural in nature and either do not affect the physical environment or would have no noticeable effects. Further, the NRC has evaluated the final requirements of interest to stakeholders based on interactions described in section 6, ''Environmental Impacts of the Proposed Action,'' of this environmental assessment that have the potential to affect the human environment, including the scalable approach for determining the size of the plume exposure pathway EPZ under § 50.33(g) and the ingestion response planning requirements under § 50.160(b)(4), and determined that this final rule does not have a significant environmental impact for the following reasons. Under the existing EP requirements and these final alternative EP requirements, the dose criteria under which predetermined protective measures would be taken (*e.g.,* evacuation, sheltering) would be similar under both rules, and therefore, the dose consequence to the public is similar. The ingestion response planning requirements under § 50.160(b)(4), while not requiring SMR and ONT applicants and licensees to establish an IPZ, provide the same capabilities available to identify and interdict contaminated food and water in the event of a radiological emergency as required under existing EP regulations. The environmental effects of the final ingestion response planning requirements are similar to that of the existing EP requirements. For these reasons, the NRC concludes that the EPZ requirement under § 50.33(g) and ingestion response planning requirement under § 50.160(b)(4) do not have a significant impact on the physical environment. Therefore, this rulemaking does not warrant preparation of an environmental impact statement. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

The determination of this environmental assessment is that there is no significant offsite impact to the public from this action. The environmental assessment is available as indicated under the ''Availability of Documents'' section.

XII. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget (OMB), approval numbers 3150–0011 and 3150–0151.

The burden to the public for the information collections is estimated to average a reduction of 548 hours per response for 10 CFR part 50 and a reduction of 200 hours per response for 10 CFR part 52, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collections create a transparent alternative EP regulatory framework that allows SMR and ONT applicants and licensees to submit for NRC approval a performance-based EP program, to include a scalable plume exposure pathway EPZ and licensee-defined performance objectives and metrics, while continuing to provide reasonable assurance that adequate protective measures can and will be implemented in a radiological emergency. Applicants or licensees requesting approval to construct or operate utilization or production facilities are required by the AEA to provide information and data that the NRC may determine necessary to ensure the adequate protection of health and safety of the public. The submission of emergency plans to the NRC is required in order to allow the NRC to determine that the emergency plans and EP programs provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Information is used by the NRC to evaluate the adequacy of the alternative EP program for approval, assess ongoing adequacy once implemented, determine whether to take actions, such as to conduct inspections or to alert other licensees to prevent similar events that may have generic implications, and to update information in the NRC Emergency Operation Center used in support of an NRC response to an actual emergency, drill, or exercise. Responses to these collections of information are required for applicants and licensees choosing to comply with 10 CFR 50.160. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0225.
- *Mail comments to:* FOIA, Library, and Information Collections Branch, Office of Information Services, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0011 and 3150–0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (CRA) (5 U.S.C. 801–808). However, OMB has not found it to be a major rule as defined in the CRA.

XIV. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this final rule that will amend §§ 50.10, 50.34, 50.47, 50.54, 50.160, and appendix E to 10 CFR part 50 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR part 50 are discussed in § 50.111.

XV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC revises regulations associated with EP in 10 CFR parts 50, 52, and 72. This action does not constitute the establishment of

a standard that contains generally applicable requirements.

XVI. Availability of Guidance

The NRC is issuing new guidance, RG 1.242, ''Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities,'' that support implementation of the requirements in this final rule. The guidance is available in ADAMS, as provided in the ''Availability of Documents'' section of this document. You may access information and comment submissions related to the guidance by searching on *https://www.regulations.gov* under Docket ID NRC–2015–0225.

The guidance document is intended for use by applicants, licensees, and NRC staff, and describes an approach and method acceptable for implementing the requirements of this final rule. As a guidance document, RG 1.242 does not establish additional requirements, and applicants and licensees are able to propose alternative ways for demonstrating compliance with the requirements in § 50.160.

XVII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/**Federal Register** citation
EPA/520/1–75–001, ''Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,'' September 1975.	ML20203M064.
NUREG–75/014, ''Reactor Safety Study—An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants,'' (WASH–1400), October 1975 (Appendices III–IV, Appendix V, Appendix VI, Appendices VII–X).	ML070610293, ML070530533, ML070600389, ML070600376.
NUREG–0396, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' December 1978.	ML051390356.
RG 2.6, ''Emergency Planning for Research Reactors,'' January 1979	ML12184A008.
''10 CFR Parts 50 and 70, Emergency Planning,'' Final Rule, August 19, 1980	45 FR 55402.
NUREG–0654/FEMA–REP–1, Revision 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' November 1980.	ML040420012.
''Emergency Planning and Preparedness,'' Final Rule, July 13, 1982	47 FR 30232.
NUREG–0849, ''Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors,'' October 1983.	ML062190191.
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List of Subjects

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the

Atomic Energy Act of 1954, as amended; the Energy Reorganization Act, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 50, 52, and 72:

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 1. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

■ 2. In § 50.2, add in alphabetical order definitions for ''Non-light-water reactor'', ''Non-power production or utilization facility'', and ''Small modular reactor'' to read as follows:

§ 50.2 Definitions.

* * * * *

Non-light-water reactor means a nuclear power reactor using a coolant other than light water.

Non-power production or utilization facility means a production or utilization facility, licensed under § 50.21(a) or (c), or § 50.22, as applicable, that is not a nuclear power reactor or a production facility as defined under paragraphs (1) and (2) of the definition of *Production facility* in this section.

* * * * *

Small modular reactor means a power reactor, which may be of modular design as defined in § 52.1 of this chapter, licensed under § 50.21 or § 50.22 to produce heat energy up to 1,000 megawatts thermal per module.

* * * * *

§ 50.8 [Amended]

■ 3. In § 50.8, in paragraph (b), add the citation ''50.160,'' after the citation ''50.155,''.

■ 4. In § 50.10, revise paragraph (a)(1)(vii) to read as follows:

§ 50.10 License required; limited work authorization.

(a) * * *

(1) * * *

(vii) Onsite emergency facilities necessary to comply with either § 50.160 or § 50.47 and appendix E to this part, as applicable.

* * * * *

■ 5. In § 50.33, revise paragraph (g) to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(g)(1) Except as provided in paragraph (g)(2) of this section, if the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant shall submit the radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[4] as well as the plans of State governments wholly or partially within the ingestion pathway EPZ.[5] If the application is for an early site permit that, under 10 CFR 52.17(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph. Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway shall focus on such actions as are appropriate to protect the food ingestion pathway.

* * * * *

[4] Emergency planning zones (EPZs) are discussed in NUREG–0396, EPA 520/1–78–016, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' December 1978.

[5] If the State and local emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.

(2) Small modular reactor, non-light-water reactor, or non-power production or utilization facility applicants complying with § 50.160 who apply for a construction permit or an operating license under this part, or small modular reactor or non-light-water reactor applicants complying with § 50.160 who apply for a combined license or an early site permit under part 52 of this chapter, must submit as part of the application the analysis used to determine whether the criteria in § 50.33(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Public dose, as defined in § 20.1003 of this chapter, is projected to exceed 10 mSv (1 rem) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) If the application is for an operating license or combined license or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, and if the plume exposure pathway EPZ extends beyond the site boundary:

(A) The applicant shall submit radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway EPZ.

(B) The exact configuration of the plume exposure pathway EPZ surrounding the facility shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries.

(iii) If the application is for an early site permit that, under § 52.17(b)(2)(i) of this chapter, proposes major features of the emergency plans and describes the EPZ, and if the EPZ extends beyond the site boundary, then the exact configuration of the plume exposure pathway EPZ surrounding the facility shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries.

* * * * *

■ 6. In § 50.34, revise paragraphs (a)(10) and (b)(6)(v) to read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(10) A discussion of the applicant's preliminary plans for coping with emergencies based on:

(i) Except as provided in paragraph (a)(10)(ii) of this section, the requirements in appendix E to this part.

(ii) For a small modular reactor, a non-light-water reactor, or non-power production or utilization facility construction permit applicant, the requirements in either § 50.160 or appendix E to this part.

* * * * *

(b) * * *

(6) * * *

(v) Plans for coping with emergencies based on:

(A) Except as provided in paragraph (b)(6)(v)(B) of this section, the requirements in appendix E to this part.

(B) For a small modular reactor, a non-light-water reactor, or a non-power production or utilization facility operating license applicant, the requirements in either § 50.160 or appendix E to this part.

* * * * *

■ 7. In § 50.47, revise paragraphs (a)(1)(iv), (b) introductory text, (c)(1) introductory text, (c)(1)(i), and (e) and add paragraph (f) to read as follows:

§ 50.47 Emergency plans.

* * * * *

(a) * * *

(1) * * *

(iv) If an application for an early site permit proposes major features of the emergency plans under 10 CFR 52.17(b)(2)(i), no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of either this section and appendix E to this part, or the applicable requirements of § 50.160, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

(b) The onsite and, except as provided in paragraphs (d) and (f) of this section, offsite emergency response plans for nuclear power reactors must meet the following standards:

(c)(1) Failure to meet the applicable standards set forth in either § 50.160 or paragraph (b) of this section may result in the Commission declining to issue an operating license; however, the applicant will have an opportunity to demonstrate to the satisfaction of the Commission that deficiencies in the plans are not significant for the plant in question, that adequate interim compensating actions have been or will be taken promptly, or that there are other compelling reasons to permit plant operations. Where an applicant for an operating license asserts that its inability to demonstrate compliance with the requirements in either § 50.160 or paragraph (b) of this section results wholly or substantially from the decision of State and/or local governments not to participate further in emergency planning, an operating license may be issued if the applicant demonstrates to the Commission's satisfaction that:

(i) The applicant's inability to comply with the requirements in either § 50.160 or paragraph (b) of this section is wholly or substantially the result of the non-participation of State and/or local governments.

* * * * *

(e) Notwithstanding the requirements of paragraph (b) of this section and the provisions of § 52.103 of this chapter, a holder of a combined license under part 52 of this chapter that is complying with the requirements of paragraph (b) of this section and appendix E to this part may not load fuel or operate except as provided in accordance with appendix E to this part and § 50.54(gg), and a holder of a combined license under part 52 of this chapter that is complying with the requirements of § 50.160 may not load fuel or operate except as provided in accordance with § 50.160(c)(2) and § 50.54(gg).

(f) Paragraphs (a)(2), (b), and (c)(2) of this section do not apply to offsite radiological emergency response plans if the onsite emergency plan is not required to meet paragraph (b) of this section or if the plume exposure pathway EPZ does not extend beyond the site boundary.

■ 8. In § 50.54:

■ a. Revise paragraphs (q)(1)(iii) and (q)(2) through (4);

■ b. In paragraph (q)(5), remove the words ''made after February 21, 2012'';

■ c. Add paragraph (q)(7);

■ d. In paragraph (s)(2)(ii), in the first sentence:

■ i. Remove the words ''after April 1, 1981,'';

■ ii. Remove the word ''reactor'' and add in its place the word ''facility''; and

■ iii. Add the words ''or cease operation'' after the words ''shut down''; and

■ e. Revise paragraphs (s)(3) and (gg)(1) introductory text.

The revisions and addition read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(q) * * *

(1) * * *

(iii) *Emergency planning function* means a capability or resource necessary to prepare for and respond to a radiological emergency.

* * * * *

(2)(i) Except as provided in paragraph (q)(2)(ii) of this section, a holder of a license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(ii) A holder of a license under this part for a non-power production or utilization facility, a holder of a license under this part for a small modular reactor or a non-light water reactor, or a holder of a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter for a small modular reactor or a non-light-water reactor, shall follow and maintain the effectiveness of either an emergency plan that meets the requirements in § 50.160 or an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(3)(i) Except as provided in paragraph (q)(3)(ii) of this section, the licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(ii) A non-power production or utilization facility, small modular reactor, or non-light-water reactor licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the requirements in § 50.160 or the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(4) The changes to a licensee's emergency plan that reduce the effectiveness of the plan as defined in paragraph (q)(1)(iv) of this section may not be implemented without prior approval by the NRC. A licensee

desiring to make such a change shall submit an application for an amendment to its license. In addition to the filing requirements of §§ 50.90 and 50.91, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to meet either the requirements in § 50.160 or the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

* * * * *

(7) Each holder of an operating license under this part or a combined license under part 52 of this chapter for a small modular reactor or non-light-water reactor or each holder of an operating license under this part issued after December 18, 2023 for a non-power production or utilization facility that wishes to transition to § 50.160 shall submit to the Commission, as specified in § 50.90, a license amendment request for implementing an emergency preparedness program with the associated plan modification necessary to meet the requirements of § 50.160(b). This submittal must include an explanation of the schedule and analyses supporting the implementation of the emergency preparedness program.

* * * * *

(s)

(3) If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, or if the planning activities in § 50.160(b)(1)(iv)(B) apply, then the NRC will base its finding on a review of the FEMA findings and determinations as to whether State and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. Nothing in this paragraph shall be construed as limiting the authority of the Commission to take action under any other regulation or authority of the Commission or at any time other than that specified in this paragraph.

* * * * *

(gg)(1) Notwithstanding § 52.103 of this chapter, if, following the conduct of the exercise required by either paragraph IV.f.2.a of appendix E to this part or § 50.160(c)(2), as applicable, FEMA identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license under part 52 of this chapter may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will base this finding on its assessment of the applicant's onsite emergency plans against the pertinent standards in either § 50.47 and appendix E to this part, or § 50.160, as applicable. Review of the applicant's emergency plans will include the following standards with offsite aspects:

* * * * *

■ 9. After § 50.155, add an undesignated center heading and § 50.160 to read as follows:

Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities

§ 50.160 Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities.

(a) *Definitions.* For the purpose of this section:

(1) *Site boundary* means site boundary as defined in § 20.1003 of this chapter.

(2) [Reserved]

(b) *Requirements.* The emergency plan shall contain information needed to demonstrate compliance with the elements set forth in this paragraph. The applicable requirements of § 50.47(a)(1) apply to applications submitted under this section.

(1) *Performance-based framework.* Demonstrate effective response in drills and exercises for emergency and accident conditions.

(i) *Maintenance of performance.* Maintain in effect preparedness to respond to emergency and accident conditions and describe in an emergency plan the provisions to be employed to maintain preparedness.

(ii) *Performance objectives.* (A) By the beginning of each calendar quarter, develop and maintain a complete list of performance objectives for that calendar quarter; and

(B) Maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters.

(iii) *Emergency response performance.* The emergency response team must have sufficient capability to demonstrate the following emergency response functions using drills or exercises:

(A) *Event classification and mitigation.* Assess, classify, monitor, and repair facility malfunctions in accordance with the emergency plan to return the facility to safe conditions.

(B) *Protective actions.* Implement and maintain protective actions for onsite personnel for emergency conditions, and recommend protective actions to offsite authorities as conditions warrant.

(C) *Communications.* Establish and maintain effective communications with the emergency response organization, and make notifications to response personnel and organizations who may have responsibilities for responding during emergencies.

(D) *Command and control.* Establish and maintain effective command and control for emergencies by using a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing emergency response functions as described in paragraph (b) of this section.

(E) *Staffing and operations.* Establish staffing for the facility necessary to implement the roles and responsibilities in paragraph (b)(1)(iii) of this section.

(F) *Radiological assessment.* Assess radiological conditions in and around the facility during emergencies, including:

(*1*) *Radiological conditions.* Assess, monitor, and report radiological conditions to the applicable response personnel using installed or portable equipment.

(*2*) *Protective equipment.* Issue and use protective equipment necessary to continue and expand mitigation and protective action strategies.

(*3*) *Core or vessel damage.* Assess, monitor, and report to the applicable response personnel the extent and magnitude of damage to the core or other vessel containing irradiated special nuclear material, such as fuel or targets, as applicable.

(*4*) *Releases.* Assess, monitor, and report to the applicable response personnel the extent and magnitude of all radiological releases, including releases of hazardous chemicals produced from licensed material.

(G) *Reentry.* Develop and implement reentry plans for accessing the facility after emergencies.

(H) *Critique and corrective actions.* Critique emergency response functions and implement corrective actions after drills and exercises, and after emergencies, if they occur.

(iv) *Planning activities.* (A) Maintain the capability to:

(*1*) Prepare and issue public information during emergencies.

(*2*) Implement the NRC-approved emergency response plan in conjunction

with the licensee's Safeguards Contingency Plan.

(*3*) Establish voice and data communications with the NRC for emergencies.

(*4*) Establish an emergency facility or facilities from which effective direction can be given and effective control can be exercised during an emergency, with capabilities to support the emergency response functions as described in paragraph (b)(1)(iii) of this section.

(*5*) Provide site familiarization training for any offsite organization that may respond to the site in the event of an emergency.

(*6*) Establish methods for maintaining the emergency plan, contacts and arrangements, procedures, and evacuation time estimate up to date, including periodic reviews by the onsite and offsite organizations.

(B) For a plume exposure pathway EPZ that extends beyond the site boundary, the emergency plan must describe:

(*1*) The contacts and arrangements made and documented with Federal, State, local, and Tribal governmental agencies, as applicable, with responsibilities for coping with emergencies, including the identification of the principal coordinating agencies, and the coordinated reviews of changes in offsite and onsite planning and preparation;

(*2*) Offsite organizations responsible for coping with emergencies and the means of notifying, in the event of an emergency, persons assigned to the emergency organizations, including the means of validating notifications, the time period by which notifications must be completed, and primary and secondary methods to complete notification;

(*3*) The protective measures to be taken within the EPZ to protect the health and safety of the public in the event of an emergency, including the procedures by which the protective measures are implemented, maintained, and discontinued;

(*4*) An evacuation time estimate of the areas within the EPZ;

(*5*) The offsite facility and any backup facilities to coordinate the onsite response with the offsite response;

(*6*) The means of making offsite dose projections and the means of communicating the offsite dose projections to the offsite response coordinating agencies;

(*7*) The means by which public information is provided to the members of the public concerning emergency planning information, public alert notification system, and any prompt actions that need to be taken by the public;

(*8*) The general plans and methods to allow reentry into the EPZ during and after an emergency; and

(*9*) The drill and exercise program that tests and implements major portions of planning, preparations, and the coordinated response by the onsite response organization with the offsite response organizations within the EPZ without mandatory public participation.

(2) *Hazard analysis.* Conduct a hazard analysis of any contiguous or nearby facility, such as industrial, military, and transportation facilities, and include any credible hazard into the licensee's emergency preparedness program that would adversely impact the implementation of emergency plans.

(3) *Emergency planning zone.* For an applicant whose analysis required by § 50.33(g)(2) meets the criteria in § 50.33(g)(2)(i), determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.

(4) *Ingestion response planning.* Describe or reference in the emergency plan the capabilities that provide actions to prevent contaminated food and water from entering into the ingestion pathway.

(c) *Implementation.* (1) An applicant for an operating license issued under this part after December 18, 2023 must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the issuance of an operating license for the facility described in the license application.

(2) A holder of a combined license issued under part 52 of this chapter before the Commission has made the finding under § 52.103(g) of this chapter, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the approved emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the scheduled date for initial loading of fuel.

■ 10. In appendix E to part 50, revise paragraph I.3. and footnote 2 to I.3 to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. * * *

3. The potential radiological hazards to the public associated with the operation of non-power production or utilization facilities licensed under this part and fuel facilities licensed under 10 CFR part 70 involve considerations different than those associated with nuclear power reactors. Consequently, the size of Emergency Planning Zones [1] (EPZs) for facilities other than power reactors and the degree to which compliance with the requirements of this section and sections II, III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.[2]

[1] EPZs for power reactors are discussed in NUREG–0396; EPA 520/1–78–016, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' December 1978. The size of the EPZs for a nuclear power plant shall be determined in relation to local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MW thermal. Generally, the plume exposure pathway EPZ for nuclear power plants with an authorized power level greater than 250 MW thermal shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius.

[2] Regulatory Guide 2.6, ''Emergency Planning for Research and Test Reactors and Other Non-power Production and Utilization Facilities,'' may be used as guidance for the acceptability of non-power production or utilization facility emergency response plans.

* * * * *

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

■ 11. The authority citation for part 52 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

■ 12. In § 52.1, in paragraph (a), revise the definition of ''Major feature of the emergency plans'' to read as follows:

§ 52.1 Definitions.

(a) * * *

Major feature of the emergency plans means an aspect of those plans necessary to:

(i) Address in whole or part either one or more of the 16 standards in 10 CFR 50.47(b) or the requirements of 10 CFR 50.160(b), as applicable; or

(ii) Describe the emergency planning zones as required in 10 CFR 50.33(g).

* * * * *

■ 13. In § 52.17, revise paragraphs (b)(2)(i) and (ii) to read as follows:

§ 52.17 Contents of applications; technical information.

* * * * *

(b) * * *

(2) * * *

(i) Propose major features of the emergency plans, in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, as applicable, such as the exact size and configuration of the emergency planning zones, for review and approval by the NRC, in consultation with the Federal Emergency Management Agency (FEMA), as applicable, in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with FEMA, as applicable in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter. To the extent approval of emergency plans is sought, the application must contain the information required by § 50.33(g) and (j) of this chapter.

* * * * *

■ 14. Revise § 52.18 to read as follows:

§ 52.18 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR part 50 and its appendices and 10 CFR part 100. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR part 51. The Commission shall determine, after consultation with Federal Emergency Management Agency, as applicable, whether the information required of the applicant by § 52.17(b)(1) shows that there is not a significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

■ 15. In § 52.79, revise paragraph (a)(21) to read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(21) Emergency plans complying with the requirements of § 50.47 of this chapter, and appendix E to part 50 of this chapter, or for a small modular reactor or a non-light-water reactor license applicant, emergency plans complying with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter;

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH–LEVEL RADIOACTIVE WASTE, AND REACTOR–RELATED GREATER THAN CLASS C WASTE

■ 16. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 17. In § 72.32, revise paragraph (c)(2) to read as follows:

§ 72.32 Emergency plan.

* * * * *

(c) * * *

(2) Located within the exclusion area as defined in 10 CFR part 100, of a nuclear power reactor licensed for operation by the Commission, the emergency plan that meets either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter shall be deemed to satisfy the requirements of this section.

* * * * *

Dated: November 9, 2023.

For the Nuclear Regulatory Commission.

Carrie M. Safford,

Secretary of the Commission.

[FR Doc. 2023–25163 Filed 11–15–23; 8:45 am]

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